Universitat Autònoma de Barcelona

VALIDATION OF COMPUTER NAVIGATION FOR TOTAL HIP REPLACEMENT

AAMER MALIK KHAN

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DOCTORAL THESIS

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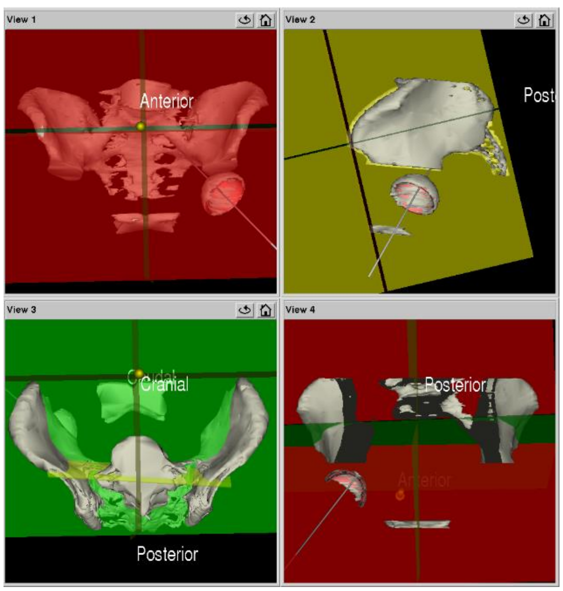

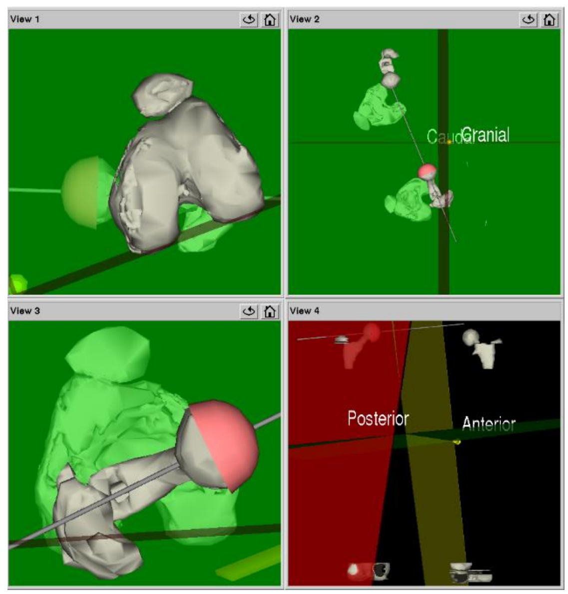

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FACULTAD DE MEDICINA
Departmento de Cirugia

VALIDATION OF COMPUTER NAVIGATION FOR TOTAL HIP REPLACEMENT

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AAMER MALIK KHAN

Barcelona, 2015.

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JUAN CARLOS MONLLAU Professor Titular de Cirurgia Ortopèdica i Traumatologia i **LLUIS PUIG VERDIE** Professor Associat de la Facultat de Medicina de la *Universitat Autònoma de Barcelona* certifiquen que el treball:

Validation of Computer Navigation for Total Hip Replacement

realitzat sota la nostra direcció per:

Aamer Malik Khan

ha estat realitzat amb la metodologia científica i reuneix les caracteristiques formals per ser defensat per obtenir el grau de Doctor en Medicina i Cirurgia

Dr. Juan Carlos Monllau Dr. Lluis Puig Verdie

Barcelona, Diciembre de 2015

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ABBREVIATIONS

CAOS: Computer Assisted Orthopedic Systems

CT Scan: Computed Tomography Scan

CN: Computer Navigation

FAV: Femoral Anteversion

CAV: Combined Anteversion

ASTM: American Society of Testing and Materials

DICOM: Digital Imaging and Communications in Medicine

3D: Three Dimensional

APP: Anterior Pelvic Plane

AI: anatomic inclination

AV: anatomic version

RI: radiographic inclination

RV: radiographic version

MIS: minimally invasive surgery

LDD: Lawrence D. Dorr (surgeon)

COR: Center of Rotation

AP: Anteroposterior

ML: Medialization

CC: Craniocaudal

APR: Anatomic Porous Replacement

ICC: Intraclass Coefficient

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1. INTRODUCTION

1.1 COMPUTER NAVIGATION IN HIP REPLACEMENT

Hip surgery is a highly cost-effective procedure with a considerable benefit to the patient through improved quality of life[1]. The demographics of joint replacement have evolved in the last decade with patients getting younger, and having a longer life expectancy[2-4]. In addition, the expectations of both patients and society after joint replacement today are achievement of higher function, quicker and with less pain[4-7]. Marketing by some physicians and industry pushes these sometimes-unrealistic expectations[8, 9]. Despite improved tribology and materials for implant stability, among other technical developments, rates of mechanical complications like dislocation, impingement and aseptic loosening have plateued and are similar to those of previous generations over 10 years ago[10-12].

In the last ten years, the surge in hard-on-hard bearings (especially metal-on-metal) brought a plague of complications that have led to limitations in their use[13, 14]. These bearings require perfect implant alignment, as they tolerate material stresses, such as edge loading and impingement, more poorly than the classic metal on polyethylene bearing surfaces[15-20].

The consequence of clinical judgment alone for implant alignment has been the risk for component malposition associated with impingement of the femoral neck on the cup or bone-on-bone, which can cause dislocation, pain, accelerated wear, and loosening(Fig 1)[21-25].

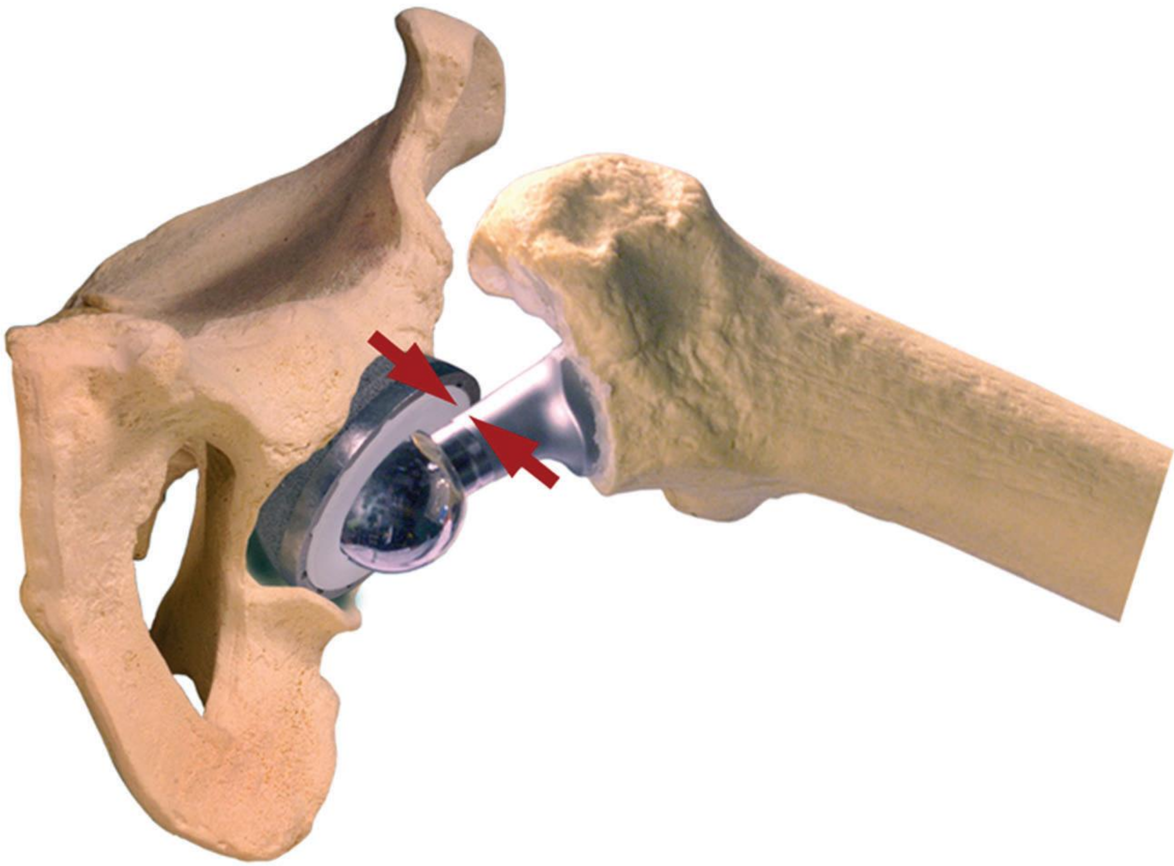


Fig. 1: Implants positioned outside of the safe zone are more likely to suffer impingement of the femoral neck on the cup or bone-on-bone, which can cause dislocation, pain, accelerated wear and loosening.

The pursuit of improved implant positioning and alignment introduced different computer assisted orthopedic systems (CAOS) in joint surgery over the last 15 years. These were initially robotic systems like the ROBODOC, but with improvement of three dimensional (3D) sensor technology navigation was developed[26-28].

Navigation is a passive system which does not perform any action on the patients[27]. It only provides information and guidance to the surgeon who still uses conventional tools to perform surgery. There are three types of Navigation: Computed Tomography (CT) based navigation, imageless navigation and fluoro-navigation[27]. CT-based navigation is the most accurate, but preoperative planning on CT images takes time that increases cost and radiation exposure[26, 27, 29, 30]. Fluoroscopic navigation is good for trauma and spine surgeries, but its benefits are limited in hip and knee reconstructive surgeries[31]. Imageless navigation does not use CT-images, but its accuracy depends on the technique of landmark pointing, and it does not take into account the individual uniqueness of the anatomy[31, 32]. The focus of our studies and the basis for this thesis is the validation of the robustness of the Navitrack® Imageless Computer Hip System (Orthosoft, Montreal, Canada).

1.1.1 Factors Related to Acetabular Anatomy and Positioning

Lewwinek proposed placing the acetabulum in a safe zone of 40 ± 10° of inclination and 15 ± 10° of anteversion systematically(Fig 1)[33]. Traditional joint replacement with mechanical guides relies on a surgeons experience and intuition in component placement towards this target position, with the acetabulum being prepared first[26, 34-39].

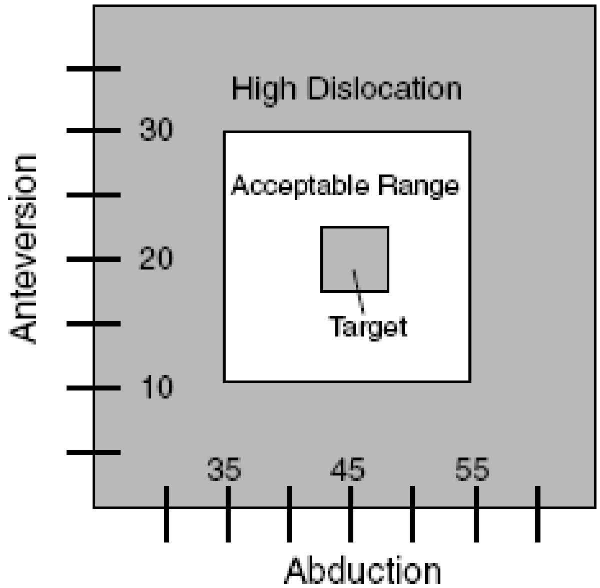


Fig 1: Implants Positioned in the safe zone are less likely to dislocate than those outside the safe zone.

Multiple studies of standard non-navigated hip replacement with postoperative validation of implant position with CT scans, have shown this method to have significant outliers. Wines and McNicol and Pierchon et al found a variability of acetabular position from 12° retroversion to 52° anteversion with outliers in upto 55% of cases. The femoral position ranged from 30° retroversion to 45° anteversion in both cemented and cementless stems with outliers in upto 62% of cases [40, 41]. Reikeras et al found a mean cup anteversion of 19° with a range from 28° retroversion to 46° anteversion with outliers in up to 50% of cases. Their mean femoral position was 23° with a range from 17° retroversion to 60° anteversion in cementless stems with outliers in upto 60% of cases[42]. Multiple studies that compared navigation with traditional hip surgery confirmed the surgeon's inability to consistently position the implants in the desired target zones(Table 1)[26, 34-39].

Table 1. Distribution of Implant Positions after Conventional Hip Replacement

	CUP Version Mean ± SD	Range	% Out of Safe zone	FEMUR Version Mean ± SD	Range	% Out of Safe zone
Wines et al	22 ± 14	-12 to 52	55%	17 ± 11	-15 to 45	30%
Pierchon et al	25	- 5 to 45	29%	17	-30 to 37	62%
Reikeras et al	19 ± 14	-28 to 46	50%	23 ± 12	-17 to 60	60%

SD = standard deviation Values are in degrees

On the other hand, the classic target ´safe zone´ for acetabular and femoral positioning are now in question for different reasons. Firstly, this technique ignores the femoral implant version, and therefore the coupling of the acetabular and femoral implants (combined anteversion). This inaccurate coupling has been shown to increase the risk for impingement, dislocation and early failure[43-46]. Secondly, this traditional implant positioning ignores the effect of pelvic tilt and hip dynamics. The acetabular position can vary by upto 30 degrees from a lying to a sitting to a standing position[27, 28, 47-49]. For now only navigation systems are capable of incorporating this variable into implant positioning intraoperatively.

Additionally, the way acetabular implant positions are reported in literature, is not standardized to any one plane of Murray[50, 51]. Different clinical studies use different methods for measurement of acetabular implant orientation (non-standardized radiographs, standardized radiographs, 2-D CT scans, 3-D CT scans)(Fig. 2 and 3) [26, 33, 45, 52-59]. Therefore, results are not directly comparable between different papers. Many clinical studies report postoperative acetabular orientation using radiographs without standardized positions of the pelvis for direction of the x-ray beam and make conclusions about acetabular implant orientation with complications such as dislocation[51, 59-62]. Another example is the study of Pierchon et al[40] who used 2-D CT scans to study dislocation and directly compared the results to plain radiographic measurements of Lewinnek et al[33]. The results reported by Pierchon et al were not referenced to a standardized anterior pelvic plane, which Lewinnek et al] did use, and the tilt of the pelvis was not considered[33;40].

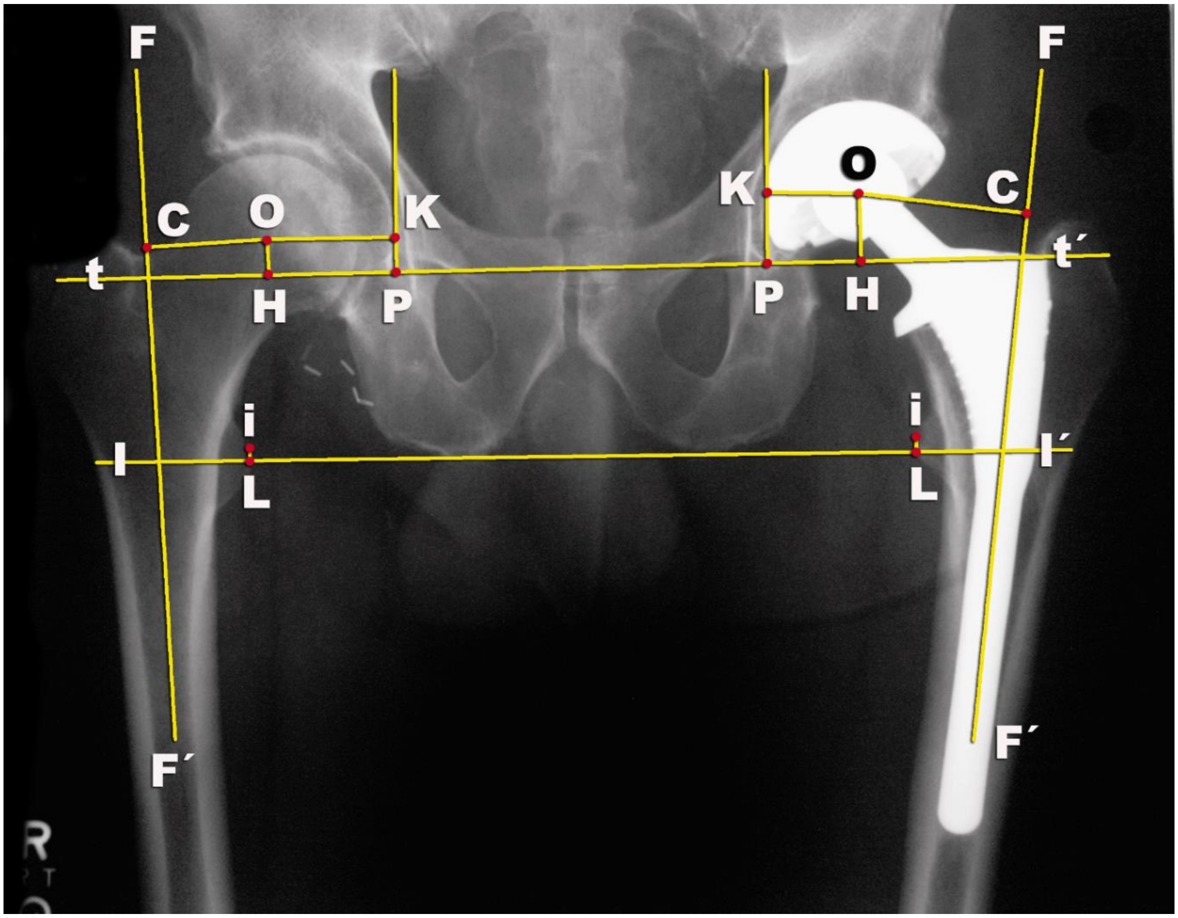


Fig. 2: Illustration demonstrating the multiple measurements used for calculating femoral implant positioning on an anteroposterior pelvic radiograph. These subjective measurements, associated with errors during the realisation of the radiograph by the patients or X-ray beams positioning, can induce a combination of errors.

The surgeon's performance of component implantation has always been measured by plain radiographs, which have been imprecise in comparison to the true position of the cup (Fig 2 and 3)[63, 64]. The advent of computer navigation algorithms with three dimensional computed tomography reconstructions have revealed the imprecision of plain radiographic measurements and of surgeons using mechanical guides for implant positioning(Fig.3).[37, 38, 61, 65, 66]

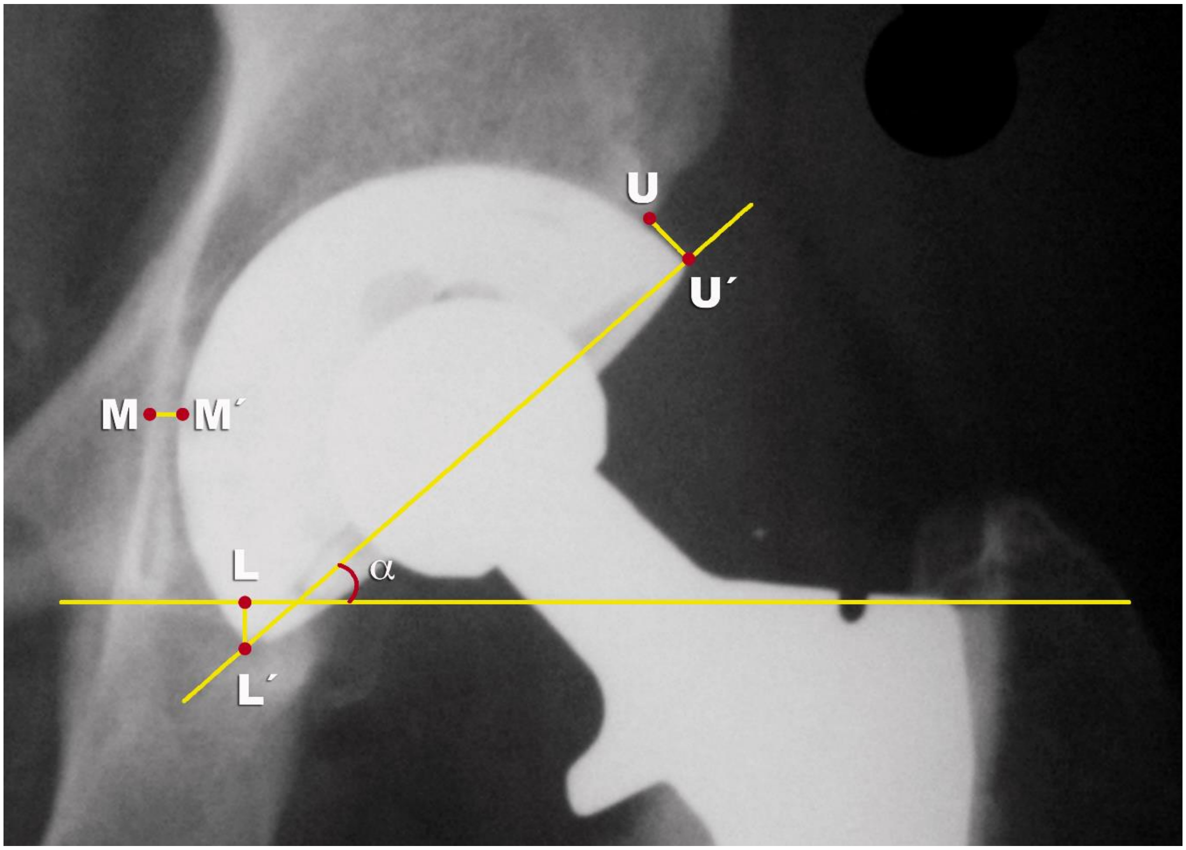


Fig. 3: Illustration demonstrating the multiple measurements used for calculating acetabular implant positioning on an anteroposterior pelvic radiograph. These subjective measurements, associated with errors during the realisation of the radiograph by the patients or X-ray beams positioning, can induce a combination of errors.

1.1.2 Factors Related to Femoral Anatomy and Positioning

The superior survivorship of non-cemented acetabulums has made acetabular cementing rare in our day[67]. Despite the excellent results of cemented femoral implants, non-cemented hip replacement is predominant in many health care systems[68, 69].

Many studies focusing on a ¨safe zone¨ and techniques for correct acetabular positioning in total hip surgery, completely ignored the femoral implants´ position [26, 33, 70, 71]. The femoral implant was assumed to be positioned in about 15 to 20 degrees of anteversion consistently. Anatomic and cadaver studies have confirmed the great variability in the anatomy of the native non-arthritic hip (Table 1)[72]. Variables such as acetabular inclination and anteversion, femoral neck shaft angle, femoral version, femoral bow and bone qualities have been shown to vary with gender, age, race and congenital abnormalities such as Dysplasia, Perthes etc (Fig. 1) [41, 72-76].

Table 1. Hip Anatomic Variables from 200 cadaver skeletons of non-arthritic hips.

	Mean Acet. Version	**Range**	**Mean Femur Version**	**Range**
Global	20	7 a 42	10	-15 a 34
Female	21		11	
Males	18		9	

Table of the distribution of acetabular and femoral versions in a study by Maruyama of 200 skeletons without associated pathology. Note the great range in the versions of the acetabulum and femur, and the gender differences between the skeletons. (Acet - Acetabular).

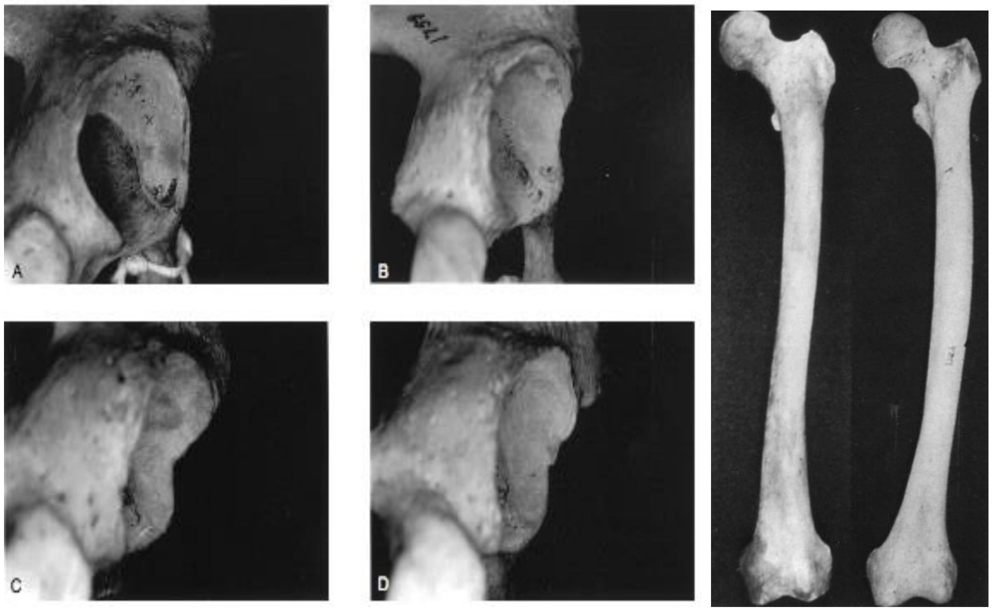


Fig. 1. Images of variables and differences in the native anatomy of the acetabulum and femur as published by Maruyama of non-arthritic skeletons with no associated pathologies.

The non-cemented femoral stem must have a stable press-fit to obtain bone fixation. A stable press-fit means the stem must adapt to the femoral bone geometry, which is highly variable. As mentioned in Maruyamas´ study, femoral version was found to range from -15° (retroversion) to 30° (anteversion) in adult cadavers without arthritis[72]. In a published study we undertook of 109 hips with postoperative CT scans the version of cementless femoral stems ranged from 17° retroversion to 28° anteversion[77]. The studies of McNicol and Pierchon we mentioned previously, using postoperative CT scans, found 30° retroversion to 45° anteversion for both cemented and cementless stems [40, 41]. With cemented arthroplasty, the surgeon can easily control anteversion to 10-20° with a small stem in the rasped canal. In cementless arthroplasty the anteversion of a tightly fit press-fit stem is restricted by the anatomy of the femoral neck, the diaphyseal bow, the anterior-posterior isthmus at the level of the lesser trochanter created by the true femoral calcar and the posterior fin of bone in Dorr type A and B bone(Fig. 2)[23, 46, 72, 78]. Tapered stems may have up to 5° of freedom of rotation whereas metaphyseal-filling stems are inflexible.

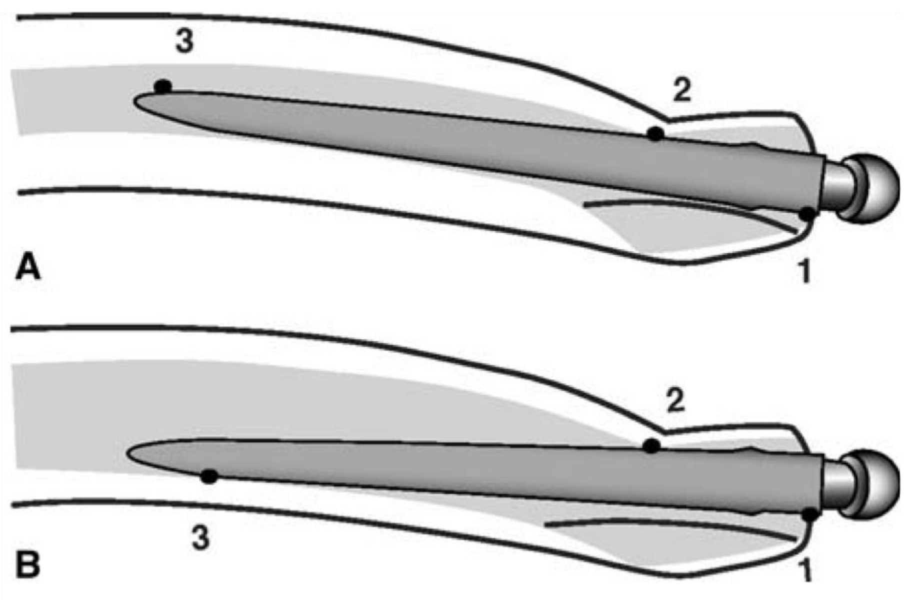


Fig 2A: Diagram illustrates the anteversion of the femoral stem controlled by the anteversion of the neck, the anterior-posterior isthmus (anterior cortex and true femoral calcar) at the level of the lesser trochanter, and the posterior fin of bone in types A and B. Femoral stem anteversion decreases as the bow of the femur increases or the posterior fin thickness increases. 1, 2, and 3 are three points of rotational stability.

Fig 2B: Type C osteoporotic bone has a wide intramedullary canal so the isthmus and diaphysis have less influence on the stem anteversion. 1, 2, and 3 are three points of rotational stability

1.1.3 Rationale for Combined Anteversion

Impingement of the cup and stem, or of bone-on-bone, is a cause for dislocation, accelerated wear, and pain in patients with total hip arthroplasty[25, 46, 79, 80] (Fig 1). Accuracy of coupling of femoral stem anteversion and acetabular cup anteversion would ensure mating of the femoral head in the cup without impingement of the two throughout all body positions. This requires a technique, which reproducibly creates this combined anteversion.

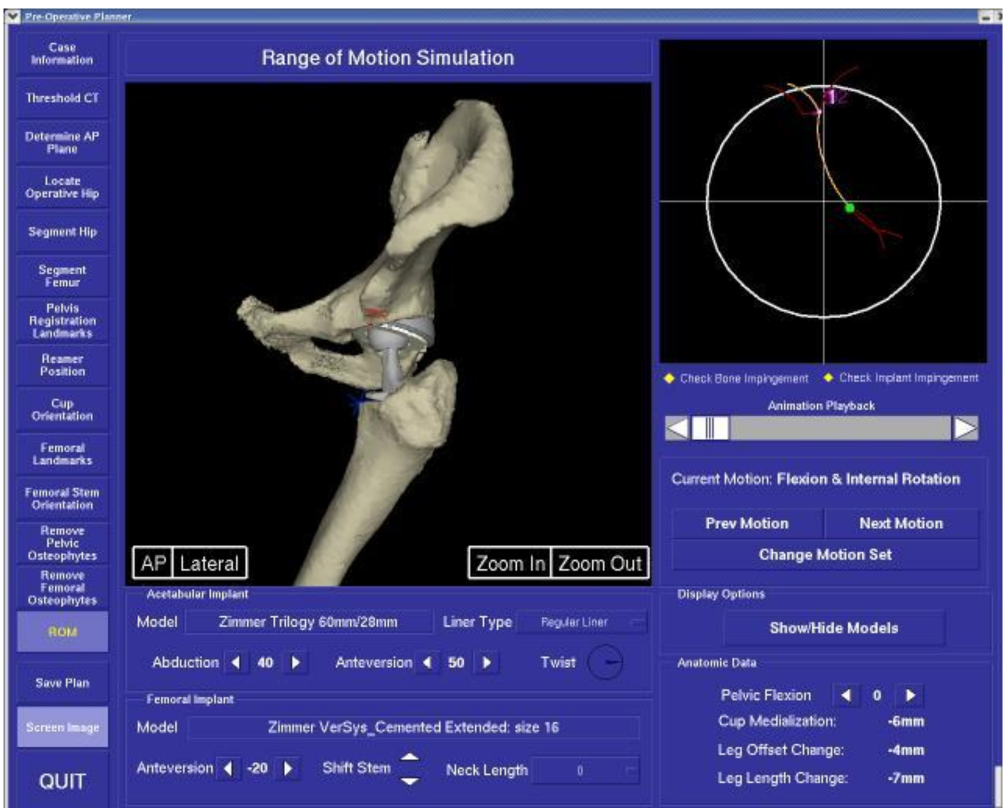


Fig.1: A screenshot image of the HipNav® navigation screen which shows the importance of correct combined anteversion. For any one given motion path (flexion, extension, internal rotation, etc) the implant positions influence the range of motion to impingement and thus risk for dislocation, wear and loosening.

In total hip arthroplasty (THA) combined anteversion is defined as the sum of the cup and stem anteversion[76, 81]. McKibben first introduced this term in a study of infant cadavers and defined 30-40° combined anteversion as being normal, with 15° anteversion of the femur[43]. Males had lower combined anteversion than females. In a study of 200 adult cadavers the combined anteversion for men was a mean 29.6° and women 33.5 ° with femoral anteversion a mean 11.6 ° (men were 11.1° and women 12.2°)[72]. A finite element study of THA investigated combined anteversion to find an optimal combination to avoid impingement and concluded it was 37.3° [81]. Mathematical models also confirmed combined anteversion to be the measurement that must be considered to avoid impingement [76]. Clinical use of combined anteversion has determined men to be between 25-35 ° and up to 50 ° in women[82,83, 84].

Combined anteversion has become more relevant with the use of non-cemented implants. The acetabular cup position has traditionally been anteverted with the assumption the femoral component would be a mean 15° anteverted. The arthritic acetabulum has a mean 12° anteversion and non-arthritic acetabulae have mean anteversion of 19.9° $\pm$ 6.6° with the mean in women being 21.3° and men 18.5°[50][72]. Therefore, the traditional safe zone for cup placement has been 15 $\pm$ 10° or 20 $\pm$ 10° [33, 62, 70, 85]. If the stem has only 5° of anteversion, the acetabular safe zone of 15-20° does not give an acceptable combined anteversion[81, 82]. This risk is compounded in 10% of hips in which the pelvis is tilted 10° or more from neutral and the surgeon's estimate of anteversion can be wrong by 10° [36]. In clinical studies, cup anteversion is not within the desired safe zone as often as 55% to 78% of the time[61, 65, 86, 87].

We were interested in learning how we could technically best provide combined anteversion to prevent impingement of the stem on the cup (we were aware that avoidance of bone-on-bone impingement requires correct reconstruction of the hip length and offset)[46]. When we realized the studies on combined anteversion, we had already established the advantage of imageless computer navigation, which measures pelvic tilt, in accurately positioning cup anteversion on the coronal plane of the body as we will later show in each corresponding part of this thesis[36, 88]. In the second part of the study on femoral and combined anteversion, our concern was measurement of femoral anteversion so that a combined anteversion in a safe zone of 25-50 ° could be obtained every time. We raised the upper limit of the safe zone from 45° to 50° because we had experienced anterior dislocations only if more than 50° combined anteversion were present[82].

1.1.4 Basis For Computer Navigation

The consequence of clinical judgment alone for hip reconstruction has been the risk of component malposition associated with impingement of the femoral neck on the cup, which can cause dislocation, pain, accelerated wear, and loosening[21-25]. The primary function of imageless computer navigation is to be an instrument that provides precise intraoperative knowledge to the surgeon for implant positioning and placement. Orthopedic surgeons have assumed more accurate placement of components will provide fewer short-term complications and better long-term durability[22, 33, 62, 89, 90]. Previous studies with computer navigation have confirmed its function as an instrument for improved component placement[37, 38, 61, 65, 66]. These studies show that computer navigation assisted component placement by the surgeon is more predictable and reproducible because there is knowledge of the position of the acetabulum relative to the pelvis.

However, when we initiated our studies no other groups had measured and reported the accuracy and precision of the computer navigation systems in clinical use. Previous clinical reports suggest the reduced deviation from a target number for cup inclination and anteversion when using computer navigation, but did not include the navigation systems accuracy with precision and bias[38, 61, 65, 66]. The focus of our studies, and the basis for this thesis, is the chronological process in the validation of the robustness of the Navitrack® Imageless Computer Hip System (Orthosoft, Montreal, Canada). This involved a first phase validation with a phantom model and a second phase clinical validation[36, 83, 91]. The clinical validation was first of the acetabulum (because its software and hardware were developed first) and then posteriorly of the femur. We will show how the novel data and information that we obtained in our clinical studies was the basis for the modification of our surgical technique with its clinical application in the combined anteversion technique for total hip recontruction[36, 38, 83].

For clarity, we have considered that as the phantom model was the first phase of our validation process (and has no clinical indication), to include its methodology and results within the introduction section. We only include our clinical data in the material and methods and results sections of this thesis.

The data included in this thesis was collected approximately between 2004 and 2009. The Dorr Arthritis Insitute had a volume of 400 to 500 joint replacements a year, and navigation was routinely used in the majority of surgeries after 2005. The patients reported are in different groups as consecutive series. They included only those who had complete data within each study. The details of each group are included in its pertinent section.

1.2 METHODOLOGY OF THREE-DIMENSIONAL COMPUTED TOMOGRAPHY RECONSTRUCION FOR VALIDATION OF NAVIGATION AND STATISTICS.

1.2.1 American Society for Testing and Methods Definitions.

For reporting the accuracy of industrial tools and methods, measurements of means with standard deviations are not reliable or sufficient[92, 93]. According to the American Society of Testing and Materials (ASTM) only the words precision and bias and number of outliers should be used as descriptors of accuracy of any given method[92, 93]. When we initiated our investigations into computer navigation no clinical studies had measured and reported the accuracy as precision and bias of their systems. Previous pioneering studies reported the reduced deviation from a target number for cup inclination and anteversion when using computer navigation.[38, 61, 65, 66] We report our results using the American Society for testing and materials (ASTM) definitions[92, 93].

Accuracy is the closeness between a test result and an accepted reference value or the true value (computed tomography scan values in our study). Precision (randomized error) depends on the distribution of random errors. It is the closeness of agreement between repeated measurements made under similar conditions and represents reliability and reproducibility of the test. In the phantom model precision was defined as the closeness of agreement between each independent measurement of anteversion obtained by either the navigation system or from the computed tomography scan to the phantoms real anteversion values. For example, a low precision number means that the test is very reproducible. In our clinical studies precision was the closeness of agreement between independent measurements of the acetabular inclination, anteversion and femoral anteversion in degrees (surgeons estimates, radiographic measurements, computer navigation readings) versus the true value (computed tomography scan values).

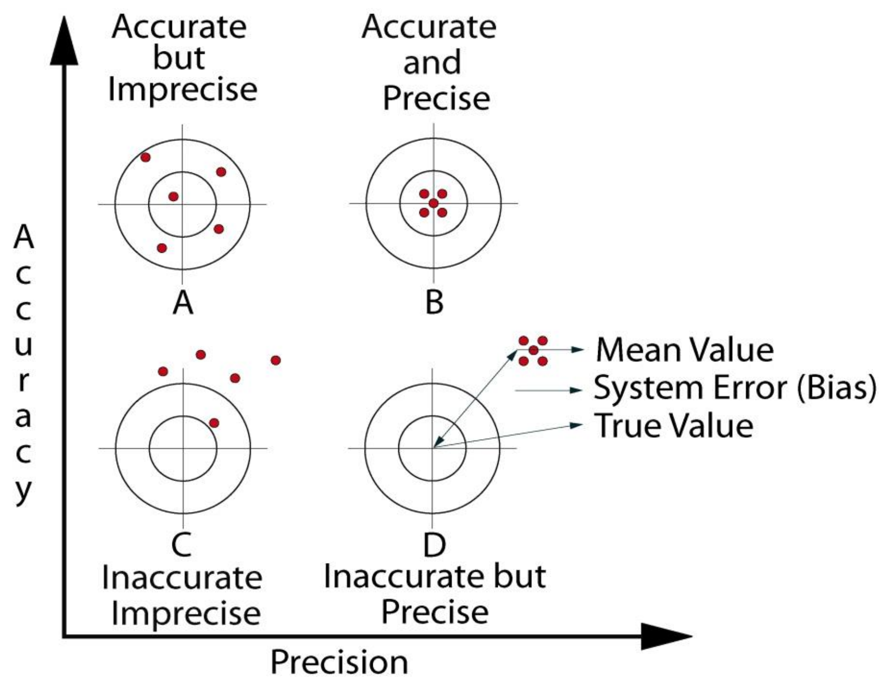


Figure: Illustration demonstrating the relation between accuracy, precision and bias. Accuracy refers to a combination of randomized (precision) and system errors (bias).

In contrast with random error, bias is the systematic error. Bias is the numerical difference between the average value of all measurements (i.e.

surgeon estimate, navigation value, radiographic value) of one method and the accepted reference or true value(CT value)[94, 95]. For example a low bias number means that the average of the test number and true value are very close.

We defined outliers as implants positioned more than ± 5 degrees from the desired target position. This gave an acceptable range of 10 degrees from the desired target position, and had previously been reported in literature in similar studies[33, 62, 70]. 10 degrees are considered an acceptable range because within this range clinical complications are unlikely to occur. A cup between 35 and 45 degrees of inclination or 15 to 25 degrees of anteversion is unlikely to have outliers with clinical consequences. If outliers of implants positioned more than ± 10 degrees from the desired target position are accepted the target range would change to 30 to 50 degrees for inclination and 10 to 30 degrees for anteversion. This range is considered to probably have outliers which are likely to have clinical complications (eg. cup with > 50˚ inclination is more likely to dislocate).

1.2.2 Methodology of Computed Tomography Three Dimensional Reconstruction

1.2.2.1 Technique for Computed Tomography Scanning.

Postoperative acetabular and femoral position results reported with radiographs are inaccurate because of the inherent errors incurred during the realization and posterior measurement of the radiographs as mentioned earlier. Minor errors always occur during patient and X-ray beam positioning, and in the posterior subjective measurement methods of the radiograph[26, 44, 45, 64, 75, 86, 94, 96-100].

Computed Tomography (CT) scans minimize patient positioning and subjective measurement errors. Therefore, CT scans of the phantom and patients postoperatively were the basis for validation of our study results. The CT scans were the gold standard or true value for validating implant position, as has been recommended in literature[26, 44, 45, 64, 75, 86, 94, 96-100]. In this section we will outline the methodology that was undertaken in this very labor intensive and time consuming process.

CT scans of the phantom cup positions were obtained using an MX Highland Phillips Scanner and stored in a Digital Imaging and Standard For Communications in Medicine (DICOM) format. For the phantom the CT scan protocol was set at roughly 100 slices in each scan, 0.5 mm thickness and 1 mm slice intervals at an intensity that measured the materials of the phantom. The phantom was placed in the scanner to simulate the supine position of the patient entering the scanner headfirst. Scans were taken to include both the superior reference markers, both cups, and the inferior reference marker (please refer to section of phantom validation for details).

All patients reported in this thesis also underwent postoperative computed axial tomography scans (MX8000, Phillips, Highland Heights, OH). The scan was obtained from the level of the fourth lumbar vertebra proximally to the knee including the entire distal femoral condyles distally. Each scan was performed at 1.3 mm intervals and 1.3 mm thickness with a field of view of 400 and a pitch of 1.250. Four hundred to 650 frames per scan were done depending on the length of the leg. This data were stored in the Digital Imaging and Communications in Medicine (DICOM) format[101, 102].

This scan data was processed using two different 3D computed tomography-based systems. The hip plan module of the Navitrack® System (Navitrack Computed Tomography Based Hip Application; Orthosoft, Montreal) and the planning module of the HipNav® System (Carnegie Mellon University, Pittsburgh, PA) with workstations for processing and determination of implant position. Both these systems rely on volumetric and surface rendering techniques to generate a three-dimensional model of the metallic acetabular and femoral component to measure implant orientation. We would like to highlight that the measurements were undertaken in two centers independently and the technicians undertaking these readings were blinded to the results of the computer navigation system and the surgeon's estimates.

The HipNav System (Carnegie Mellon University, Pittsburgh) was not involved in development and is not part of Orthosoft´s, Navitrack Imageless Navigation system in any way. It was a completely independent evaluator of our results. The processes for measurement of real implant position in our method was highly labor intensive and time consuming. Each patient scan required 2-4 hours to load, manually segment, and reconstruct the three-dimensional model for measurement of implant position. The measurements for both the cup and stems were performed by two observers. Once the CT Scan values were obtained they were compared to the results of the navigation system.

Both these systems rely on volumetric and surface rendering techniques to generate a virtual 3D model reconstructed using the DICOM files. Models of the patient's pelvis and femur, as well as of the implanted prosthetic cup and femur were generated[101, 102]. The anterior superior iliac spines and pubic tubercle midpoint were used to establish an anatomic coordinate reference system for the cup. A virtual cup from the database of the CT system was positioned over the reconstructed cup to match its position and orientation so that inclination and anteversion could then be measured. The Navitrack® system was programmed to report the anteversion and inclination of the cup on the radiographic measurement of Murray's definitions[70]. However Navitracks´ screen displayed cup orientation with both Murray's anatomic and radiographic definitions. When the coronal and the APP are the same (pelvic neutral position or no tilt), the measurements for inclination and anteversion are the same in both planes (Fig 1).

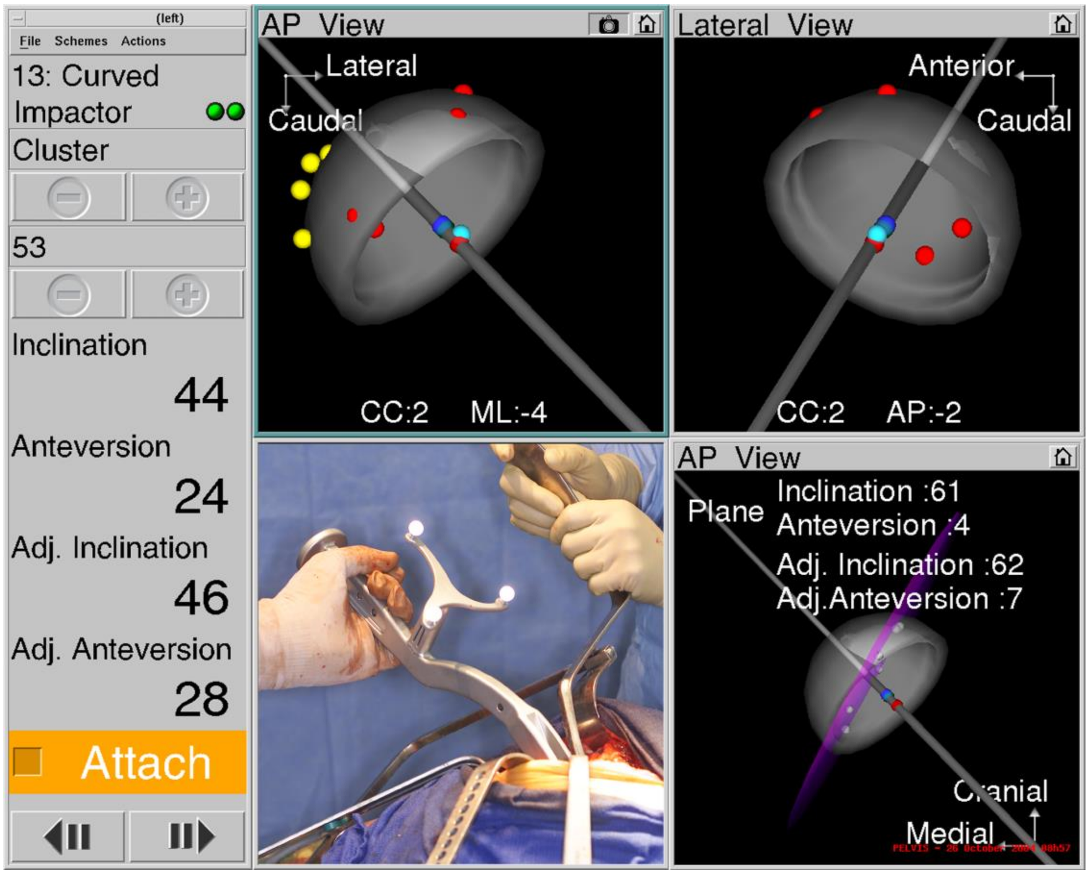
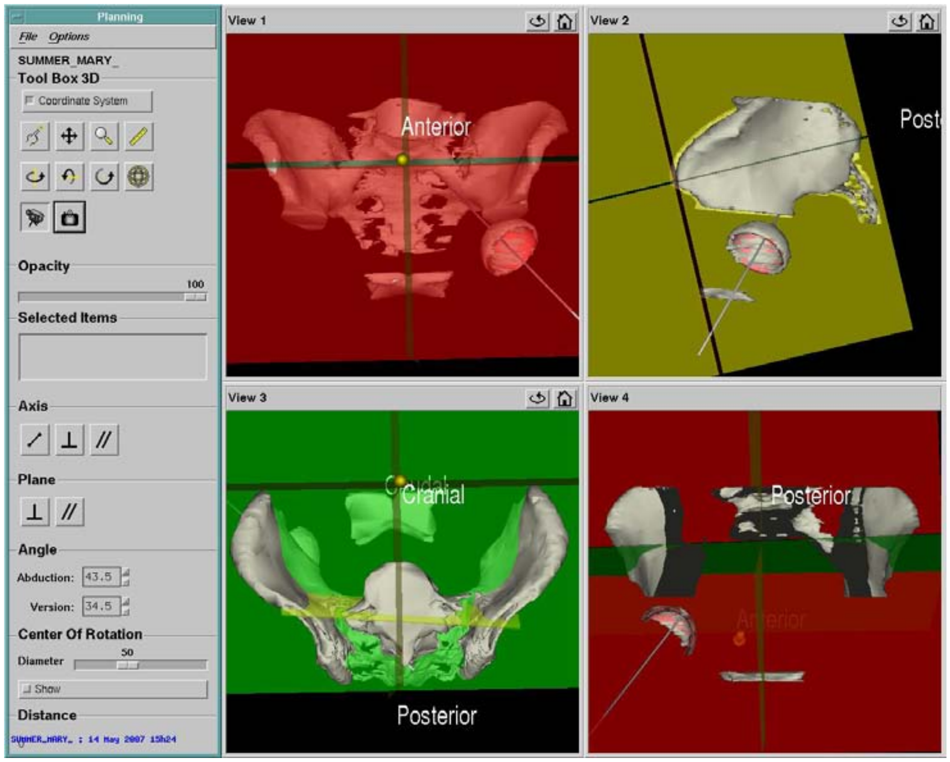
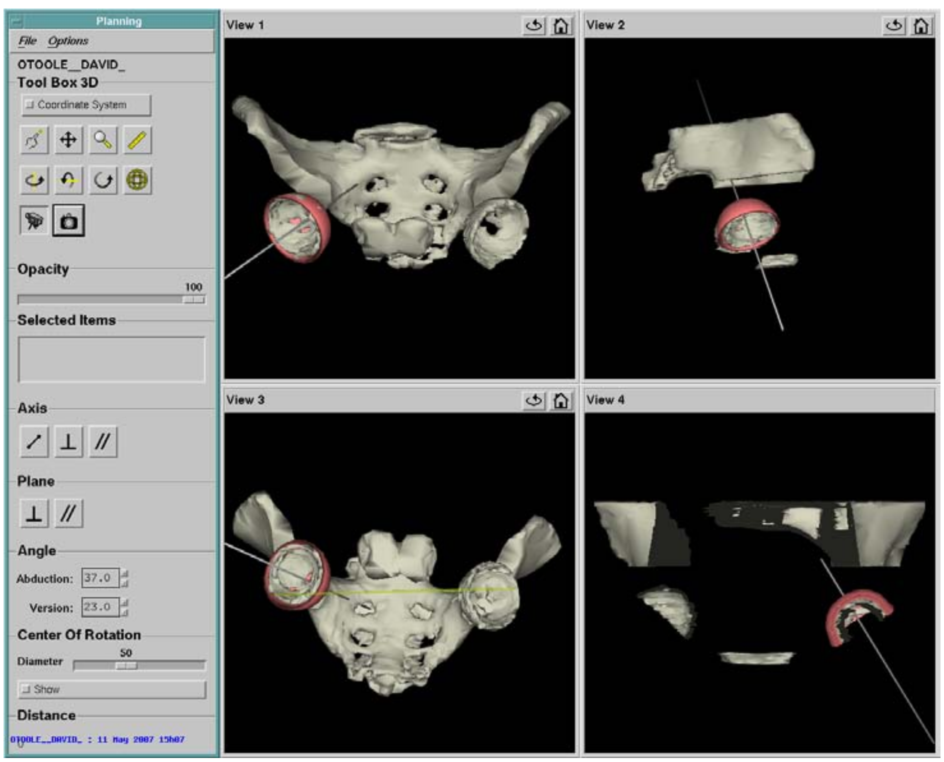


Fig 1. Screen shot of the Orthosoft Navitrack during cup implantation. The trial cup implantation is shown in the lower left quadrant. The upper quadrant shows the position of the cup relative to the acetabulum, including the medial wall. The lower right quadrant gives the native acetabulum values, and the gray lines show what portion of the cup would be uncovered. The numbers on the left give the numeric inclination and anteversion (anatomic values) and adjusted inclination and anteversion (Tilt incorporated or radiographic antevesion).

See examples of screenshots of the Orthosoft software for the process of 3D reconstruction of the pelvis, identification of the anterior pelvic plane and matching of the prosthetic cup for position in figure 2 below.



A



B

Fig 2: A and B: Screenshot of the Orthosoft Navigation system for the measurement of acetabular version. Through volumetric and surface rendering the implant and bone are reconstructed. The first stage is defining the anterior pelvic plane reference points as shown in figure A. Secondly using a best match from models of the acetabulum from the computer systems data base, the position of the prosthetic cup is obtained as shown in fig. 2 B.

In the HipNav System the 3D surface view and multiplanar formatting of the CT data was done in addition, to precisely match the cup position in the axial, sagittal, and coronal planes (Fig 3 A and B). The HipNav 3D measurement system reports according to Murray's anatomic definition and does not consider tilt [63, 70]. To be able to compare results between systems, the anatomic values with the HipNav system were converted to radiographic values using the formulas as described by Murray.

A

B

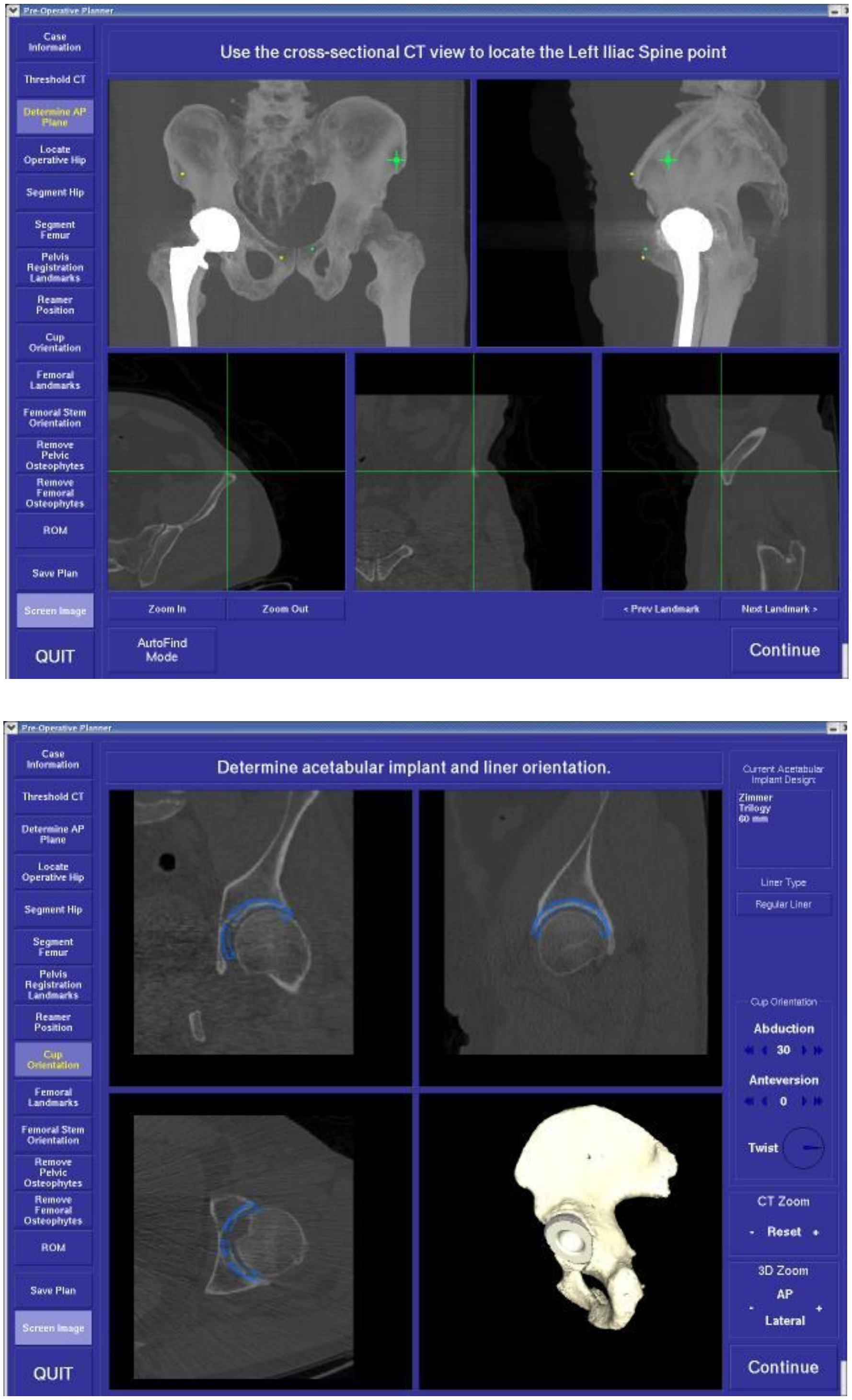


Fig 3 A and B: Screenshot of the HipNav Navigation system for the measurement of acetabular version. Through volumetric and surface rendering the implant and bone are reconstructed. The first stage is defining the anterior pelvic plane reference points as shown in figure A. Secondly from models of the acetabulum from the computer systems data base the position of the prosthetic cup is obtained as shown in Fig 3 B.

1.2.2.2 Acetabular Measurements and Definitions

The definitions for acetabular implant position and referencing are standard and routine since Murray marked them out.

1.2.2.2.1 Definitions for Acetabular Referencing

1.2.2.2.1.1 Murrays Definitions

Murray defined three different ways to measure acetabular orientation: anatomic, operative, and radiographic[70]. He defined the acetabular axis (acetabular plane) as the axis perpendicular to the rim of the cup that passes through the center of the cup. Murray's definitions were relative to the coronal plane and the longitudinal axis of the pelvis without referencing how these anatomic axes were derived[70]. These definitions form the mathematical base upon which navigation systems were designed to display implant position relative to the tracking devices (Fig 1).

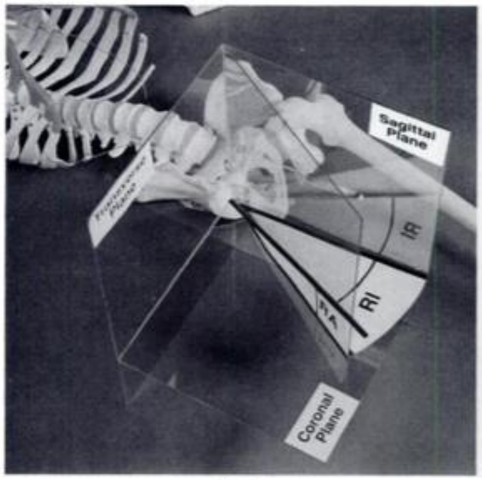


Fig. 2

Radiographic anteversion (RA) and inclination (RI).

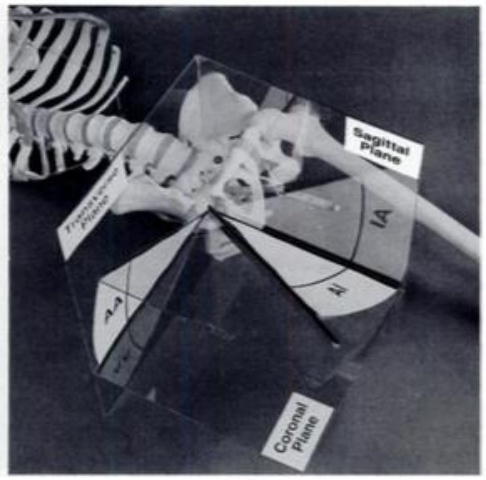


Fig. 3

Anatomical anteversion (AA) and inclination (AI).

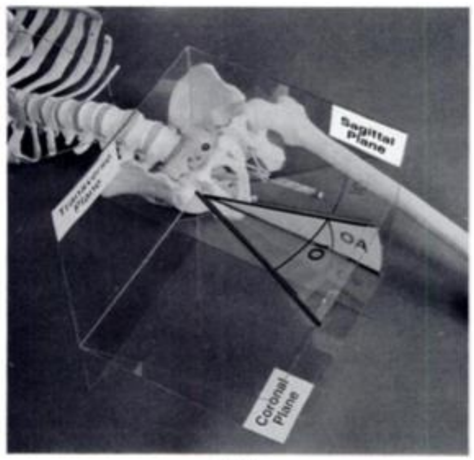


Fig. 1

Operative anteversion (OA) and inclination (OI).

Fig 1: Images from Murray´s original paper which help understand the different definitions of acetabular anteversion as radiographic, anatomic and operative depending on which plane the acetabular cup version is projected.

Murray's anatomic inclination: the angle between the acetabular axis and the longitudinal axis of the body. Anatomic anteversion is the angle between the acetabular axis and the transverse axis of the body when the acetabular axis is projected onto the transverse plane;

Murray's operative inclination: the angle between the acetabular axis and the saggital plane (the angle of abduction of the acetabular axis); Operative anteversion is the angle between the longitudinal axis of the patient and the acetabular axis when projected onto the sagittal plane;

Murray's radiographic inclination: the angle between the longitudinal axis of the body and the acetabular axis when projected onto the coronal plane. Radiographic anteversion is the angle between the acetabular axis and the coronal plane[51, 70].

The mathematical relation between Murray´s definitions are described below:

RI = atan (tan (AI) * cos (AV))

RV = asin (sin (AI) * sin (AV))

AI = acos (cos RI) * cos (RV))

AV – atan (tan (RV)/ sin (RI))

Where AI – anatomic inclination, AV – anatomic version, RI = radiographic inclination, RV = radiographic version

1.2.2.2.1.2 Definitions for Anterior Pelvic Plane and Pelvic Tilt

The Anterior Pelvic Plane is defined as the plane formed by the lines connecting the two anterior superior iliac spines and the pubic tubercles (Fig 1)

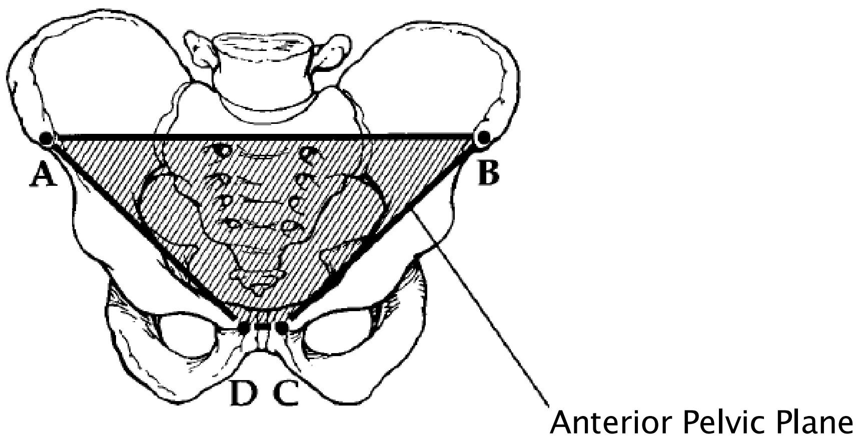


Fig.1: Illustration demonstrating the definition of the anterior pelvic plane which is formed by are the two anterior superior iliac spines (A and B) and the pubic tubercles (C and D)

Anterior pelvic tilt is defined as the distance between the middle point of the two anterior superior iliac spines and the coronal plane when this distance is greater than the distance between the anterior surface of the pubic symphysis and the coronal plane (Fig 2). Posterior pelvic tilt is defined as the distance between the middle point of the two anterior superior iliac spines and the coronal plane, but now this distance is shorter than the distance between the anterior surface of the pubic symphysis and the coronal plane.

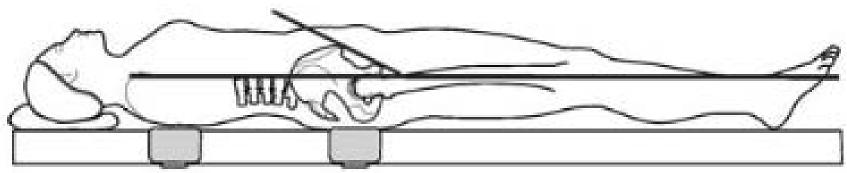


Fig. 1 A diagram demonstrates anterior pelvic tilt. The distance between the middle point of two anterosuperior iliac spines and the coronal plane is longer than that between the anterior surface of the pubic symphysis and the coronal plane.

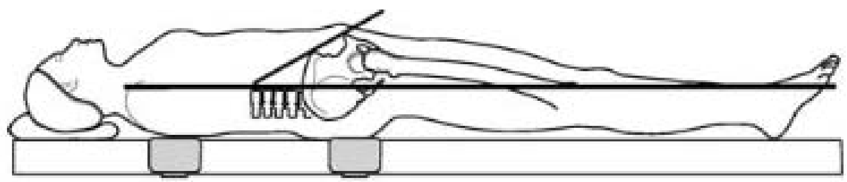


Fig. 2 A diagram demonstrates posterior pelvic tilt. The distance between the middle point of the two anterosuperior iliac spines and the coronal plane is shorter than that between the anterior surface of the pubic symphysis and the coronal plane.

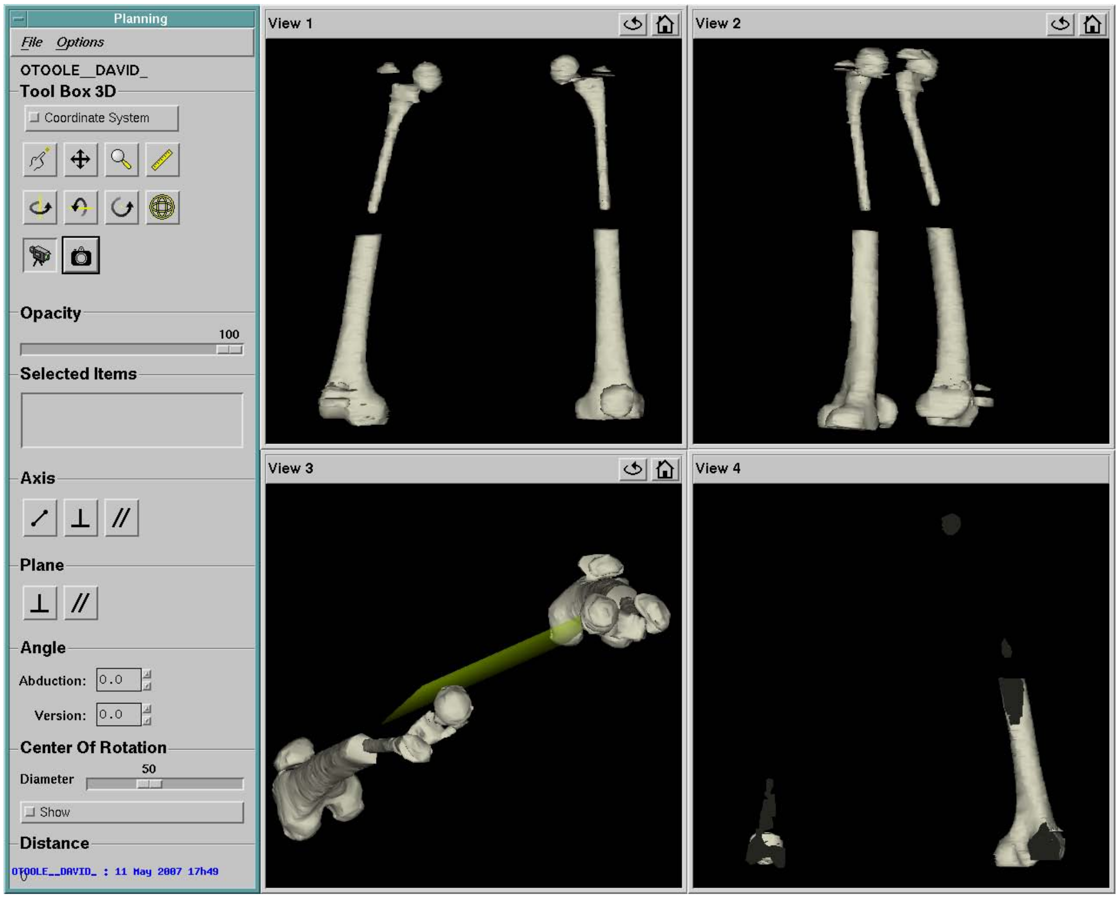
Fig 2: Illustrations demonstrating the definition of the anterior and posterior pelvic tilt. Copy from the paper of Wan et al[51]

Today, the most frequently used method of referencing the acetabulum is the anterior pelvic plane. Almost all computer navigation and computed tomography (CT) scan measurement systems reference the acetabular position relative to the anterior pelvic plane[26, 32, 48, 49, 51, 54, 57, 88, 97, 103-105]. Only when there is zero pelvic tilt are the anterior pelvic plane and the coronal plane parallel. Plain radiographs are taken, and measured, on the radiographic or coronal plane. So, if computer navigation measurements are on the APP (anatomic) plane there is a conflict of comparison with plain radiographs. This conflict is also present when studies measured on the coronal plane are compared to those on the APP (anatomic) plane[2, 5, 19, 22, 23, 74, 99, 106-110].

1.2.2.3 Femoral Measurements and Definitions

(Dorr LD, Wan Z, Malik A, Zhu J, Dastane M, Deshmane P. A comparison of surgeon estimation and computed tomographic measurement of femoral component anteversion in cementless total hip arthroplasty. J Bone Joint Surg Am. 2009 Nov;91(11):2598-604. doi: 10.2106/JBJS.H.01225. PubMed PMID: 19884433).

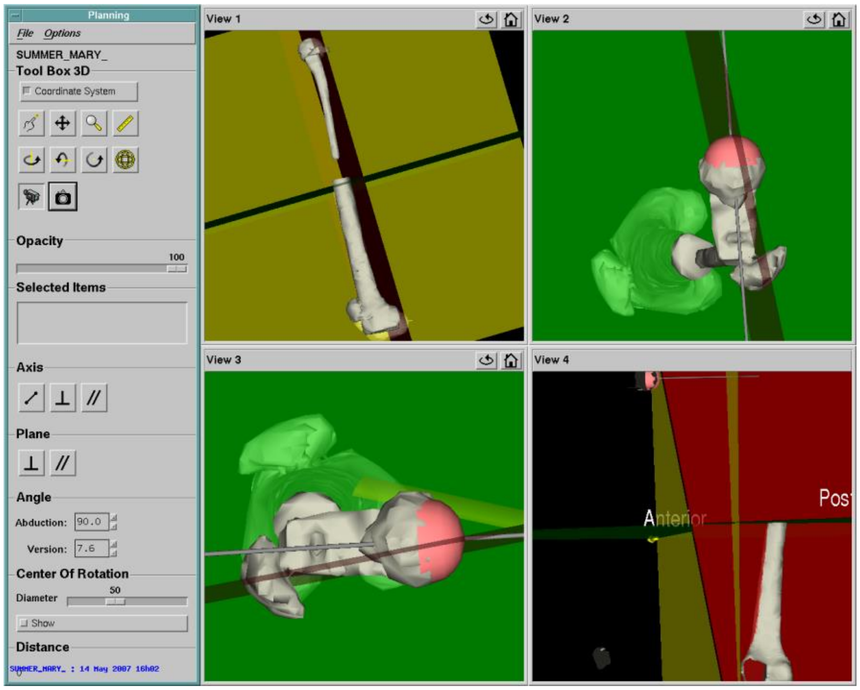
The postoperative CT femoral stem anteversion was measured using the Navitrack® three-dimensional reconstruction system on the plane of the greater trochanter proximally and femoral epicondyles distally (the same plane as the computer navigation software). With the 3-dimensional scan technique, once reconstructed the femur can be virtually moved and rotated and the most appropriate reference points selected for measurement of angles and version (Fig 1 A, B and C)[77].



A

Fig 1 A: A screenshot image of the Navitrack® CT scan-based module shows how femoral version is determined. Through volumetric and surface rendering the implant and bone are reconstructed as shown in figure A

B



C

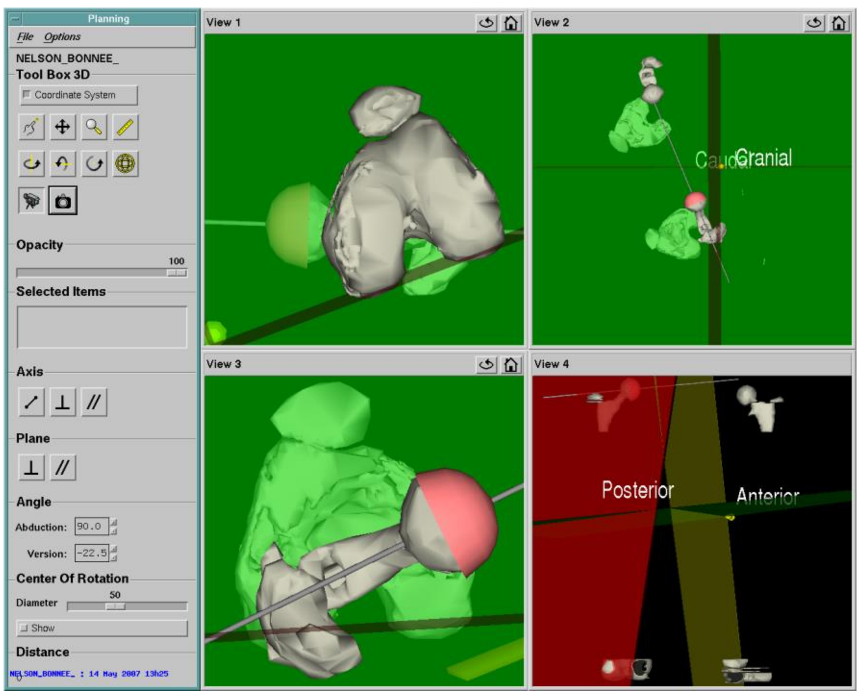
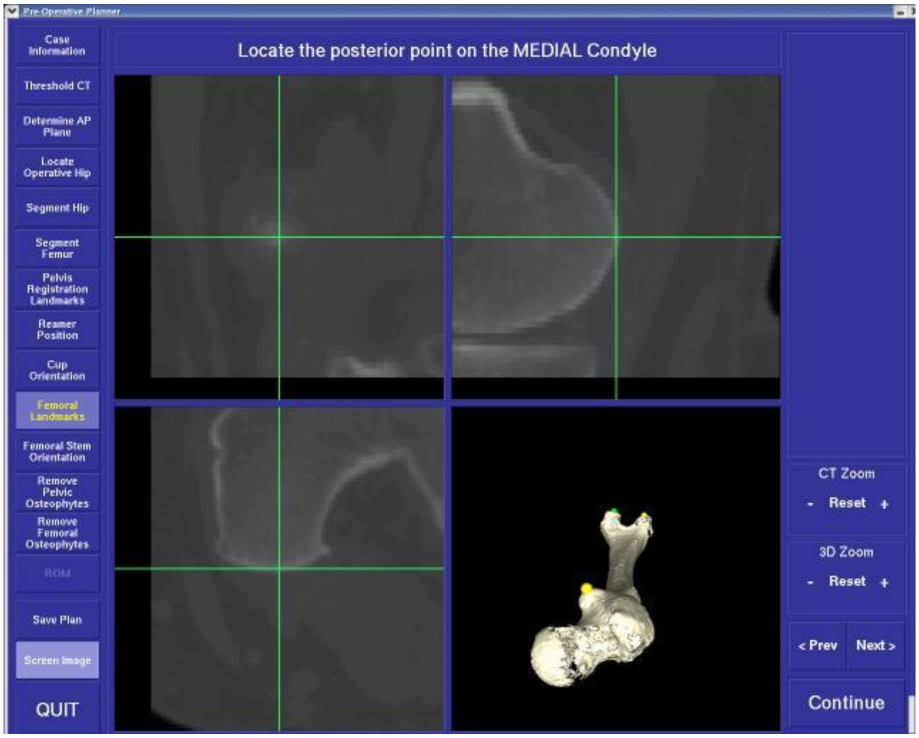


Fig 1 B and C: A screenshot image of the Navitrack® CT scan-based module shows how femoral anteversion is determined. Through volumetric and surface rendering the implant and bone are reconstructed as shown in figure A. The virtual model femoral head is positioned over the implant femoral head and aligned until the axis of the model coincides with the axis of the proximal head and neck. Anteversion is the angle between this axis and the femoral plane established as the plane passing through both medial and lateral epicondyles of the femur and the mid-high point of the greater trochanter as shown in figure B. The difference of femoral version of the implants in different patients can be observed when comparing a retroverted stem in Fig B with a highly anteverted stem in Fig C.

In the Hip Nav system the plane of the leg is identified by selecting the two femoral condyles and the lesser trochanter. This differs from orthosoft in that they choose the plane of the leg from the two posterior condyles and the tip of the greater trochanter. This could explain the approximately 3 to 4 degrees systematic difference in the numbers for femoral version between the two (Fig. 2).

The reconstructed model of the femurs position is determined in the threes planes as can be seen in the figures above. Next from a library of computer aided design models a specific component is sized and positioned over the model that has been generated. Once correctly positioned the numbers obtained are those for the femoral version. This whole process takes roughly half an hour on the Hip Nav workstation while it takes around two hours on the Orthosoft workstation



A

B

Fig 2 A and B: A screenshot image of the HipNav® CT scan-based module shows how femoral anteversion is determined. Through volumetric and surface rendering the implant and bone are reconstructed as shown in figure A. The virtual model femoral head is positioned over the implant femoral head and aligned until the axis of the model coincides with the axis of the proximal head and neck. Anteversion is the angle between this axis and the femoral plane established as the plane passing through both medial and lateral epicondyles of the femur and the mid-high point of the greater trochanter as shown in figure B.

Femoral measurements are more complex because there is no clear consensus on which points should be selected to define a reference plane for femoral anteversion[72, 77, 107, 111-115]. To date there is no gold standard for this measurement when using 3-D reconstructions. As this was a relatively new technique we developed a new methodology, which was validated and posteriorly published[77]. We measured the femoral planes by using the mid-high point of the greater trochanter and the epicondylar axis as one method, and the mid-high point of the greater trochanter and the posterior condylar axis as a second method (Fig. 2).

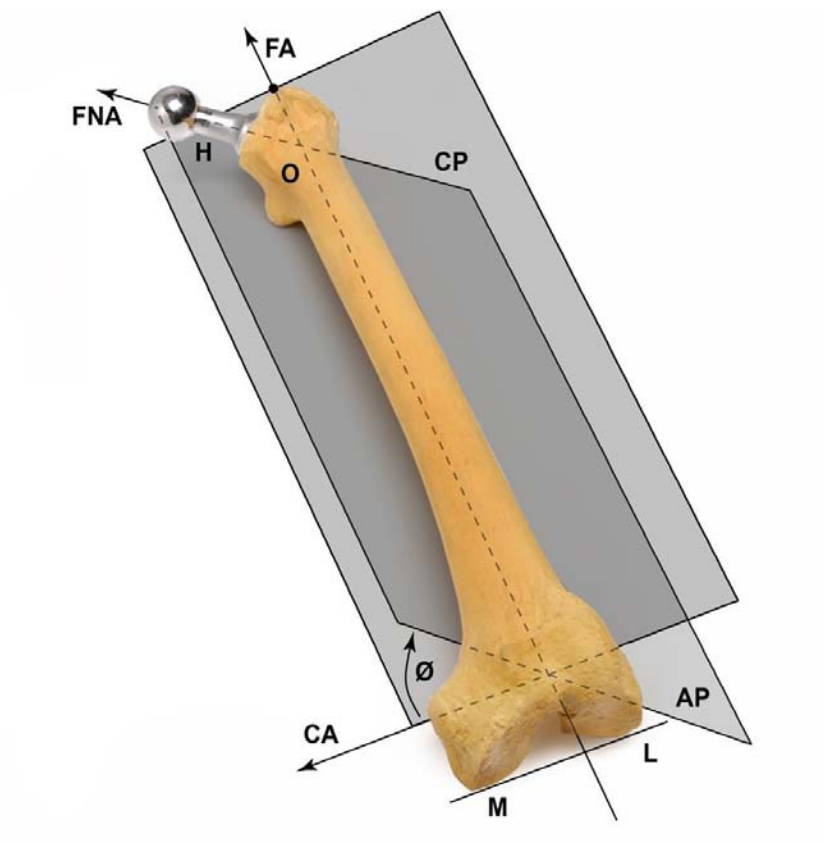


Figure 2. The longitudinal femoral axis (FA), the axis of the femoral neck (FNA), and the condylar axis (CA) form the three major reference axes of the femur. These axes define two planes: the condylar plane (CP) and the anteversion plane (AP). The angle of femoral anteversion (Ø) is the angle in the transverse plane between the anteversion plane and the condylar plane.

Measurements of the posterior condylar axis were used to validate the epicondylar axis[114]. The femur was segmented from the pelvis and a reconstructed 3-dimensional model of the femoral implant, greater trochanter, and the entire distal femoral condyles obtained. The software removes the soft tissue from the computed tomography images and extracts just the bone and implant. The femoral anteversion was measured from this computer-rendered femur image. In the 3-dimensional computed tomography reconstructive technique, femoral anteversion was the angle between the axis of the femoral neck and the epicondylar plane. The femoral neck axis was easily identified because of the high density of the metal and the sharp contour of the metal neck.

Two observers independently measured the femoral anteversion on all computed tomography scans in both the epicondylar and postcondylar planes. One observer was experienced at reading computed tomography scans and one was inexperienced. One observer (experienced) measured each scan a second time with a minimal interval of two months between readings. Intraobserver error was calculated by comparing the two independent measurements by the same person; interobserver error was the comparison of the measurements between the two observers. Only the first set of readings by one observer (experienced) were used for all of the other analyses. The mean and standard deviation, and error, of these measurements were calculated. Univariate analysis of variance was used to analyze the factors (gender and stem types) that influence the femoral anteversion[41].

<u>Comparison of Accuracy and Precision of the Epicondylar Plane and the Posterior Condylar Plane:</u> Using the epicondylar plane as reference, the mean femoral stem anteversion was 10.2 +/- 7.5° (range -8.6 to 27.1°). Using the postcondylar plane, the mean stem anteversion was 12.2 +/- 7.7° (range -7.4 to 29.5°). There was good correlation between both reference planes with a correlation coefficient of 0.994 (p = 0.001), intraclass coefficient of 0.997, bias of 2° and precision of 1.7° (Fig. 3). Therefore, the epicondylar plane was used for all comparisons to surgeon estimates because the surgeon used the epicondyles intraoperatively to judge stem anteversion.

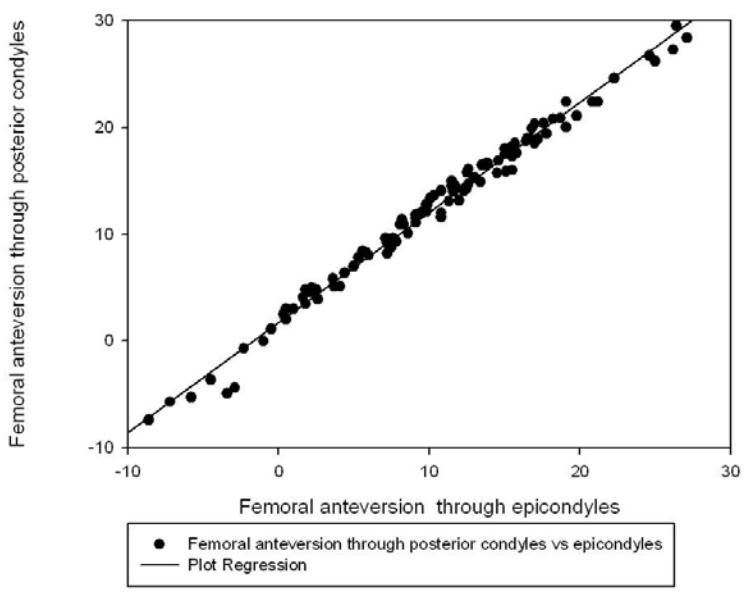


Fig 3: Scatter gram of computed tomography scans of the epicondylar axis and the posterior condylar axis shows high correlation.

Inter and intraobserver variability: For measurements by computed tomography scan the intraobserver error was 0.09 +/- 0.62° for the epicondylar plane and 0.003 +/- 0.37 ° for the postcondylar plane. The inter-observer error was 0.002 +/- 1.1° for the epicondylar plane and 0.007 +/- 1.0 ° for the postcondylar plane.

For femoral anteversion measurement in our study we slightly modified the definition of Billing[111] and Murphy et al[114] because of the type of software and reconstruction method. We used the middle high point of the greater trochanter instead of the center of the base of the femoral neck, which they used. We do not believe this influenced the accuracy of measurements. Whereas the medial-lateral displacement between these two points has no influence because it is on the femoral plane, the anterior-posterior displacement may affect the femoral plane. Strecker et al[116] reported that the average length of the femur was 463 mm. Five mm anterior-posterior displacement would theoretically create 0.62° of change in the femoral plane. However, the influence to femoral anteversion would be less than this. We tested this by changing the point on the greater trochanter during measurement of the computed tomography scan and there was no effect on the measurement of femoral anteversion. Two-dimensional computed tomography scan measurements only use the posterior femoral condylar axis and completely omitted the proximal point of the femur [41, 107, 112-114, 117, 118].

1.2.2.4 Statistics

The statistical analysis was performed with SPSS software (SPSS, Inc, Chicago, IL). We used the Kolmogorov-Smirnov test to ascertain normal distribution before further statistical analysis was conducted. For analysis of measurements, the means and standard deviations were calculated.

One-way analysis of variance was used to determine the statistical difference in measurements between anteroposterior pelvic tilt. The repeatability between acetabular inclination and anteversion of computer navigation and computed tomography scans was calculated using intraclass correlation coefficient using the reliability analysis. A p value of less than or equal to 0.05 was considered statistically different. The surgeons' estimates were evaluated as mean +/- standard deviation, precision and bias, and as outliers greater than 5 degrees compared with the computer navigation values.

Student's t test was used to compare femoral anteversion and combined anteversion between men and women. The repeatability between femoral anteversion of computer navigation and CT scans was calculated using intraclass correlation coefficient by reliability analysis. A p value of less than or equal to 0.05 was considered statistically different.

The bias and precision were calculated according to the American Society for Testing and Materials definitions[93]. We used the ASTM preferred index of precision[93]. The preferred index was the 95% limit on the difference between the two test results. The ASTM preferred index of precision was calculated as follows:

r = 1.96 $\sqrt{2}$ Sr and

$$S_r = \sqrt{\frac{\sum_{j=1}^{c}\sum_{i=1}^{n}\left(X_{ij} - \bar{X}_j\right)}{\sum_{j=1}^{c}\left(n_j - 1\right)}}$$

In the equation, (r) is the 95% repeatability limit [92] and (Sr) is the repeatability standard deviation derived from ASTM E691[92]. For the phantom model, precision was defined as the closeness of agreement between each independent measurement of anteversion obtained by either the navigation system or from the computed tomography scan to the true models anteversion values. To compare accuracy of femoral and combined anteversion, the bias and precision were calculated according to the American Society for Testing and Materials definitions[93].

1.3 VALIDATION OF NAVIGATION IN A LABORATORY MODEL.

(Malik A, Wan Z, Jaramaz B, Bowman G, Dorr LD. A validation model for measurement of acetabular component position. J Arthroplasty. 2010 Aug;25(5):812-9. doi: 10.1016/j.arth.2009.04.021. Epub 2009 Jun 24. PubMed PMID: 19553075)

1.3.1 Development of a Laboratory Model.

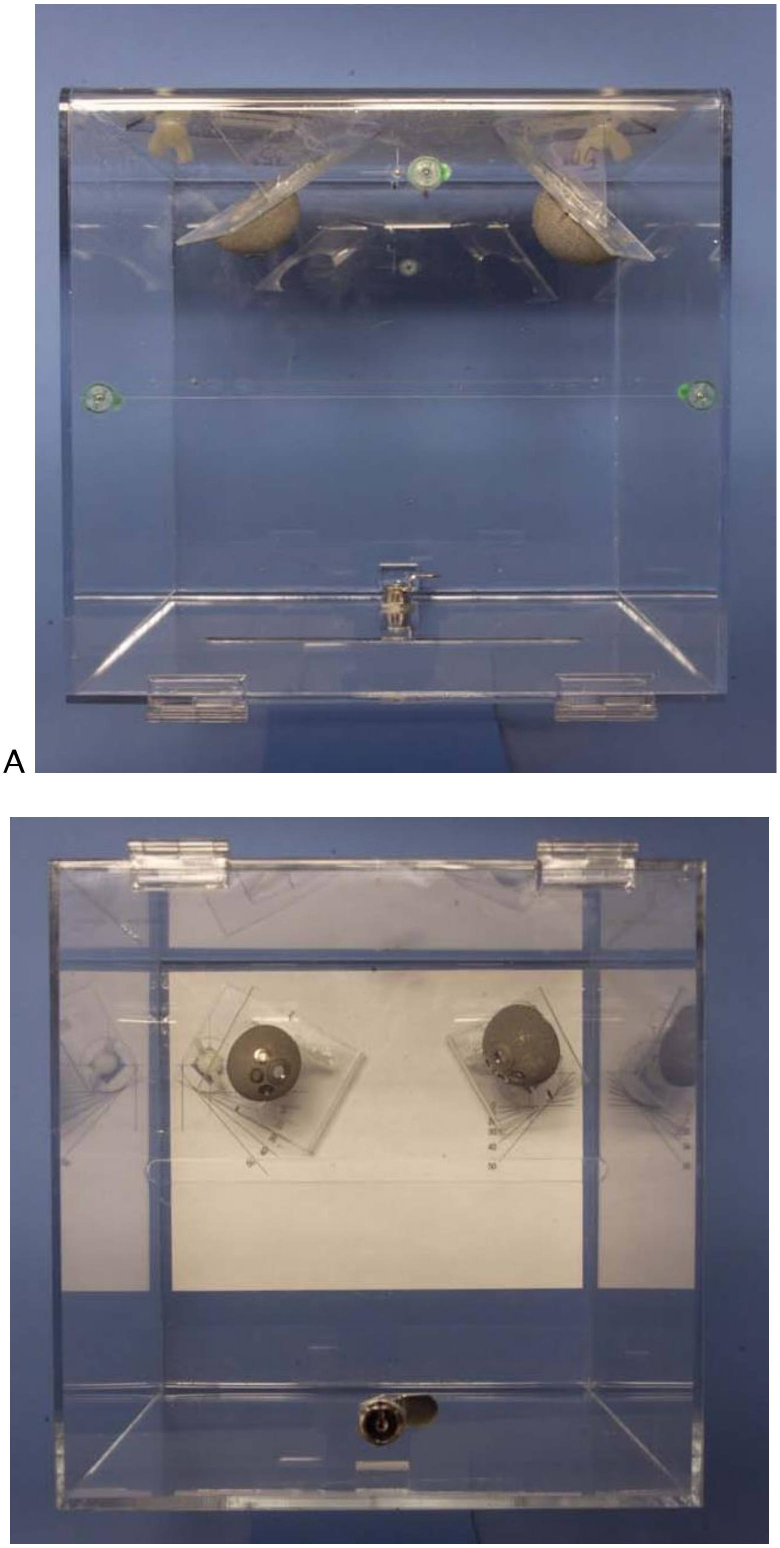
Understanding the interaction between pelvic orientation and final acetabular component position is important for achieving correct hip biomechanics with total hip arthroplasty[63]. Failure to achieve the correct acetabular component orientation for each patient can result in adverse outcomes[33, 45, 85]. Different techniques for cup placement such as freehand, mechanical guides, or computer assisted have been described but there has been no consensus on one method as superior. No single standardized measurement method or definition of cup orientation has been agreed upon[51, 52, 63].

This has resulted in variability in the accepted acetabular safe zones and target numbers both for intraoperative cup positioning and postoperative measurement[26, 33, 44, 45, 51]. This variability in target numbers for cup anteversion is influenced by the surgical approach and the definition of cup orientation used by the surgeon[36, 51, 52].

We designed a phantom model to validate, in the laboratory, the measurements of acetabular orientation as performed respectively by a computer navigation software and postoperative 3D computed tomography (3D CT) scans[36]. Computed tomography scans are the accepted standard for postoperative validation of implant position in total hip arthroplasty[45, 63, 94, 115, 119-121]. We used two different 3D CT reconstruction systems to measure cup orientation. Discrepancies in measured cup positions between CT scans and computer navigation have been reported[31, 32, 63]. Using a phantom model, in which the true cup orientation can be directly measured, we could validate the computer navigation system and resolve discrepancies between two 3D CT measurement systems.

1.3.2 Materials and Methods of the Phantom Model.

The phantom model was constructed to scale to reproduce an anatomic human pelvis maintaining comparable distances between the anterior superior iliac spines, the pubic tubercles, and the acetabular cups (Fig. 1 A and B).



A

Fig. 1 A and B: The phantom model is a symmetrical silicone cube incorporating embedded markers for the APP and 2 calibrated acetabular implants that represent the right and left hips, respectively. The cube is constructed to scale to represent an anatomic pelvic with 2 prosthetic acetabulae implanted in each hip. The superior view of the phantom cube illustrates the acetabular position marked by angle measurement references on a protractor.

The anterior pelvic plane was constructed by imbedding three metal markers to represent the right and left anterior superior iliac spines and the pubic tubercle midpoint. Each of the two acetabular cups inside a clear Plexiglas cube was mounted on a rotating base, which could control anteversion while keeping the anatomic inclination fixed. The anteversion was set by a protractor incorporated into the base of the phantom that could position the cups in six different positions for anteversion (0, 10, 20, 30, 40 and 50 degrees) (Fig 2).

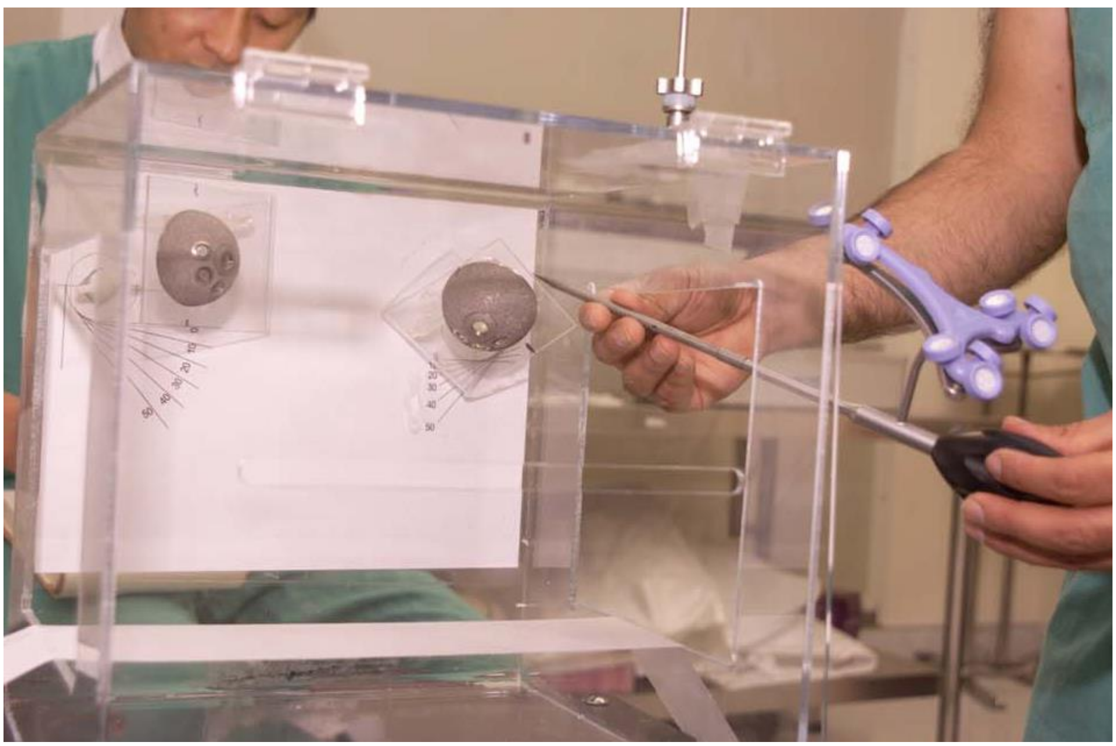


Fig. 2: Detail showing the different cup positions for anteversion and the process of registration of the acetabulum for validation of navigation and computer tomography scan inclination and anteversion.

Cup inclination was fixed at 35 degrees for the left cup and 48 degrees for the right cup. To evaluate the influence of tilt on measured component inclination and anteversion, a block was placed at the apex of the phantom so that three different tilt positions were generated: 6 degree anterior tilt, 0 degree tilt, and 6 degrees posterior tilt) (Fig 3).

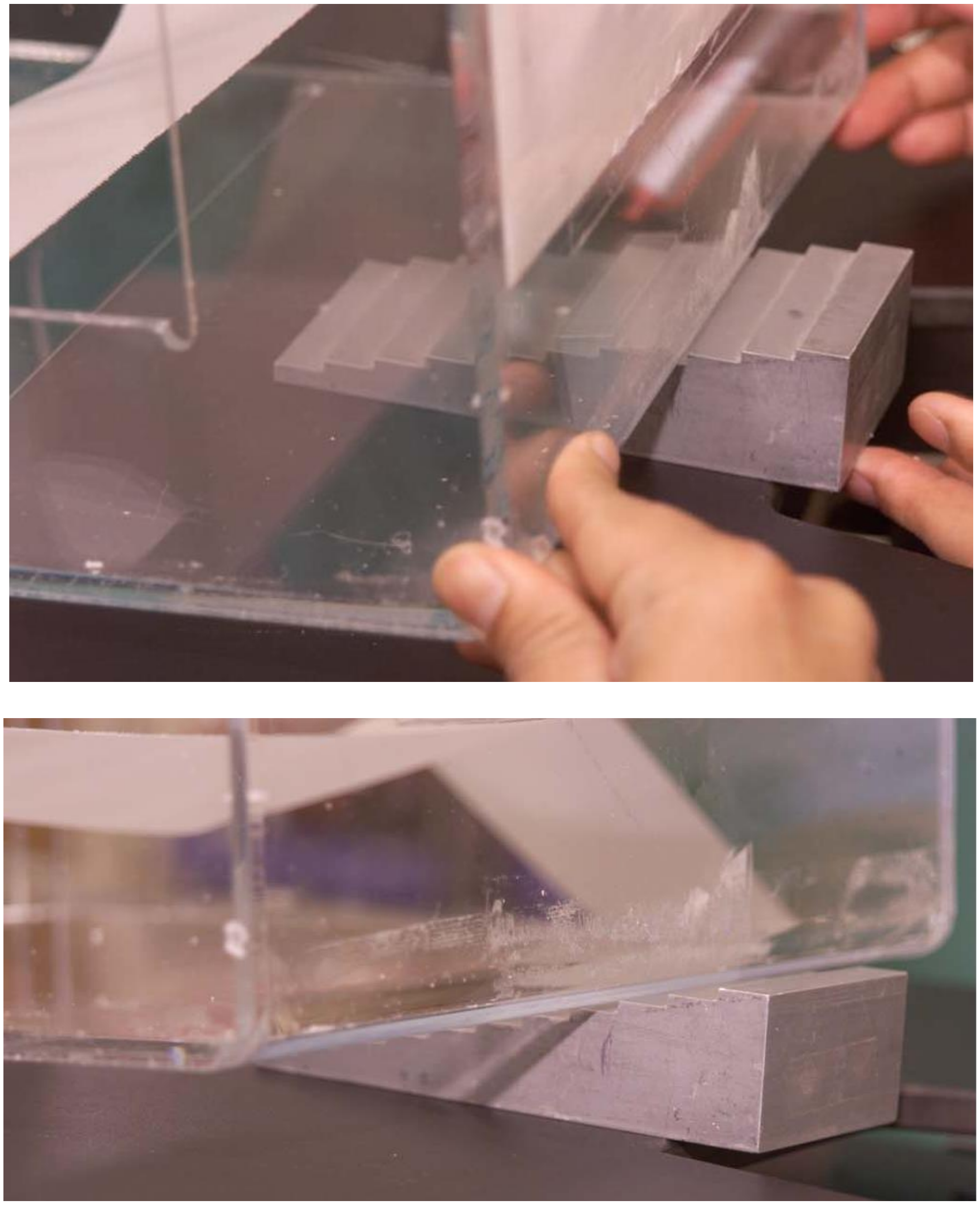


Fig. 3: Detail showing the device used to study the influence of pelvic tilt. A block was placed at the apex of the phantom so that three different tilt positions

A total of 18 readings were obtained for each test (6 positions of anteversion and 3 positions of tilt). The implants were titanium Converge cups (Zimmer, Warsaw, IN) with the left being size 57 mm and the right 53 mm.

Directly measured cup inclination and anteversion were considered true values to which all other measured values were compared. Cup orientation at each selected position was measured with two different methods. One was using an imageless navigation system (Orthosoft Navitrack Navigation System, Montreal, Canada) and the second was from CT scans which were processed using two different 3D CT based systems, the Navitrack System (Fig 4), and the planning module of the HipNav System (Carnegie Mellon University, Pittsburgh, PA) as previously described.

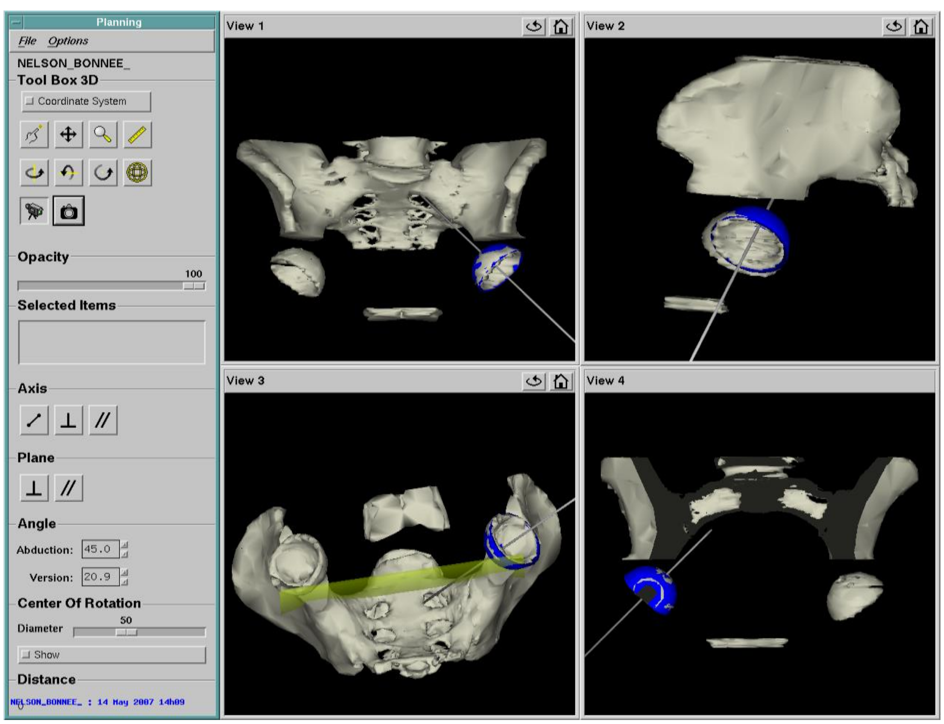
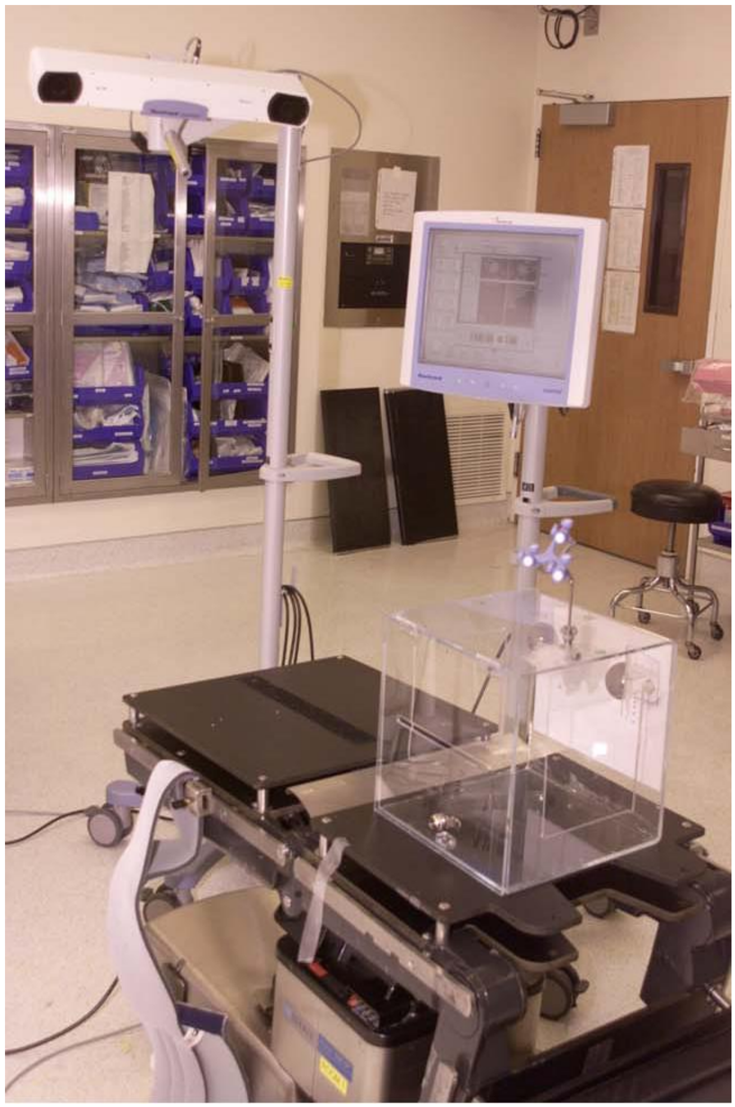


Fig. 4: Screen Shots of the Orthosoft Navitrack software for processing of acetabular implant position within the reconstructed model of the patients pelvis.

The testing with the Navitrack Imageless Navigation System was performed in the operating theatre to emulate the conditions of the total hip operative procedure (Fig. 5 A and B).



A

Fig 5 A: The setup of the operating room with the phantom model and the Navitrack Imageless Navigation System with its sensor and display screen. A rigid tracking device used to reference acetabular cup positions during registration is shown. The setup is euivalent to the clinically navigated cup in a patient during surgery.

B

Fig 5 B: Registration process with the pointer to measure the acetabular cups position simitar to a surgeical procedure with readings obtained for each cup position (non adjusted anatomic plane and adjusted for tilt coronal plane) displayed on the screen..

A rigid tracking device was attached first on the right side of the phantom, and then on the left side, to simulate the equivalent attachment during the navigation of the right and left hip. The test positions were then conducted and the navigation screen gave two values, the nonadjusted anatomic plane and the adjusted for tilt coronal plane (Fig. 5 B). Cup position was measured with computer navigation by touching 6 points on the rim of the cup with an optically tracked pointer guide. To reduce measurement errors, three measurements were obtained for each cup position and the mean of these were used as the result.

CT scans of the phantom cup positions were obtained using an MX Highland Phillips Scanner and stored in a Digital Imaging and Standard For Communications in Medicine (DICOM) format. The CT scan protocol was set at roughly 100 slices in each scan, 0.5 mm thickness and 1 mm slice intervals at an intensity that measured the materials of the phantom. The phantom was placed in the scanner to simulate the supine position of the patient entering the scanner headfirst. Scans were taken to include both the superior reference markers, both cups, and the inferior reference marker. The scans were transferred to the Navitrack and HipNav workstations for processing and determination of implant position. The volumetric and surface rendering techniques used are described in the pertinent section.

1.3.3 Results that Validate Navigation

Cup inclination and anteversion obtained by computer navigation and the two 3D CT scan measurements were compared to the true values of the phantom (Tables 1 and 2). The Imageless Computer Navigation System had a precision of 1 degree and a bias of 0.02 degrees for inclination and a precision of 1.3 degrees and a bias of 0 degrees for anteversion measurements. For inclination, both the 3D HipNav and the Navitrack CT scan measurement systems had a precision of 1 degree and a bias of 0.5 degrees; for anteversion the HipNav system had a precision of 0.4 degrees with a bias of 0.2 degrees, while the Navitrack system had a precision of 1.3 degrees with a bias of 0.2 degrees. When conversion was done of the HipNav system from anatomic to radiographic definition, results between systems were found to be equivalent (Tables 1 and 2).

Table 1 Table showing the difference between anatomic and radiographic values obtained from postoperative CT scans and by computer navigation for the Jig with the Acetabulum fixed at 35 degrees of Inclination and variable anteversion

	JIG: REAL ANTE-VERSION	INCLINATION				ANTEVERSION			
		Anatomic Values	Radiographic Values			Anatomic Values	Radiographic Values		
		HipNav	Hip Nav **	Navi track CT	Navi track CN	HipNav	HipNav**	Navi track CT	Navitrack CN
No tilt	0	35	35.0	35.2	35.3	0	0.0	0.1	-0.3
	10	36	35.5	34.6	34.7	11	6.4	6	6.3
	20	35	33.3	33.6	33.0	20	11.3	11.2	12.0
	30	35	31.2	31	31.3	30	16.7	16.5	17.0
	40	35	27.9	28.2	28.3	41	22.1	21.3	21.7
	50	35	24.2	23.8	24.0	50	26.1	26	26.3
Pelvic Posterior tilt 6 degrees	0	35	35.0	35	34.3	0	0.0	0	0.3
	10	35	34.5	34.5	34.0	11	6.3	5.9	6.0
	20	35	33.3	33.8	33.3	20	11.3	11.5	11.3
	30	35	31.0	31.5	31.0	31	17.2	16.4	16.3
	40	35	27.9	28.5	27.3	41	22.1	22	22.0
	50	36	25.0	24.5	24.0	50	26.8	26.4	26.3
Pelvic Anterior tilt 6 degrees	0	35	35.0	34.5	34.3	0	0.0	0.1	0.7
	10	35	34.6	34.2	34.7	10	5.7	5.7	5.7
	20	35	33.3	33.4	33.7	20	11.3	11.2	11.0
	30	35	31.0	31	31.3	31	17.2	16.5	16.3
	40	35	28.2	28.5	29.7	40	21.6	21.5	22.0
	50	35	24.2	24.3	24.3	50	26.1	26	26.3

** These values were calculated from anatomic values reported from HipNAV, which were converted to the radiographic plane using the mathematical correlation of Murray.

HipNav = CT based 3 D Measurement system ICAOS Pittsburgh

Navitrack CT = CT based 3 D Measurement system, Orthosoft, Montreal, Canada.

Navitrack CN = Imageless Navigation system, Orthosoft, Montreal, Canada.

Table 2 Table showing the difference between anatomic and radiographic values obtained from postoperative CT scans and by computer navigation for the Jig with the Acetabulum fixed at 47 degrees of Inclination and variable anteversion

	Jig : Real anteversion	INCLINATION				ANTEVERSION			
		Anatomic Values	Radiographic Values			Anatomic Values	Radiographic Values		
		HipNav	HipNav **	Navi track CT	Navi track CN	HipNav	HipNav **	Navi track CT	Navi track CN
No tilt	0	48	48.0	47.9	46.7	-1	-0.7	0	1.3
	10	48	47.6	47.3	46.7	10	7.4	7.8	6.3
	20	48	46.4	46.3	45.0	19	14.0	15	15.0
	30	48	43.9	43.9	43.0	30	21.8	21.5	21.3
	40	48	40.8	40.9	40.0	39	27.9	28.3	27.7
	50	48	35.5	35.4	34.7	50	34.7	34.4	33.3
Pelvic Posterior tilt 6 degrees	0	48	48.0	48.2	47.0	0	0.0	0	1.0
	10	48	47.7	47.6	45.3	8	5.9	7.7	7.0
	20	48	46.4	46	45.7	19	14.0	14.8	14.0
	30	48	43.9	44	43.0	30	21.8	22	20.7
	40	48	40.4	40.1	40.3	40	28.5	28	27.0
	50	48	36.6	36	35.7	48	33.5	35.1	33.0
Pelvic Anterior tilt 6 degrees	0	48	48.0	48.3	47.3	0	0.0	0	0.3
	10	48	47.6	47.3	46.7	10	7.4	7.5	7.0
	20	48	46.2	46	45.0	20	14.7	15.3	14.0
	30	48	44.2	44.1	43.0	29	21.1	21.8	20.3
	40	48	40.4	40.6	40.0	40	28.5	28	27.3
	50	48	35.5	35.4	35.0	50	34.7	34.7	33.7

** These values were calculated from anatomic values reported from HipNAV, which were converted to the radiographic plane using the mathematical correlation of Murray.

HipNav = CT based 3 D Measurement system ICAOS Pittsburgh
Navitrack CT = CT based 3 D Measurement system, Orthosoft, Montreal, Canada.
Navitrack CN = Imageless Navigation system, Orthosoft, Montreal, Canada.

More tilt and greater amount of anteversion increased differences between Murray's anatomic and radiographic definitions. These differences were not so accentuated with inclination. For example, at 50 degrees of anteversion the difference between the radiographic and anatomic definitions is nearly 25 degrees. Pelvic posterior tilt increased the inclination and anteversion of the cup on the coronal plane and pelvic anterior tilt decreased the measurements on that plane (Table 3). One degree of tilt changed anteversion by an average 0.8 degrees.

Table 3. Influence of Adjustment of Tilt on Values of Inclination and Anteversion in the Imageless Navitrack, Orthosoft Navigation system.

	Real Cup anteversion	Real inclination 47 degrees		Real inclination 35 degrees	
		Navitrack CN Inclination	Navitrack CN anteversion	Navitrack CN inclination	Navitrack CN anteversion
No tilt	0	46.7	1.3	35.3	-0.3
	10	46.7	6.7	34.7	6.3
	20	45.0	15.3	33.0	12.0
	30	43.0	22.0	31.3	17.0
	40	40.0	27.7	28.3	21.7
	50	34.7	33.3	24.0	26.3
Pelvic Posterior tilt 6 degrees	0	47.3	3.0	34.7	5.0
	10	45.3	10.7	34.3	10.7
	20	47.0	18.0	33.7	16.3
	30	44.3	24.7	32.0	21.0
	40	42.3	31.3	28.7	26.7
	50	38.3	37.3	25.0	31.3
Pelvic Anterior tilt 6 degrees	0	47.3	-3.3	34.3	-4.7
	10	46.0	3.7	34.7	1.7
	20	44.7	10.0	33.0	7.0
	30	42.0	17.0	30.7	12.0
	40	38.3	23.3	29.0	18.0
	50	33.3	30.0	23.7	21.7

1.4 SURGICAL TECHNIQUE: NAVIGATED POSTERIOR MINI-INCISION TOTAL HIP SURGERY

(Malik A, Dorr LD. The science of minimally invasive total hip arthroplasty. Clin Orthop Relat Res. 2007 Oct;463:74-84. PMID: 17621231 PubMed)

Posterior MIS Technique

The operative technique for the total hip replacement was the posterior minimally invasive surgery (MIS) operation, which was performed by one experienced hip surgeon (LDD)[6, 122-124]. Components used were the porous coated Converge cup (Zimmer, Warsaw, IN) and Anatomic Porous Replacement (APR) stem (Zimmer), which were implanted cementless.

Computer Registration

The instrumentation for computer navigation was calibrated while the patient was prepared for anesthesia. After the patient was anesthetized, a metal base plate for the pelvic tracker was secured with three 1/8-inch threaded pins to the thickest portion of the pelvic brim. An optical tracker was attached to the baseplate. With the patient supine, the anterior pelvic plane registration was performed by puncturing the skin to obtain bony contact to both anterior-superior iliac spines and the pubic bone near the pubic tubercles (Fig 1). This is a vital step that requires care to ensure bony contact even in obese patients. In obese patients a scalpel is inserted through the skin to the bone to create a track for the registration pointer. The pubis is identified by palpating the superior border in the midline of the body and the registration pointer is contacted to the bone just distal to this midline border.

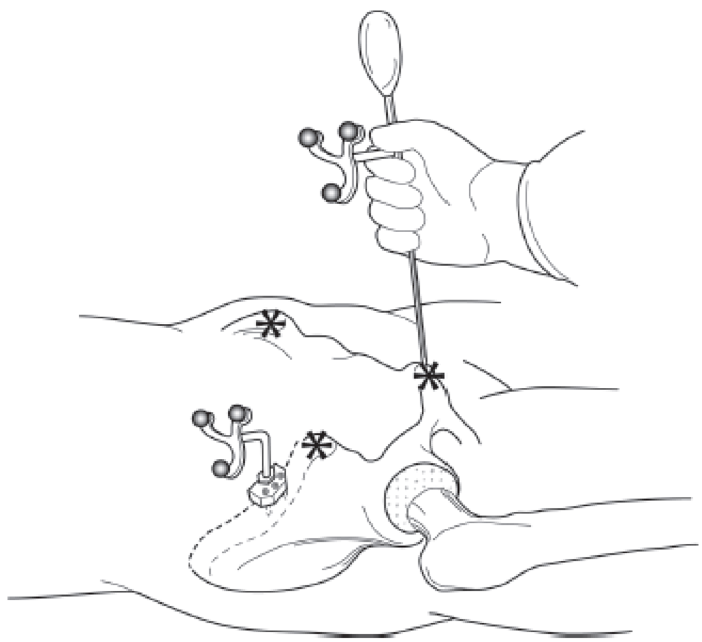


Fig. 1 The pelvic base antenna is pinned to the iliac crest. The two anterosuperior iliac spines and symphysis pubis are touched by the pointer guide. Percutaneous incisions are made to ensure that the guide obtains bony contact through the skin

The femoral baseplate was attached to the anterior lateral femur 8 cm cephalad from the superior pole of the patella and anterior to the anterior edge of the iliotibial band (Fig 2). The patient was then turned to the lateral position for the operation. The longitudinal axis of the patient was registered by using the posterior body supports - the Flip technique (Fig. 2). The pelvic tilt with the patient in the lateral position was calculated by computer software relative to the APP. The acetabular component position was displayed on the screen as adjusted inclination and anteversion, being adjusted for the pelvic tilt. This adjustment changed the inclination and anteversion from the anatomic plane to the radiographic plane as defined by Murray[70]. The longitudinal plane of the leg was registered from the two femoral condyles and ankle malleoli.

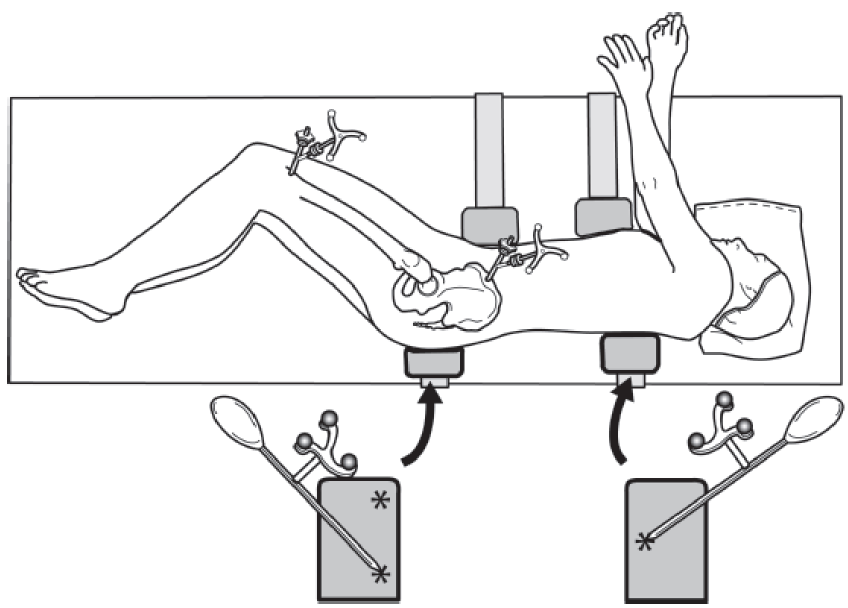


Fig. 2. In the flip technique, once the patient is changed to a lateral decubitus position, a triangle is formed using the posterior supports of the pelvis and chest to register the longitudinal axis of the body. Pelvic tilt in the lateral position relative to the longitudinal axis is also obtained

Posterior Approach

The incision is made over the posterior 1/3 of the trochanter, and extends proximally from the level of the vastus tubercle for 8-10 cm cephalad (Fig.

3). The first incision into hip tissue is done in the gluteus maximus muscle, which is incised for 6–8 cm along the posterior border of the greater trochanter. The second is through the small external rotators and the posterior capsule with the leg held in internal rotation. It is made as a single flap from the proximal edge of the quadratus femoris muscle to the piriformis tendon, then directed posteriorly parallel to the tendon to the edge of the acetabulum (it is important not to go beyond the acetabular edge to protect the sciatic nerve). Thereafter, the hip is dislocated and the neck is cut at the level preoperatively templated to best restore leg length and offset if the hip center of rotation is restored (Fig. 4). The third incision is of the inferior medial capsule, which is incised from the anterior femur to the acetabulum through the transverse acetabular ligament.

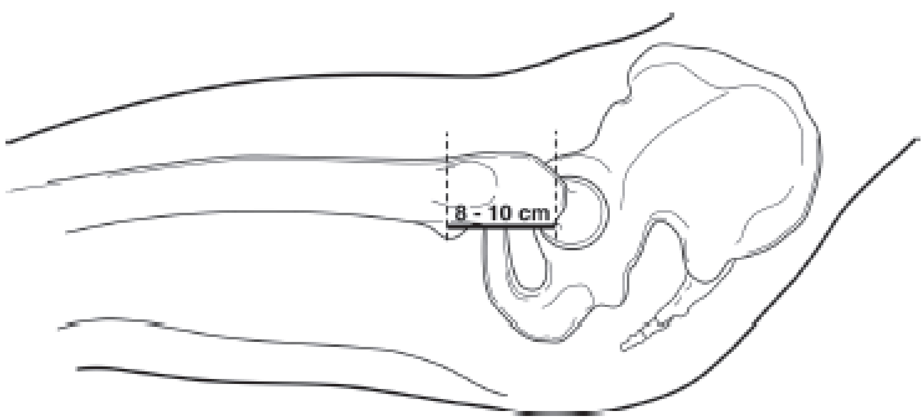


Fig. 3 Schematic representation of cut 1. The incision must be made along the posterior border of the greater trochanter. The average length of the incision is 8–10 cm

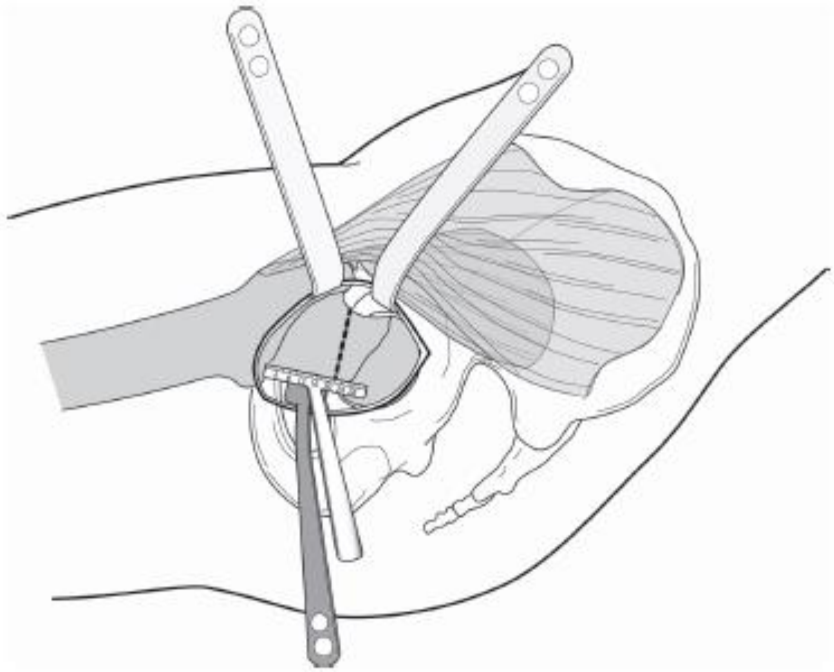


Fig. 4 The neck cut that has been templated preoperatively is validated for hip and leg length measurement. A ruler is used to measure the cut from the distal edge of the femoral head because the lesser trochanter is not visible because the quadratus is not incised

Femoral Preparation

The preparation of the femur was performed first so that the anteversion of the femur was known prior to the preparation and implantation of the acetabulum. The femur is presented through the wound by the positioning of special long-handled retractors (Zimmer and Innomed) as shown in Fig. 5.

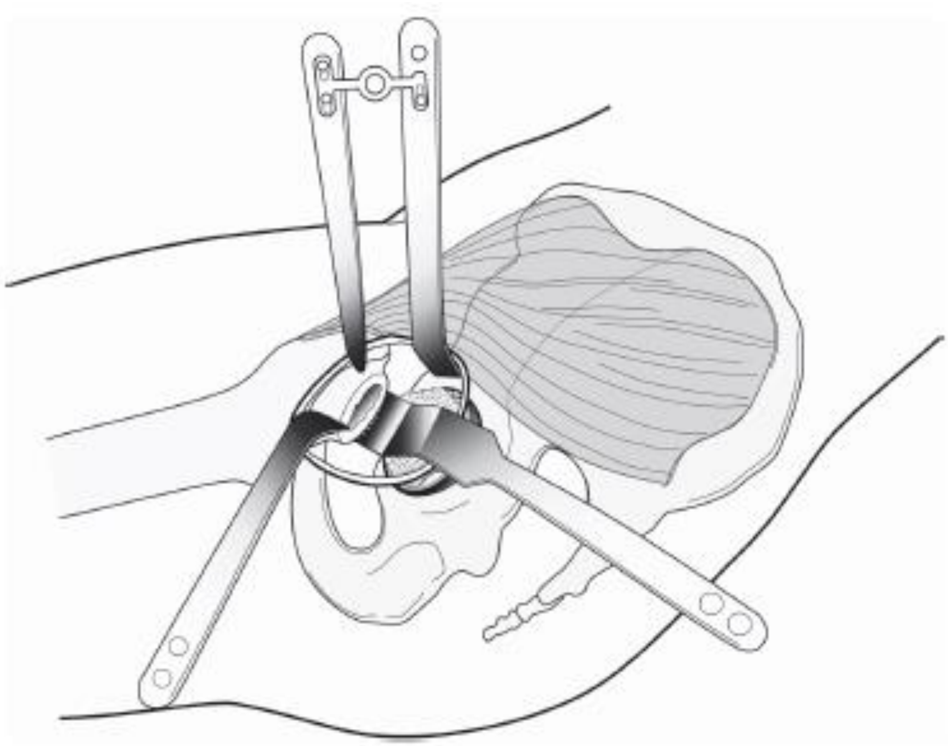


Fig. 5 Femoral exposure: the femur is presented through the wound posterior with the aid of the special long retractors. The anterior retractors separate the greater trochanter and the gluteus medius tendon. The posterior retractor inferiorly is placed retracting the quadratus muscle and either the big or baby jaws retractor is under the anterior femoral neck

Femoral preparation was done by reaming and broaching. The intramedullary canal of the femur was registered by inserting the tool into the opened intramedullary canal and registering five points of the intramedullary canal into the software. The software could then determine the position of the implants in the femoral bone by calculating the intramedullary canal relative to the plane of the leg. The anteversion of the broach (and subsequently the stem) was computed as it was implanted into the bone (Fig. 6 and 7).

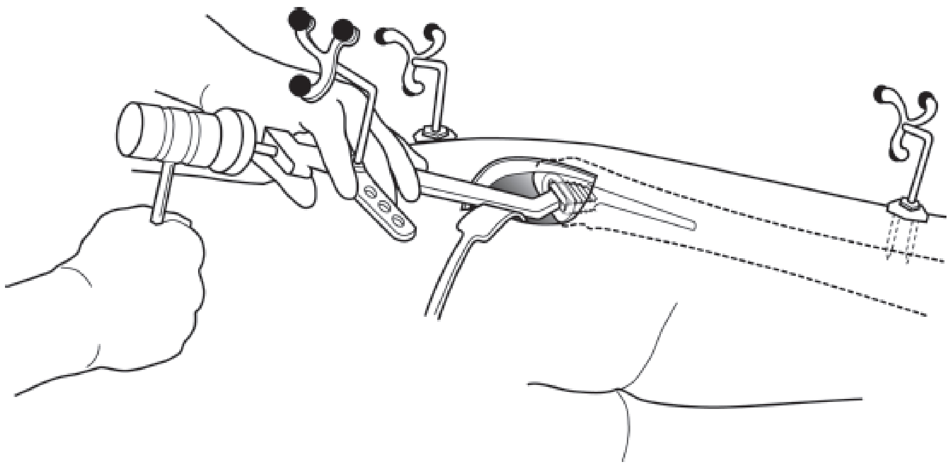


Fig. 6 The broach is inserted into the femur and the light-emitting diode (LED) on the broach handle allows the computer to recognize the broach position in the intramedullary canal. The anteversion of the femur is thus obtained from this broach so that the combined anteversion can be obtained for acetabular cup placement

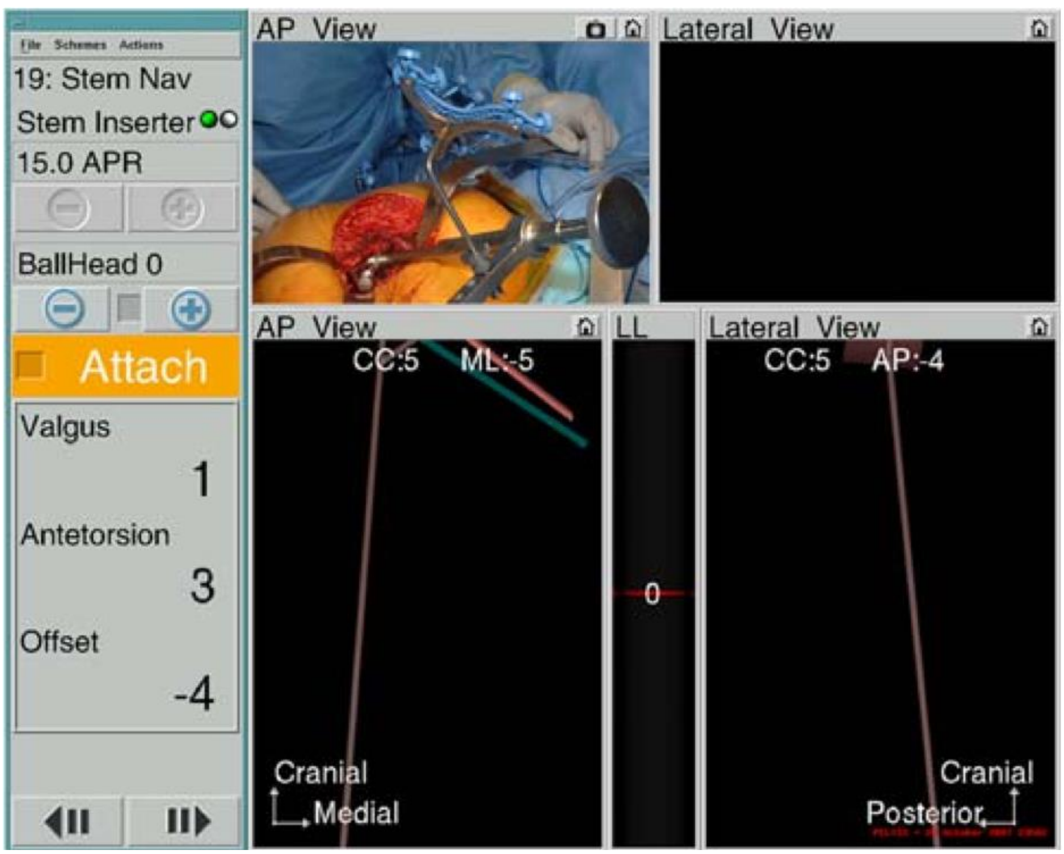
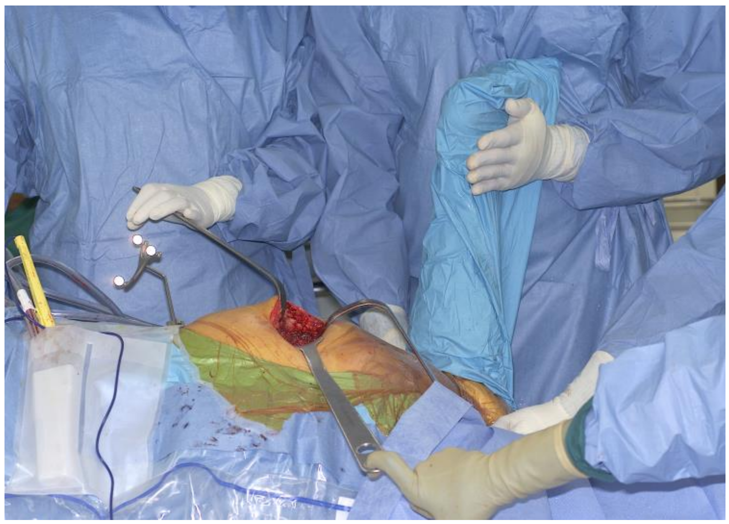


Fig. 7: A screenshot image of the Navitrack® navigation screen shows femoral anteversion when using a tracked femoral broach or stem inserter as shown in the inset in the upper left-hand corner. Anteversion is 3 degrees, stem is in 1 degree valgus, and with a neutral head the off-set of the femoral head is decreased 4 mm. CC is craniocaudal height of the femoral head center which in increased 5 mm; ML is the mediolateral displacement of the head center which is 5 mm medial; AP is anteroposterior displacement of head center which is 4 mm posterior which contributes to retroversion of the stem (see Fig. 1).

During our study once the final broach was seated, the trial neck was placed and the surgeon blinded to the results of the computer navigator by turning away the screen from our field of view. The surgeon then estimated femoral anteversion by judging it against the axis of the femur (Fig. 8). We prepared our femur first in line with the hip reconstruction towards a targeted numerical combined anteversion



A

B

Fig. 8 A and B. The surgeon can estimate femoral anteversion by judging the trial neck or final stem axis against the axis of the femur when the leg is held perpendicular to the plane of the floor

Acetabular Preparation

Once again, specialized long-handled retractors are placed to obtain correct exposure of the acetabulum (Fig. 9).

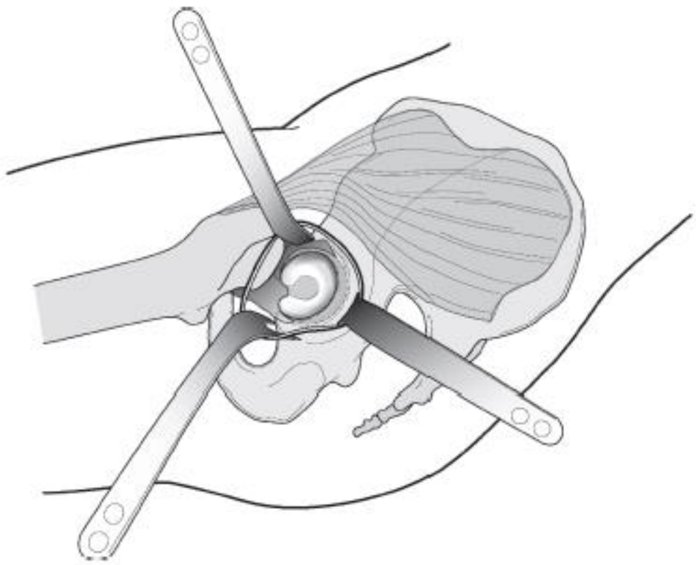


Fig. 9 Acetabular exposure: the snake retractor is placed anteriorly on the ilium through an incision made on the anterosuperior acetabulum and retracts the greater trochanter anteriorly. The anterior-superior acetabular wall is thus visualized. The number 7 inferior retractor is placed with its tip on the cotyloid notch and the paddle on the ischium. The number 4 retractor is placed posterosuperiorly and the whole acetabulum can be visualized.

Three registrations of the acetabulum are done prior to acetabular preparation: (1) center of rotation (COR) and diameter of the bony acetabulum; the acetabulum is digitized 16 times to obtain these values; (2) three to four points on the cortical bone on the cotyloid notch to digitize the medial wall; and (3) inclination and anteversion of the native acetabulum is registered by touching the periphery of the acetabular bone 6 times, which is displayed on the computer screen as both anatomic and adjusted values which is the radiographic definition of Murray (Fig 10).

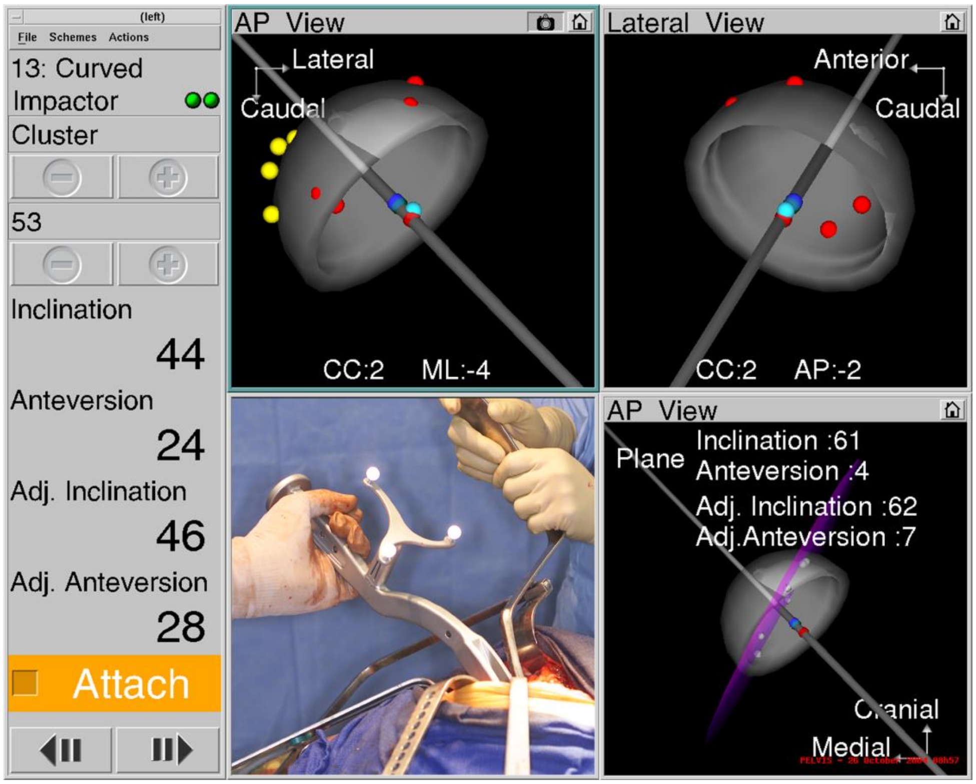


Fig 10. The trial cup implantation is shown in the lower left quadrant. The upper quadrant shows the position of the cup relative to the acetabulum, including the medial wall. The CC, ML, and AP numbers provide the center of rotation superior displacement (CC), medialization (ML), and anteroposterior displacement (AP). The numbers on the left give the numeric inclination anatomic anteversion and adjusted (radiographic) inclination and anteversion. The lower right quadrant gives the native acetabulum values, and the gray lines show what portion of the cup would be uncovered. We can see the values of the anatomic anteversion 24 degrees and the radiographic or adjusted anteversion which incorporates tilt as 28 degrees in this case.

The surgeon can control the depth of reaming in both the medial and superior directions while visualizing the change in the COR position on the computer screen. This is important because it allows the surgeon to obtain the correct depth that permits adequate coverage of the cup with an inclination between 35 and 45˚; and it gives the surgeon the ability to keep the COR within 3 mm of the original native COR.

During our study once the final reamer was seated, the trial acetabulum was placed with the surgeon blinded to the results of the computer navigator by turning away the screen from our field of view. The surgeon then estimated acetabular inclination and anteversion by his clinical intuition and judgment in line with traditional acetabular positioning. The final cup was placed with direct visualization of the screen of the navigation system.

2 HYPOTHESIS

2.1 Computer Navigation in the clinical setting is accurate to within 5 degrees of the desired target position for acetabular inclination and anteversion

2.2 Computer Navigation in the clinical setting is accurate to within 5 degrees of the desired target position for femoral version

2.3 Surgeons are less precise than navigation for positioning implants in the desired target position

2.4 Femoral Version in non cemented implants is more varied than the desired 15 degrees

2.5 Computer navigation can quantitatively keep the combined anteversion in the safe zone of 25° to 50° for each patient

2.6 The surgeon can accurately estimate correct combined anteversion with the Ranawat test

3 OBJECTIVES

3.1 Validate that Computer Navigation in the clinical setting is accurate to within 5 degrees of the desired target position in the acetabulum

3.2 Validate that Computer Navigation in the clinical setting is accurate to within 5 degrees of the real position for femoral version

3.3 Confirm that surgeons are less accurate than navigation for positioning implants in the desired target positions

3.4 Confirm that femoral version in non cemented implants is more varied than the desired 15 degrees

3.5 Evaluate if Computer Navigation can assist in hip reconstruction towards the target numbers for the combined anteversion technique

3.6 Confirm whether the Ranawat test is precise for estimating the combined anteversion between acetabulum and femur

4 MATERIALS AND METHODS: CLINICAL VALIDATION OF ACCURACY OF TOTAL HIP SURGERY WITH IMAGELESS COMPUTER NAVIGATION

4.1 ACETABULAR INCLINATION AND ANTEVERSION

(Dorr LD, Malik A, Wan Z, Long WT, Harris M. Precision and bias of imageless computer navigation and surgeon estimates for acetabular component position. ClinOrthop Relat Res. 2007 Dec;465:92-9. PubMed PMID: 17693877).

All patients had primary total hip replacement performed using the Navitrack Imageless Computer Hip System (Orthosoft, Montreal, Canada). Institution Review Board approval for computed tomography scans and informed consent for prospective review of data was obtained. Our study focused on the accuracy of computer navigation as intraoperative instrumentation and therefore clinical outcome data were not included.

In the first phase of the study 35 patients were invited to enroll by obtaining a postoperative computer tomography scan. Thirty patients with 30 hips, who agreed to a postoperative computer tomography scan, had a comparison of their computer navigation values and computed tomography (CT) values for cup inclination and anteversion.

Thirty patients were selected for this study because according to the American Standards for Testing and Materials (ASTM) criterion at least 30 cases are required to correctly calculate the values for precision and bias. In this study the sample error of a mean value was 2.4% for inclination and 4.4% for anteversion when the sample size reached 30 hips.

The second phase of the study was a comparison of surgeons' estimates of cup position to the true value of computer navigation. Computer navigation was used as the true value because of its validation in phase 1. In the initial phase, thirty-five hips (including the 30 with CT scans) had had a surgeon estimate (LDD) for the trial cup position. The surgeon's estimates were not consistently close to the computer values. Therefore, the second phase of the study was designed with a protocol for comparison of estimates of two surgeons (2 observers), one experienced (LDD), and one less experienced (a fellow), to the cup position measured by the computer. The surgeon estimated the inclination and anteversion of the trial cup position which was compared to the computer navigation numbers for inclination and anteversion of the trial cup. Surgeons were blinded to the computer navigation numbers. Surgeons' estimates were given simultaneously to the recording nurse. The trial cup position was used because computer navigation values were known to be precise and the final cup could then be placed with computer control to obtain the desired position. One hundred hips were the goal for comparison and 101 hips in 99 patients were included. These were consecutive operations in which a fellow was in attendance with the senior surgeon (LDD). Therefore 88 of 189 hips were excluded with 35 in the preliminary single surgeon estimates, 16 in simultaneous bilateral hips in which the second hip did not have navigation, and 37 in which a fellow was not in attendance at the operation.

The diagnosis of the initial CT scan group was osteoarthritis in 28 hips, dysplasia in one hip, and rheumatoid arthritis in one hip. The diagnosis of the patient group which had surgeon estimates was osteoarthritis in 85 hips, dysplasia in ten, avascular necrosis in three, rheumatoid arthritis in two, and posttraumatic osteoarthritis in one. Demographics are shown in Table 1.

Table 1. Demographics

	CT Scan Group	**Surgeon Estimate Group**
Number of patients (hips)	30 (30)	99 (101)
Age (years)	67.9 (42-89) *	63.7 (33-89)
Gender (male/female ratio)	17/13	60/41
Height (meters)	1.69 (1.42- 1.91)	1.70 (1.33-1.98)
Weight (kilograms)	78.1 (50-131)	84.1 (45-140)
Body mass index (kg/m^2)	26.8 (20-39)	28.0 (17-40)

*Ranges shown in parentheses
CT Scan = computed tomography scan

The surgical procedure and navigation registration process have been described previously.

As indicated in the surgical technique section, intraoperative references were obtained by registration of the native bony acetabulum. The change in position of the center of rotation during trial and cup placement was quantified in the cephalocaudad and mediolateral direction. Inclination and anteversion of the trial cup, and the actual acetabular component, was measured quantitatively (Fig 1).

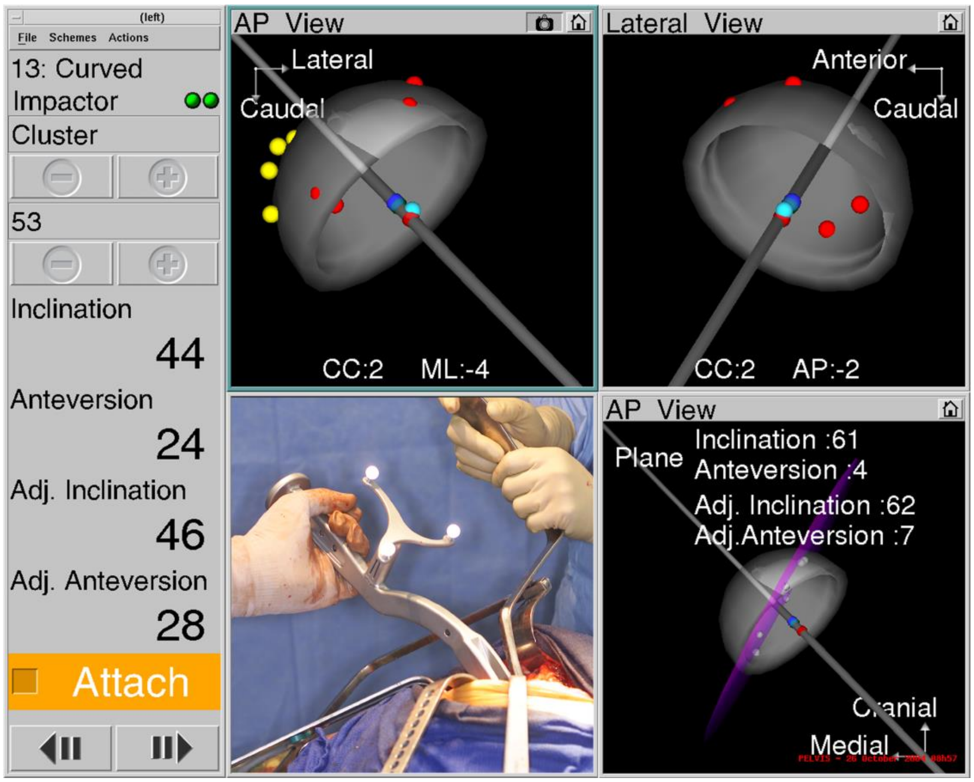


Fig 1. The trial cup implantation is shown in the lower left quadrant. The upper quadrant shows the position of the cup relative to the acetabulum, including the medial wall. The CC, ML, and AP numbers provide the center of rotation superior displacement (CC), medialization (ML), and anteroposterior displacement (AP). The numbers on the left give the numeric inclination anteroposterior anteversion and adjusted inclination and anteversion. The lower right quadrant gives the native acetabulum values, and the gray lines show what portion of the cup would be uncovered.

Based on Murrays definitions the software of the computer is designed to provide on the computer screen both the anatomic and radiographic plane values of the acetabular component in the pelvis[70]. In this navigation system adjusted inclination and anteversion represent the radiographic inclination and anteversion of Murray. Surgeons who operate in the posterior position visualize the acetabular inclination and anteversion in a similar plane as the radiographic plane when positioning the cup. The radiographic plane position (adjusted position) is also the traditional plane used for data comparison with postoperative radiographs. It was important to us that the software be formatted with the numeric component positions with which we were familiar, which is why we determined the pelvic tilt in the lateral position to obtain the adjusted radiographic values.

The final acetabular component was manipulated into the desired inclination, which was targeted between 35 degrees and 45 degrees. A combined anteversion technique of the femoral and acetabular components was used for implant positioning. The femoral stem anteversion was measured using the computer software before the acetabular preparation. The acetabular component anteversion was then determined according to the stem anteversion so that there would be a combined anteversion of 30-40 degrees for men, and 35-45 degrees for women. This concept was similar to that proposed by Widmer and Zurfluh in their finite element study, although we did not use their formula[81] We based our desired combined anteversion on the clinical experience of Ranawat and our previous experience[82, 122, 123].

The numeric position for inclination and anteversion had to also be combined with cup position within the bony socket in order to obtain correct bony coverage. The desired position of the cup was one that avoided lateralization of the metal shell and provided adequate bony coverage. If the anterior-superior portion of the cup was flush with bone, the metal neck would not impinge on the metal cup during flexion and particularly flexion, internal rotation, and adduction. The posterior-superior edge of the cup could project 3 mm lateral to the posterior-superior bone. The inferior-medial edge of the metal shell was placed level with or just superior to the bony edge of the cortical bone of the cotyloid notch (inside the transverse acetabular ligament). The center of rotation of the acetabulum was reamed medially and cephalad sufficiently to ensure this cup coverage. From previous studies, we knew this meant reaming an average of 6 mm medial and 5 mm superior[123, 125]. The reaming was medialized to the cortical bone of the cotyloid notch. The offset of the hip had to be correct to also prevent impingement of the trochanter against the pelvic bone (bone-to-bone impingement).

Movement of the cup can occur with the pounding in of the polyethylene to lock it in place. If the implanted cup moved more than 5 degrees after polyethylene insertion, it was considered an unstable cup and to create stability, the polyethylene would have to be removed and screw fixation added or the cup size changed[123, 125]. In this series no cup required repositioning to add screws. Screws were placed in three hips for fixation because the metal shell was not considered stable during its implantation. The final cup position was measured after the polyethylene liner installation because the numbers can change by 1-3 degrees. The computer navigation cup plane values obtained by digitizing the metal shell equator after liner installation were the values used to compare with the postoperative computed tomography scans because they were the final measured values.

Thirty patients had postoperative computed axial tomography scans (MX 8000; Phillips, Highland Heights, OH). The processing of these patients CT scans has been described in its pertinent section. We validated the accuracy of the computer navigation by the comparison of the postoperative computed tomography scans and the computer navigation measurements of inclination and anteversion from these 30 patients. Postoperative computed tomography scans showed the true value because they have been accepted as the gold standard in the literature for validating cup position[26, 64, 94, 95].

The anteroposterior pelvic radiograph was taken in the supine position with the beam centered over the symphysis pubis. Measurement of the radiographic cup inclination was performed using the method of Callaghan et al[106] and anteversion using the modified method of Ackland with a correction factor of 4 degrees[110, 126]. The radiographic measurements were evaluated as mean +/- standard deviation.

4.2 FEMORAL VERSION AND COMBINED ANTEVERSION

(Dorr LD, Malik A, Dastane M, Wan Z. Combined anteversion technique for total hip arthroplasty. Clin Orthop Relat Res. 2009 Jan;467(1):119-27. doi:10.1007/s11999-008-0598-4. Epub 2008 Nov 1. PubMed PMID: 18979146; PubMed Central PMCID: PMC2600986.).

We compared the surgeon's estimate of combined anteversion to that by navigation and postoperative CT scan in 46 patients (47 hips). Institutional Review Board approval for CT scans was obtained, as was informed consent for prospective review of data from each patient. Demographics include 41% female patients and a mean age of 62.1 ± 8.6 years (Table 1). The reason for surgery was osteoarthritis in 42 hips, dysplasia in 3, avascular necrosis in 1, and posttraumatic arthritis in 1.

Table 1.

Patient Demographics

Demographic	**Navigated Femur Group**
Number of patients (hips)	46(47)
Gender (male/female ratio)	28/19
Age (years)	62.1 ± 8.6
Height (cm)	175.9 ± 9.0
Weight (Kg)	85.6 ± 13.6
Body mass index (kg/m^2)	27.7 ± 4.0

Values are expressed as mean ± standard deviation

cm = centimeters

Kg – kilogram

Kg/m3 = kilogram per square meter

*Ranges shown in parentheses
CT Scan = computed tomography scan

The concept of quantitative positioning of implants is applicable to all designs. We used implants we have long employed. The cementless stem was the anatomic porous replacement[127, 128] (APR®, Zimmer, Inc) and the cup was the Converge (Zimmer, Inc) which is the successor to the Anatomic Porous Replacement cup[129] , with the singular change being a better locking mechanism.

The details of the operative technique, which prepares the femur first, have been described above and published previously[50, 124, 125]. We had already shown this computer navigation system allows precise placement of the cup for both anteversion and inclination[36]. One experienced surgeon (LDD) performed all surgeries using the posterior mini-incision[124]. All patients had primary THA performed using the Navitrack® Imageless Computer Navigation System (ORTHOsoft, Inc, Montreal, Canada) whose numeric cup values are reported using the radiographic measurement of Murray[70]. Navigation was used for cup positioning in all hips. Both instrumented navigation for measurement of femoral stem anteversion and the physician estimate of stem anteversion were performed in all 47 hips.

All 46 patients had a postoperative CT scan (Mx8000™; Phillips, Highland Heights, OH). The technical details of the CT scan method have been described previously. Once the CT Scan values were obtained they were compared to the results of the navigation system. Femoral anteversion was measured by (1) surgeon estimate of broach anteversion validated by computer navigation, and (2) stem anteversion measured by intraoperative computer navigation validated by postoperative CT scans (Fig. 1).

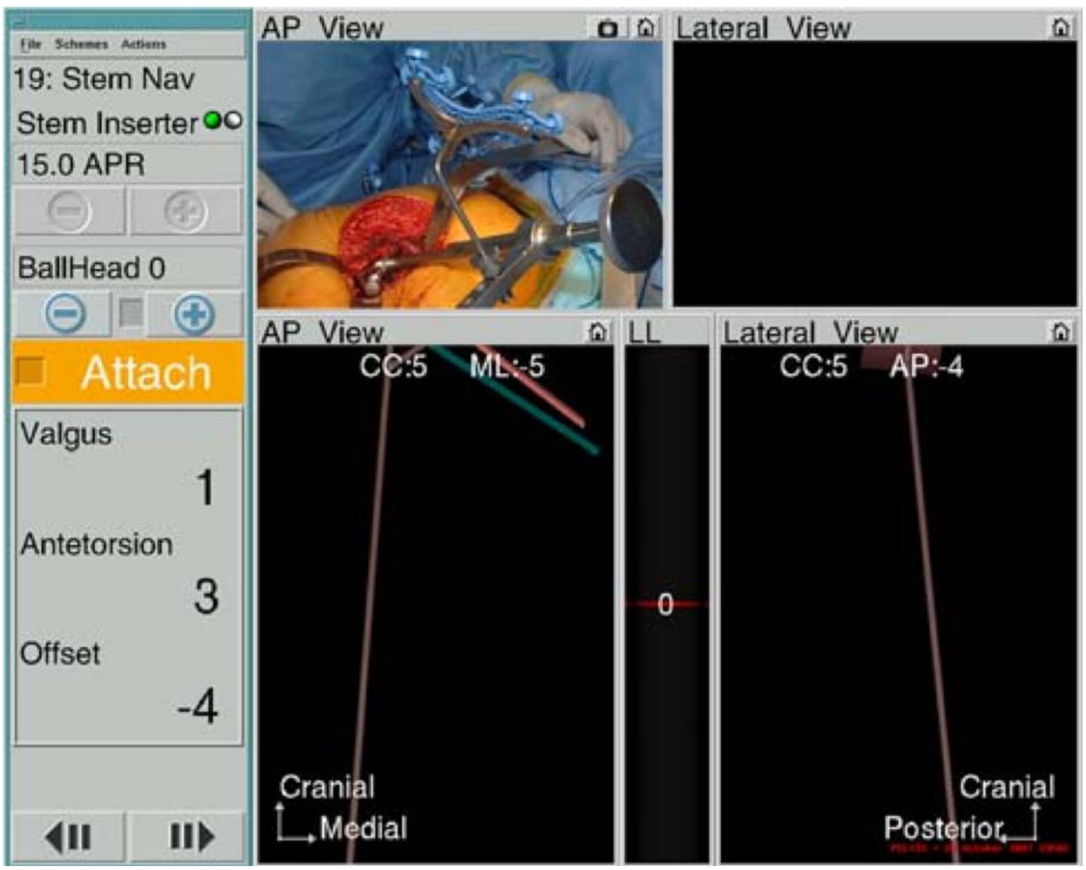


Fig. 1: A screenshot image of the Navitrack® navigation screen shows femoral anteversion when using a tracked femoral broach or stem inserter as shown in the inset in the upper left-hand corner. Anteversion is 3 degrees, stem is in 1 degree valgus, and with a neutral head the off-set of the femoral head is decreased 4 mm. CC is craniocaudal height of the femoral head center which in increased 5 mm; ml is the mediolateral displacement of the head center which is 5 mm medial; AP is anteroposterior displacement of head center which is 4 mm posterior which contributes to retroversion of the stem.

Combined anteversion was the sum of stem and cup anteversion and was measured both by the sum of stem and cup anteversion with intraoperative computer navigation and stem and cup anteversion on postoperative CT scan. Outliers of combined anteversion from the safe zone of 25° to 50° were identified, both by computer navigation and by CT scan.

The broach anteversion was judged by the experienced surgeon and the fellows. These estimates were similar (0.77, p=0.591) so for data analysis only the experienced surgeon estimates were used. The surgeon estimate was compared to the computer navigation value. The computer screen was hidden from the view of the surgeon while the broach anteversion estimate of the surgeon was recorded. The broach was used instead of the stem because if the stem were inserted at this time it would interfere with the preparation of the acetabulum.

The Ranawat test[82] for combined anteversion between the cup and stem was performed in 33 hips and compared to the reference value of the postoperative CT scan combined anteversion for that hip. This test is a visual judgment of the combined anteversion when the femoral neck and head are aligned coplanar to the acetabular mouth. The degree of internal rotation to produce a coplanar head and cup is the combined anteversion.

5 RESULTS

5.1 ACETABULAR INCLINATION AND ANTEVERSION

Phase I: Computer navigation was found to be reproducible and predictable to within 5 degrees of the computed tomography scan with precision being 4.4 degrees for inclination and 4.1 degrees for anteversion. The navigation system had no outliers greater than 5 degrees when compared to postoperative CT scans. On comparing the computer navigation system and CT scans there was a bias of less than 1 degrees for both inclination and anteversion (Table 1). The intraclass correlation between the navigation system and CT scans was 0.92 for inclination and 0.97 for anteversion.

Table 1. Accuracy of Computer Navigation for Acetabulum

	CT Scan Inclination	Navitrack Inclination	CT Scan Anteversion	Navitrack Anteversion
Number of hips studied	30	30	30	30
Mean (degrees)	41.0 ± 4.7	41.0 ± 3.8	27.5 ± 6.3	26.7 ± 6.4
Precision (degrees)	4.4		4.1	
Bias (mean of differences; degrees)	0.03		0.73	
Intraclass correlation coefficient	0.92		0.97	

CT = computed tomography scan

Phase II: Computer navigation for all 101 hips showed a mean adjusted inclination of 39.8 degrees +/- 4.7 degrees (range, 27 - 54 degrees) and mean adjusted anteversion of 25.1degrees +/- 5.9 degrees (range, 10 – 39 degrees). The radiographic mean for 101 hips for inclination was 43.1 degrees +/- 4.7 degrees (range, 35 – 58 degrees); anteversion was mean 23.2 degrees +/- 4.9 degrees (range, 9 – 34 degrees).

The magnitude of pelvic tilt influences the surgeon's visualization of the bony acetabulum at the operation. Patients with high pelvic tilt values (10-20 degrees) required a greater adjustment of the anatomic plane to give the equivalent radiographic plane values of inclination and anteversion (Table 2).

Table 2. Influence of Anteroposterior Pelvic Tilt on Inclination and Anteversion (N = 101)

Computer Measurement	Posterior Tilt 10°-20°	Posterior Tilt 1°-9°	Anterior Tilt 0°-9°	Anterior Tilt 10°-20°	p Value
Computer inclination*	36.8 ± 1.9	39.0 ± 3.7	41.6 ± 3.7	47.0 ± 2.5	0.000
Computer-adjusted inclination	40.7 ± 2.8	40.4 ± 3.9	40.1 ± 3.9	42.0 ± 1.8	0.791
Computer anteversion*	18.6 ± 5.5	22.8 ± 4.0	28.7 ± 4.9	37.0 ± 2.7	0.000
Computed-adjusted anteversion*	29.1 ± 5.3	26.5 ± 3.6	25.5 ± 4.5	29.6.0 ± 2.6	0.038

Numbers in degrees.

The anteroposterior tilt of the pelvis is divided into four categories according to the number of degrees of tilt

The effect of adjustment by pelvic tilt is shown by the difference in adjusted and adjusted numbers.

* Using the One way Anova test we found that there is a statistically significant difference between the means of the four groups for computer inclination, computer anteversion and computer adjusted anteversion

The experienced surgeons' mean estimate for cup inclination was not statistically different than that of computer navigation, but anteversion was (Table 3). The inexperienced surgeons' mean estimates were statistically different from computer navigation values for both inclination and anteversion (Table 3).

Table 3. Computer and surgeon measurements of trial cup

Measurement 101 hips	Mean ± SD (range) degrees
Trial cup computer inclination* (1)	39.8 ± 4.7 (27-54)
Trial cup computer anteversion* (2)	25.1 ± 5.9 (10-39)
Experienced surgeons' inclination (3)	40.7 ± 4.2 (33-55)
Experienced surgeons' anteversion (4)	23.0 ± 4.8 (5-35)
Less experienced surgeons' inclination (5)	42.4 ± 4.7 (25-54)
Less experienced surgeons' anteversion (6)	23.2 ± 5.7 (5-36)

*Adjusted for tilt measurement
SD = standard deviation
(1) vs (3) $p = 0.067$
(1) vs (5) $p = 0.001$
(2) vs (4) $p = 0.006$
(3) vs (6) $p = 0.010$

Both surgeons' estimates were worse than the computer for precision and bias (Table 4). The intraclass coefficient for the computer for inclination was 0.92 vs. 0.084 for the experienced surgeon and 0.087 for inexperienced surgeons; for computer anteversion it was 0.97 vs. 0.311 for the experienced surgeon and 0.14 for inexperienced surgeons.

Table 4. Precision of Surgeon Estimates

Surgeon	Precision Inclination	Bias Inclination	ICC	Precision Anteversion	Bias Anteversion	ICC
Experienced surgeon (LDD)	11.5	1.0	0.084	12.3	2.1	0.311
Inexperienced surgeons (fellows)	13.1	2.6	0.087	13.9	1.9	0.14

ICC = Intraclass Coefficient

Experienced surgeons had fewer outliers beyond both 5 degrees and 10 degrees than did the inexperienced surgeons, but this was not statistically different (Table 5). Outliers beyond 10 degrees are most likely to cause adverse clinical outcomes such as instability or accelerated wear. Experienced surgeons had outliers 10 degrees or more of inclination in 6% of hips and anteversion in 12% of hips.

Table 5. Surgeons' Outliers

Trial Cup Position (Total 101 hips)		0°-5°	6°-10°	Greater Than 10°	Total Outliers
Inclination	Exp	70	25	6	31
	Inexp	56	33	12	45
Anteversion	Exp	62	29	10	39
	Inexp	55	31	15	46

The numbers are in percentage of 101 hips.

The outliers are those based on the numbers comparing the surgeon to the computer navigation of the trial cup.

When comparing outliers between experienced and inexperienced surgeons for inclination no statistically significant difference was found (p=0.097)

When comparing outliers between experienced and inexperienced surgeons for inclination no statistically significant difference was found (p=0.476).

exp = experienced surgeon (LDD).
inexp = inexperienced surgeons (fellows),
0-5 degrees = difference from computer;
6-10 degrees = difference from computer;

greater than 10 degrees = difference from computer.

5.2 FEMORAL AND COMBINED ANTEVERSION

The first question we asked was whether computer navigation can measure stem anteversion with a precision of 5 ° and whether surgeons can estimate femoral broach anteversion as precisely as that measured by computer navigation. Computer navigation was more precise than the surgeon and was able to measure with a precision of 5° as validated by the postoperative CT scans (Table 1). There were no outliers of 6° or more of stem anteversion by computer navigation.

Table 1.

Precision and Bias of Surgeons Guesses and of the computer navigation system for femoral anteversion (N = 47 hips)

	Surgeon Broach Estimate	CN Broach Value	CN Stem Value	CT Scan Stem Value
Mean	8.6 +/- 8.9	8.4 +/- 9.1	10.9 +/- 9.0	10.6 +/- 8.0
Precision (°)	16.8		4.8	
Bias (°)	0.3		0.2	
Intraclass Coefficient	0.73		0.96	
Correlation Coefficient (p-value)	0.57 (p = 0.000)		0.97 (p = 0.000)	

Values are expressed as mean ± standard deviation

Values for Precision, Bias and Intraclass Coefficient (ICC) in column one are obtained by comparing the experienced surgeons estimate vs the computer navigation (CN) trial broach value for femoral anteversion. Values for Precision, Bias and Intraclass Coefficient (ICC) in column two are obtained by comparing the values of the computer navigation (CN) values for final femoral stem anteversion vs the postoperative computed tomography(CT) scan value for femoral anteversion.
CN= computer navigation
CT Scan = computed tomography scan

The mean stem anteversion on postoperative CT scan and computer navigation was essentially the same (Table 2).

Table 2.

Comparison of anteversion measurements between computer navigation and the postoperative computed tomography scans (N=47)

Values in degrees	Computer Navigation	CT Scan Orthosoft
Femoral Anteversion	10. 9+/- 9.0 (-12 to 28)	10.6 +/- 8.0 (- 8 to 27)
Cup Anteversion	25.1 +/- 4.6 (14 to 36)	27.0 +/- 4.6 (8.8 to 39)
Combined Anteversion	35.9 +/- 6.7 (16 to 47)	37.6 +/- 7 (19 to 50)

Values are expressed as mean ± standard deviation

CT Scan = computed tomography scan
Ranges are in parentheses

Between intraoperative computer navigation and postoperative CT scan the precision was 4.8° and the bias 0.2°. There is a good linear regression between computer navigation and CT scan femoral anteversion (Fig 1).

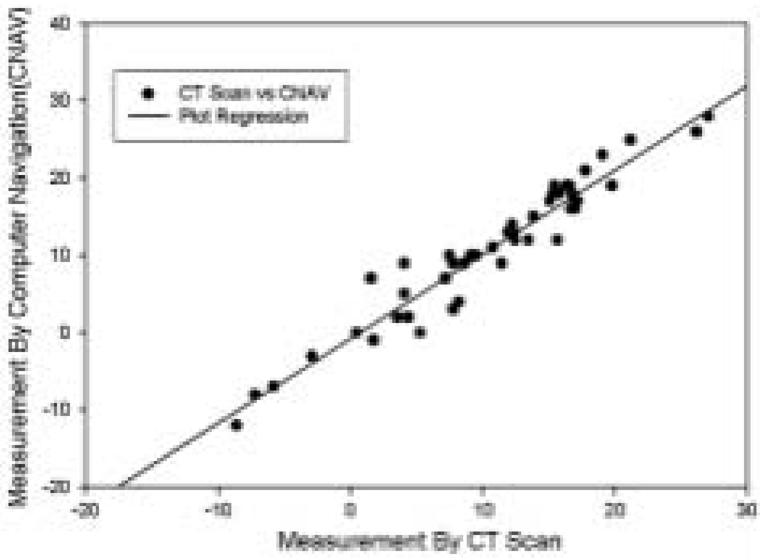


Fig. 1. Femoral stem anteversion of 47 APR® stems measured by computer navigation compared to CT scan shows excellent regression. The solid line represents a simple linear regression fit(r=0.97, p=0.000).

Surgeons could not measure femoral anteversion as precisely as computer navigation with surgeon estimates having a precision of 16.8˚ and a bias of 0.3˚ (Table 1). The surgeon's estimates had outliers of 6˚ to 10˚ in 11 of 47 (23.4%) hips and more than 10˚ in 11 of 47 (23.4%), which gives wide scatter on linear regression (Fig. 2). As the stem became more retroverted the surgeon erred toward estimating more anteversion than was present; as the stem became more anteverted the surgeon's estimate erred toward less anteversion than was present

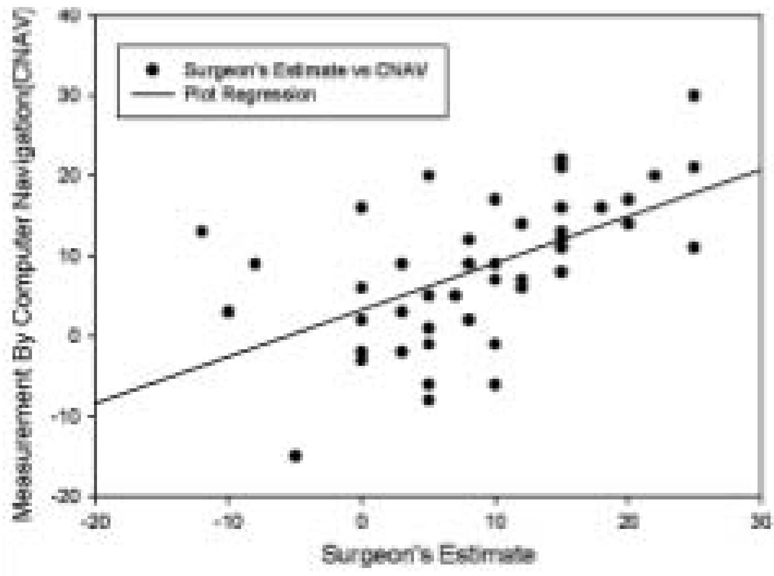


Fig. 2: Femoral stem anteversion of 47 APR® broaches measured by computer navigation compared to surgeon's estimation shows wide scatter. The solid line represents a simple linear regression fit(r=0.57, p=0.000).

The second question we asked was whether computer navigation can quantitatively keep the combined anteversion within the safe zone (25˚–50˚) for each patient. The combined anteversion with computer navigation was within the safe zone for 45 of 47 (96%) hips. Postoperative CT scans had the same values for the same hips (96% in safe zone). The mean combined anteversion was 35.9˚ ± 6.7˚ (range, 16˚–47˚) by computer navigation and 37.6˚ ± 7.0˚ (range, 19˚–50˚) by postoperative CT scan (Table 2). There were two hips known intraoperatively to have a combined anteversion less than 25˚ (19˚ and 21˚) and were accepted because the stem was retroverted (−5.7˚ and −7.4˚) and the cup was anteverted as much as anatomically possible. It is very difficult to antevert a cup more than 30 ° without uncovering the cup posteriorly, or reaming excessively medially or superiorly. In these two hips, stability without manually palpated impingement was present throughout the range of motion. Intraoperative computer navigation combined anteversion was superior to the surgeon's estimate of femoral anteversion plus the navigated cup anteversion, which had eight outliers from the safe zone. For combined anteversion determined by computer navigation, the precision was 4.8˚ and bias was 0.2˚ (ICC = 0.96) with good linear regression (Fig. 3).

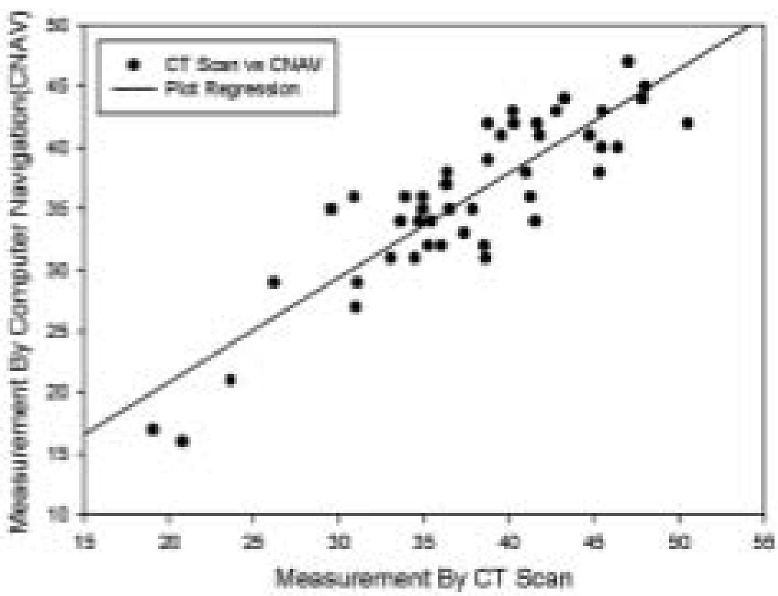


Fig. 3: Combined cup and stem anteversion of 47 hips measured by computer navigation compared to CT scan shows good regression. The solid line represents a simple linear regression fit(r=0.88, p=0.000).

For the surgeon's estimates the precision was 18˚, and bias was 3.7˚ (ICC = 0.5) with wide scatter on linear regression (Fig. 4).

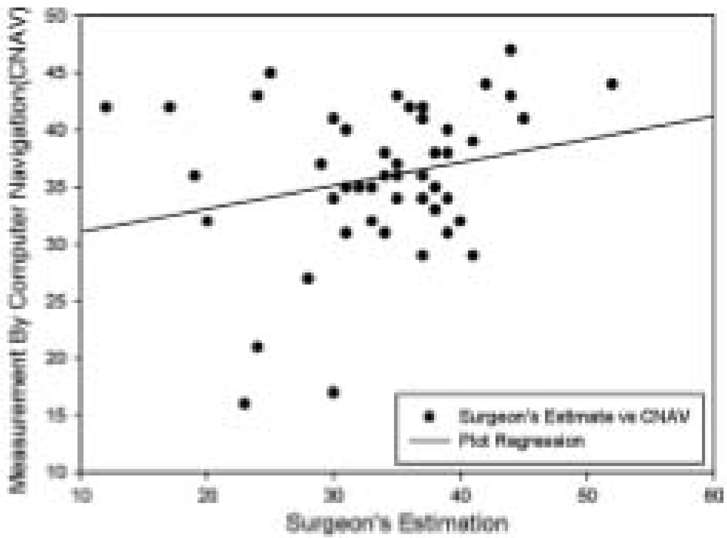


Fig. 4: Combined cup and stem anteversion of 47 hips measured by computer navigation compared to surgeon's estimation shows poor regression with wide scatter. The solid line represents a simple linear regression fit(r=0.24, p=0.11).

The third question we asked was whether the visual Ranawat test accurately measured combined anteversion after THA. This test had a mean combined anteversion of 27.8° ± 8.8˚ (range, 15˚– 45˚) and the postoperative CT combined anteversion of the same hips was 38.8˚ ± 7.8˚ (range, 13.6˚– 49.6˚). The precision was 19˚ and the bias was 11˚ with the same scatter (Fig. 5) as the surgeon's estimates of combined anteversion (Fig. 4).

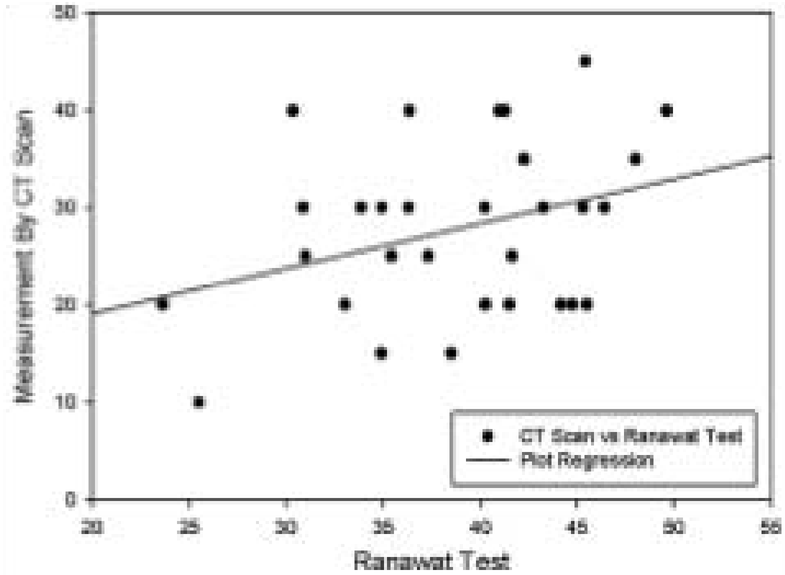


Fig. 5: A plot of combined cup and stem anteversion of 33 hips measured by computer navigation compared to Ranawat test shows wide scatter. The solid line represents a simple linear regression fit($r=0.33$, $p=0.11$).

6 DISCUSSION

To address the limitations of each of the phases of the studies (Phantom model, acetabular validation and femoral and combined anteversion validation) we have maintained parts of the discussions specific to each section separate.

The tests with the phantom model proved the computer navigation and computed tomography systems tested to be accurate. The Navitrack Imageless Computer Navigation System had a precision of 1 degree and a bias of 0.02 degrees for inclination and a precision of 1.3 degrees and a bias of 0 degrees for anteversion measurements in both the anatomic and radiographic planes, which confirmed a previous report on the precision of the system in a cadaver model[32].

There were two limitations of this study. The first limitation is that direct extrapolation of the accuracy of registration of the phantom model to registration in the clinical setting is not possible. The precision with the phantom of 1 degree with bias of 0.02 degrees for inclination compares to our clinical experience with precision of 4.4 degrees and bias of 0.03 degrees for inclination; likewise, anteversion in the phantom had precision of 1.3 degrees with bias of 0 degrees, compared to clinical precision of 4.1 degrees and bias of 0.7 degrees[36, 91].

This difference is explained by the decreased difficulty in measuring acetabular orientation in the phantom model as compared to the clinical setting. Minor registration errors generated in the phantom model could occur during manual positioning of the acetabulum. However, in measuring clinical postoperative acetabular component orientation on CT scans for navigated cup positions, errors can occur during surgical navigation while registering APP references, calibrating navigation tools or if intraoperative loosening of the trackers occurs. Errors in registration of the anterior superior iliac spines and pubis can be minimized by direct bony contact of the registration pointer through percutaneous stab wounds to the bone, particularly in obese patients[36]. A second limitation is the greater accuracy in processing and measuring acetabular orientation from CT scans of the phantom model as compared to clinical postoperative CT scans. There is no artifact from bony or soft tissues in the phantom and the anterior pelvic plane markers are much more precisely marked in the phantom than clinically which requires manual selection of the bony landmark[31, 63, 121].

The influence of pelvic tilt on the adjusted values of cup inclination and anteversion are evident using the phantom model. Functional acetabular component anteversion is often different than the anteversion referenced only on the anterior pelvic plane, and may influence the complications of total hip replacement[51, 54, 62, 64, 86, 104]. Acetabular anteversion reported relative to the coronal plane of the body (on the radiographic plane) provides a more functional cup position than the anatomic anteversion reported relative to the anterior pelvic plane [51, 52, 54, 104, 105, 121]. Navigated acetabular component placement by the APP without adjustment for pelvic anterior-posterior tilt measures the cup only relative to a known pelvic position and ignores the functional relation of the pelvis relative to the longitudinal axis of the body[36, 40, 54, 55, 63]. The greater the pelvic anterior or posterior tilt the greater is the difference between the anterior pelvic plane and the functional acetabular plane[103].

Acetabular validation

The study focused on accuracy of acetabular cup placement was designed to validate the accuracy of the imageless navigation system to within 5 degrees for inclination and anteversion of the true value. This was confirmed by validation with postoperative computed tomography scans with accuracy of the navigation system being 4.4 degrees precision (0.03 degrees bias) for inclination and 4.1 degrees (0.73 degrees bias) for anteversion with no outliers greater than 5 degrees. Secondly, we compared the precision of computer navigation to the clinical judgment of surgeons for acetabular component positioning. The experienced surgeon's precision was 11.5 degrees versus 4.4 degrees for computer navigation for inclination and 12.3 degrees versus 4.1 degrees computer navigation for anteversion. The experienced surgeon had outliers greater than 10 degrees in 6% of estimates for inclination and 10% of estimates for anteversion while the computer had none. In all studies, inclination is more accurately measured than anteversion by computer navigation and surgeons[26, 64-66, 130].

The first limitation of this study was that the computed tomography scan procedure and reconstruction technique we used was specific for the software of this computer navigation system. The comparison of computed tomography scans values to computer navigation values is based on using the same reference of the anterior pelvic plane for both systems. Murrays definitions are used to develop the mathematical formulas which determine the anatomic and radiographic values of navigation systems[70]. The application and use of these algorithms may differ between the software of different navigation systems and therefore may not allow direct comparison of results between them. The second limitation is that all patients did not have a postoperative scan, but we purposefully limited the number because ASTM recommends 30 scans for precision and bias and the intraclass coefficients were above 0.90. The third limitation of this study was that we compared surgeons' estimates to computer navigation and not to the computed tomography scan because the surgeon estimate was done with the trial implant. Computer navigation values could be used as the true value for comparison of surgeon estimates because they had been validated in phase I of the study. The fourth limitation is the human factor of the surgeons involved in estimating the cup position, which certainly can vary from surgeon to surgeon. Our results are limited to the experience and ability of the surgeons involved in this study. However, the senior surgeon (LDD) has nearly 30 years of experience with THA, having performed several thousand cases. The surgeons in fellowship did not vary greatly from the experienced surgeon, although their values were statistically different from the computer navigation values for both inclination and anteversion. A fifth limitation was the use of the posterior approach with visualization of cup position in the radiographic plane[70]. Surgeons who operate supine (anterior approach) might vary by visualization of the cup in the anatomic plane. A sixth limitation was the navigation system used. Errors produced by each navigation system are a combination of errors of registration, landmark identification, optical camera and tracking devices, and of the different algorithms used in the software. Therefore, the accuracy of this navigation system cannot be transposed to other navigation systems. A seventh limitation is the necessity of percutaneous pins for this optical-guided navigation. None of 99 patients reported iliac crest pin problems and three of 99 (3.0%) reported continued pain at the distal femoral pin site 6 weeks postoperatively, which subsequently resolved. Currently we are administering local anesthetic to reduce pain at this distal femoral pin site. There were no complications of hematoma or fracture from the pins.

These results validated registration of the anteroposterior plane, the longitudinal axis of the body, and the pelvic tilt measurements. With adjustment for tilt, the inclination values are able to be targeted to a mean of 40 degrees and the anteversion can be adjusted to provide a combined acetabular-femoral anteversion of 30-50 degrees. The “flip technique,” involving the measurement of the long axis by triangulation on the posterior pelvis and spine supports, provided accurate results with correct adjusted values of cup position. The correlation of the postoperative computed tomography scans to intraoperative computer navigation values means the software calculations of the pelvic position remained accurate even with any pelvic movement during the operation.

We utilize imageless technology because preoperative image-based programs do not account for intraoperative deviations of reaming or cup placement from intended targets as was observed with the use of preoperative image-based programs[26]. Imageless technologies allows real-time intraoperative knowledge of the quantitative reaming direction and depth; adjustment of reaming for variations in bony anatomy to allow correct cup coverage with optimal inclination; and adjustment of cup anteversion for desired combined anteversion when there is knowledge of the fixed femoral anteversion.

One reason for accelerated wear in some cases in clinical series may be the imprecision of the surgeons' intraoperative judgment of cup position, which is magnified by the imprecision of radiographic measurements which surgeons use to confirm their technique of cup placement. [109, 131-135] In studies of implants, there is always a percentage of hips that have excessive and accelerated wear, which often results in osteolysis, but the reasons for this can often not be identified. These cases of accelerated wear have been attributed to 32-mm head size titanium femoral heads, activity of the patient, or cup design[109, 131-135]. One possibility to explain the cause of accelerated wear is the occurrence of impingement. In the retrieval study of Yamaguchi et al, wear was significantly increased in the cups that had impingement[25]. Our data suggest a computer navigation system, validated for accuracy and precision, is the only method currently available to ensure reliability of the component position which can minimize impingement[23, 24, 81, 136]. Component inclination must be no more than 45 degrees to prevent accelerated wear[136, 137]. As the computer has a precision of 4.1 degrees for inclination, we target cup inclination at 40 degrees. Combined anteversion of the cup and stem should be 30-40 degrees for men and 35-45 degrees for women[43, 82, 83, 123].

Femoral and Combined Anteversion

We investigated whether computer navigation provided improved technical ability for the surgeon to achieve correct combined anteversion of the stem and cup for THA as compared to the surgeons' experience and judgment. We asked the questions: (1) Can computer navigation measure femoral stem anteversion with a precision of 5° and can surgeons estimate the femoral anteversion as precisely as that measured by computer navigation? (2) Can computer navigation quantitatively keep the combined anteversion in the safe zone of 25 ° to 50 ° for each patient? (3) Can the surgeon accurately estimate correct combined anteversion with the Ranawat test? In this study, we focused on cementless femoral stem anteversion and the technique of positioning the stem and cup by the concept of combined anteversion because we had previously published the accuracy of computer navigation for cup anteversion[36].

There were several limitations to our study. The precision of surgeon estimates can vary from surgeon to surgeon so the learning curve can differ from the surgeon in this study. For the surgeon in this study the precision of the estimate was improved after 15 hips (Fig. 1).

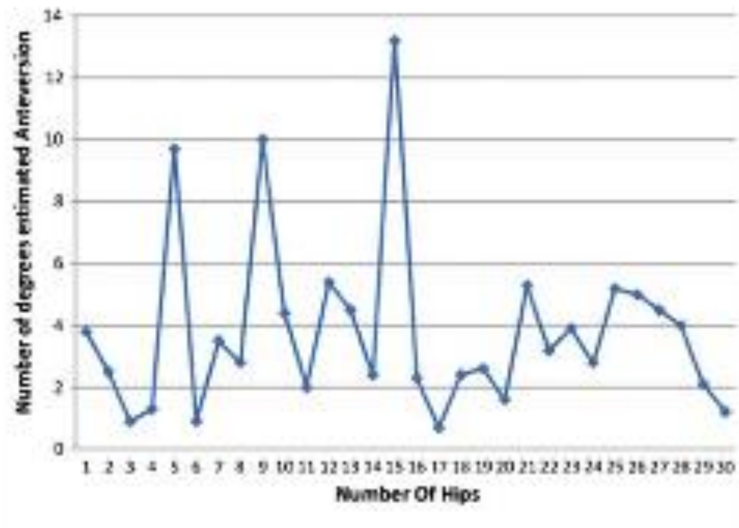


Fig. 1: The estimated anteversion (degrees) could be determined within 5 degrees of the reference value by surgeon estimate alone after a learning curve of 15 hips.

The more the surgeon concentrates on judging the femoral anteversion, the better is the estimate. The estimate by broach may have been improved if a trial neck and head were placed on the broach because this improves the three dimensional visualization of the implant anteversion to the leg axis. In 30 Zweymuller stems (Zimmer, Inc.) subsequently studied with surgeon estimates and postoperative CT scans, there were only two of 30 (6.7%) with a surgeon estimate outlier of more than 10° and four of 30 (13.4%) with 6-10 degree outliers. This reflects the surgeon's experience and the use of a trial stem for estimate. The second limitation is that these results for precision and bias are specific to the Navitrack® navigation system and cannot be transposed to other navigation systems. Differences between systems include the algorithms and mathematical models used in the software for measurement of implant position. The third limitation is that our results are from the posterior approach. Surgeons who operate with the patient in the supine position may visualize the femur and cup in a different plane.

The first question was whether the femoral stem anteversion by computer navigation would have a precision of 5˚ and be better than a surgeon's estimate. The answer was affirmative because precision of the navigation system for femoral anteversion was 4.8˚ with no outliers beyond 6˚. Using the surgeon's estimate of femoral anteversion in the same hips, the precision was 16.8˚ and there were 11 of 47 (23.4%) outliers between 6˚ and 9˚ and 11 of 47 (23.4%) more than 10˚. Our data confirmed a wide variability of femoral anteversion with cementless stems of both the so-called anatomic design used in this study and our experience with the tapered Zweymuller.

In a separate study of femoral anteversion for 109 hips that we have posteriorly published there was a great variability of femoral anteversion as measured on computed tomography scans shown in table 1. Forty-nine of 109 hips (45%) using the epicondylar plane as reference had stem values between 10-20º, nine hips (8.3%) had retroversion of the stem, and eight hips (7.3%) had stem anteversion values greater than 20º [77].

Table 1. Distribution of Femoral Anteversion measured by Post-OP CT Scan

FAV (degrees)	Epicondyles	
	Hips	Percentage
<0(retroversion)	9	8.3
0-4	19	17.4
5-9	24	22.0
10-20	49	45.0
>20	8	7.3
Total	109	100

The distribution of femoral anteversion measured by computed tomography scan using the epicondyles as distal femoral reference for the diaphyseal femoral plane.
CT = computed tomography
FAV = femoral anteversion

In this same study the factors we found that influence femoral anteversion were Gender and design of stem. On CT scans, women had a mean femoral anteversion of 11.6 +/- 7.4°, and men had 8.2 +/- 7.2° (p = 0.001). On computed tomography scans, the mean anteversion of the anatomic stems was 10.9 +/- 7.4°, and for the tapered stems it was 8.0 +/- 7.3° (p = 0.003). Twenty-three of twenty-eight stems with anteversion less than 5° (-8.6 to + 4° anteversion), as measured on computed tomography scans, were in hips that had preoperative cam impingement (a low head-neck ratio) and were evenly divided between men and women.

Two other studies confirm this wide variability of stem position in THA[40, 41]. It is probable that the increased prevalence of dislocations as a cause of revision with cementless THA is because of this variability of cementless stem position[138].

Our second question was whether combined anteversion of the femoral stem and cup would be within the safe zone of 25˚ to 50˚ in each patient. There is a wide safe zone of 25˚ to 50˚ for combined anteversion for THA, which explains why most THAs are successful when performed using the surgeons' experience and judgment alone. Combined anteversion is nature's method of stability and it is the most important measure for stability of a THA[43, 45, 72]. Measurement of the acetabular position alone is not diagnostic of the cause of dislocation[40]. Combined anteversion explains why the hip remains stable throughout the wide flexion arc (35 °) of the acetabulum in the change of body position from supine to sitting[26, 30]. Reference to a safe zone for THA in the future should be to combined anteversion, rather than isolating a safe zone for the acetabulum. The safe zone for combined anteversion is 37 $\pm$ 12° in our studies, and the mean of 37° agrees with finite element data[81]. Combined anteversion is lower in men mostly because femoral anteversion is lower (mean 8.7° in men vs. 10.7° in women in our study). To reproducibly accomplish the combined anteversion requires femoral preparation first so the cup can be adjusted to the stem. This requires change by the surgeon in the order of the operation, which is initially disruptive, but knowledge of femoral stem anteversion prior to acetabular position has been shown to be preferable in laboratory studies as well as by this clinical study[76, 81].

The third question of our study was whether the visual method of estimating combined anteversion by the Ranawat test was accurate, and it was not. The precision of surgeons with visual estimates seems to have a similar pattern no matter the test. Achieving accuracy with combined anteversion by computer navigation does give precision of both acetabular and femoral component positions. The cup can be accurately placed within 5˚ on the coronal plane when pelvic tilt is measured as shown in our prior study where computer navigation cup anteversion had a precision of 4.1˚ and a bias of 0.73˚[36]. Cup anteversion will always be best determined by computer navigation because the surgeon cannot know the tilt of the pelvis. In our experience, the tilt changes cup anteversion by 10˚ or more from that visualized in 7.5% of hips and 6˚ to 9˚ in 21% of hips. In this study, we validated femoral stem anteversion by computer navigation to also be within 5˚ (precision, 4.8˚; bias, 0.3˚), but with experience the surgeon's judgment can be within 5° 85-90% of the time.

The combined anteversion technique for cementless stems can assure elimination of stem-on-cup impingement if it is combined with correct coverage of the cementless cup and correct hip length and offset. Correct coverage of the cup may require medializing the center of rotation so the inclination can be kept below 45° and the metal edges are flush with the bone (except posterior-superior) (Fig 2)[51]. Elimination of impingement provides the best condition for minimizing wear and optimizing stability[34, 124, 137].

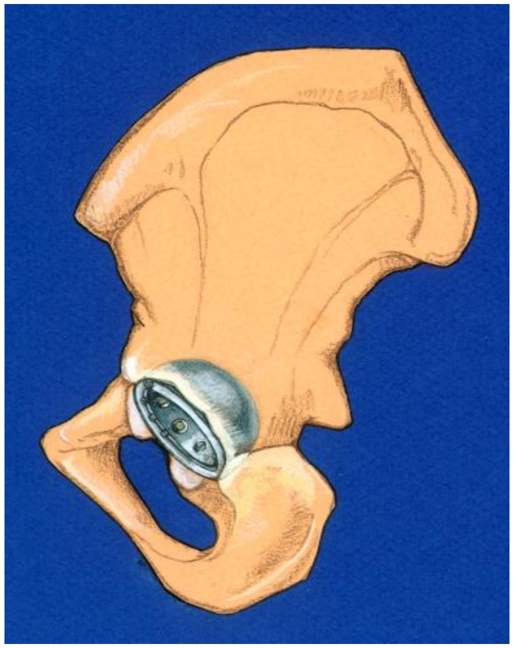


Fig.2: Correct coverage means the cup edge inferomedially is just inside the transverse acetabular ligament; superior-anteriorly the cup cannot be proud of the edge of the ilium as it can irritate the iliopsoas tendon. Posterior-superior there may be 3-5 mm of cup which protrudes beyond the bone. Posterior-inferiorly the cup should be below the cortex of the ischium.

Intraoperative quantitative knowledge improves the technical performance of the surgeon. Preoperative templating does not substitute for intraoperative knowledge because plain radiographic techniques do not give precision for the surgeon to predict femoral anteversion. We have measured 57 hips with preoperative crosstable lateral radiographs templated with both the anatomic and tapered stems. The preoperative templated femoral anteversion was compared to postoperative CT scan anteversion and had a precision of 21.4° (unpublished data).

One important goal that we wish to achieve from our studies is that the reporting of the acetabular cup orientation be consistent in all cases[30-32, 51, 63, 121]. Navigation systems and published literature results are based both on Murray's radiographic definitions of cup orientation and the anterior pelvic plane as the anatomic reference. Different clinical studies have used different methods for measurement of acetabular implant orientation (non-standardized radiographs, standardized radiographs, 2-D CT scans, 3-D CT scans) [26, 33, 45, 52-59]. Many clinical studies report postoperative acetabular orientation using radiographs without standardized positions of the pelvis for direction of the x-ray beam and make conclusions about acetabular implant orientation with complications such as dislocation[51, 59-62]. Another example is the study of Pierchon et al[40] who used 2-D CT scans to study dislocation and directly compared the results to plain radiographic measurements of Lewinnek et al[33]. The results reported by Pierchon et al[40] were not referenced to a standardized anterior pelvic plane, which Lewinnek et al[33] did use, and the tilt of the pelvis was not considered.

We propose the acetabular orientation be reported using the radiographic plane that is the coronal plane of the body, which would be the plane, that AP x-rays are taken[46, 51, 91]. The anatomic plane is referenced only to the pelvic bone position. The radiographic plane (coronal plane) with imageless computer navigation incorporates the tilt of the pelvis and reports a more functional acetabular position customized to the anatomy of the individual patient[51]. In addition, radiographs remain the most universally available and economical method for preoperative planning and postoperative measurement of cup position, and these are measured in the radiographic plane.

Our method of performing cementless THA at this time is to prepare the femur first, estimate the femoral stem anteversion, and then implant the cup with computer navigation. Our goal is a combined anteversion of 25˚ - 50˚ with a mean of 37˚[46, 83, 91]. Lower combined anteversion occurs when the femoral stem anteversion is low (more common in men). If anatomic anteversion is low it is better to compensate with more cup anteversion than increasing stem anteversion to 15˚ to 20˚ to avoid in toeing of the leg and foot by creating a new anteverted position of the leg. If the stem is to be cemented, we implant the cup at 20˚ to 25˚ anteversion and cement the stem at 10˚ to 15˚ anteversion, lower for low anatomic anteversion. We obtain 40˚ inclination with computer navigation. We always use the largest femoral head that can be implanted with highly crosslinked polyethylene according to the acetabular size.

New technologies and methods need to be introduced in stages. Computer navigation equipment is expensive and its use prolongs surgical times[139, 140]. With scarce resources at our disposal, it is important that these new techniques are cost effective in optimizing health benefits[141]. These systems have been validated mostly in high volume centers where their frequent use them makes them more cost effective[140, 142, 143]. However, advocates consider the utility of this tool in the low volume surgeon due to the higher probability of placing implants more precisely[108, 140]. As it is an expensive tool to add to a hospitals inventory, it is important to validate its utility in more precise implant placing. Multiple different studies have analyzed the cost-effectiveness of computer assisted joint replacement with different economic models. They confirmed that costs can be offset when variables such as surgical ability, volume, revision rates, patient age at surgery and outliers are considered[10, 14, 90, 142].

We have validated in this thesis the benefit of a numeric hip reconstruction with precise numbers for implant position, which results in a predictable joint reconstruction. The Orthosoft Navitrack® Navigation system was confirmed to have a clinical precision within 5 degrees, with a bias less than 1 degree, and significantly superior results to surgeons' judgment[36, 51, 77, 83, 91]. These data provide knowledge to the surgeons that they can trust a validated computer-navigated system for implant position. This is important in our evolution of understanding computer navigation benefits, but must be combined with data on precision of leg length and offset for complete validation of the use of these systems in total hip replacement.

The contribution of the use of computer navigation to improved clinical outcomes has been confirmed with clinical prospective randomized trials and metanalysis in the short term for intraoperative and early postoperative complications[66, 87, 144, 145]. It will take years for final clinical outcomes. A recent publication from the Australian registry data confirms that the survival of navigated knee replacement is significantly improved compared to standard knee replacement in young patients[90]. It is fair to say accurate reproducible implant positions that avoid outliers with a reconstruction free from impingement will benefit patient outcome. Long-term studies that validate improved implant survival and cost effectiveness with this expensive technology will help determine its future role in our day-to-day hip surgery[10, 14, 27, 90, 142, 143].

7 CONCLUSIONS

7.1 Computer Navigation is accurate to within 5 degrees for acetabular implant position

7.2 Computer Navigation is accurate to within 5 degrees for femoral implant position

7.3 Surgeons are less accurate in their implant positioning than navigation system

7.4 Femoral Version in non-cemented implants is highly variable

7.5 Using computer navigation a correct combined anteversion of the hip replacement can be obtained

7.6 The Ranawat test is not precise for estimating the combined anteversion between acetabulum and femur

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9. Appendix: Publications Derived from this thesis

1: Malik A, Maheshwari A, Dorr LD. Impingement with total hip replacement. J Bone Joint Surg Am. 2007 Aug;89(8):1832-42. Review. PubMed PMID: 17671025.

2: Dorr LD, Malik A, Wan Z, Long WT, Harris M. Precision and bias of imagelesscomputer navigation and surgeon estimates for acetabular component position. ClinOrthop Relat Res. 2007 Dec;465:92-9. PubMed PMID: 17693877.

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