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Computer-Assisted Hip and Knee Arthroplasty. Navigation and Active Robotic Systems

An Evidence-Based Analysis

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About the Medical Advisory Secretariat

The Medical Advisory Secretariat is part of the Ontario Ministry of Health and Long-Term Care. The mandate of the Medical Advisory Secretariat is to provide evidence-based policy advice on the coordinated uptake of health services and new health technologies in Ontario to the Ministry of Health and Long-Term Care and to the healthcare system. The aim is to ensure that residents of Ontario have access to the best available new health technologies that will improve patient outcomes.

The Medical Advisory Secretariat also provides a secretariat function and evidence-based health technology policy analysis for review by the Ontario Health Technology Advisory Committee (OHTAC).

The Medical Advisory Secretariat conducts systematic reviews of scientific evidence and consultations with experts in the health care services community to produce the *Ontario Health Technology Assessment Series.*

About the Ontario Health Technology Assessment Series

To conduct its comprehensive analyses, the Medical Advisory Secretariat systematically reviews available scientific literature, collaborates with partners across relevant government branches, and consults with clinical and other external experts and manufacturers, and solicits any necessary advice to gather information. The Medical Advisory Secretariat makes every effort to ensure that all relevant research, nationally and internationally, is included in the systematic literature reviews conducted.

The information gathered is the foundation of the evidence to determine if a technology is effective and safe for use in a particular clinical population or setting. Information is collected to understand how a new technology fits within current practice and treatment alternatives. Details of the technology's diffusion into current practice and input from practicing medical experts and industry add important information to the review of the provision and delivery of the health technology in Ontario. Information concerning the health benefits; economic and human resources; and ethical, regulatory, social and legal issues relating to the technology assist policy makers to make timely and relevant decisions to optimize patient outcomes.

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Executive Summary

Objective

The Medical Advisory Secretariat undertook a review of the evidence on the effectiveness and cost-effectiveness of computer assisted hip and knee arthroplasty. The two computer assisted arthroplasty systems that are the topics of this review are (1) navigation and (2) robotic-assisted hip and knee arthroplasty.

The Technology

Computer-assisted arthroplasty consists of navigation and robotic systems.

Surgical navigation is a visualization system that provides positional information about surgical tools or implants relative to a target bone on a computer display. Most of the navigation-assisted arthroplasty devices that are the subject of this review are licensed by Health Canada.

Robotic systems are active robots that mill bone according to information from a computer-assisted navigation system. The robotic-assisted arthroplasty devices that are the subject of this review are not currently licensed by Health Canada.

Review Strategy

The Cochrane and International Network of Agencies for Health Technology Assessment databases did not identify any health technology assessments on navigation or robotic-assisted hip or knee arthroplasty. The MEDLINE and EMBASE databases were searched for articles published between January 1, 1996 and November 30, 2003. This search produced 367 studies, of which 9 met the inclusion criteria.

Summary of Findings

Navigation-Assisted Arthroplasty

- Five studies were identified that examined navigation-assisted arthroplasty.
- A Level 1 evidence study from Germany found a statistically significant difference in alignment and angular deviation between navigation-assisted and free-hand total knee arthroplasty in favour of navigation-assisted surgery. However, the endpoints in this study were short-term. To date, the long-term effects (need for revision, implant longevity, pain, functional performance) are unknown.(1)
- A Level 2 evidence short-term study found that navigation-assisted total knee arthroplasty was significantly better than a non-navigated procedure for one of five postoperative measured angles.(2)
- A Level 2 evidence short-term study found no statistically significant difference in the variation of the abduction angle between navigation-assisted and conventional total hip arthroplasty.(3)
- Level 3 evidence observational studies of navigation-assisted total knee arthroplasty and unicompartmental knee arthroplasty have been conducted. Two studies reported that "the follow-up of the navigated prostheses is currently too short to know if clinical outcome or survival rates are improved. Longer follow-up is required to determine the respective advantages and disadvantages of both techniques."(4;5)

Robotic-Assisted Arthroplasty

- Four studies were identified that examined robotic-assisted arthroplasty.
- A Level 1 evidence study revealed that there was no statistically significant difference between functional hip scores at 24 months post implantation between patients who underwent robotic-assisted primary hip arthroplasty and those that were treated with manual implantation.(6)
- Robotic-assisted arthroplasty had advantages in terms of preoperative planning and the accuracy of the intraoperative procedure.(6)
- Patients who underwent robotic-assisted hip arthroplasty had a higher dislocation rate and more revisions.(6)
- Robotic-assisted arthroplasty may prove effective with certain prostheses (e.g., anatomic) because their use may result in less muscle detachment.(6)
- An observational study (Level 3 evidence) found that the incidence of severe embolic events during hip relocation was lower with robotic arthroplasty than with manual surgery.(7)
- An observational study (Level 3 evidence) found that there was no significant difference in gait analyses of patients who underwent robotic-assisted total hip arthroplasty using robotic surgery compared to patients who were treated with conventional cementless total hip arthroplasty.(8)
- An observational study (Level 3 evidence) compared outcomes of total knee arthroplasty between patients undergoing robotic surgery and patients who were historical controls. Brief, qualitative results suggested that there was much broader variation of angles after manual total knee arthroplasty compared to the robotic technique and that there was no difference in knee functional scores or implant position at the 3 and 6 month follow-up.(9)

Objective

The Medical Advisory Secretariat conducted a review of the effectiveness and cost-effectiveness of computer assisted hip and knee arthroplasty. The two computer assisted arthroplasty systems that are the topics of this review are (1) navigation and (2) robotic-assisted hip and knee arthroplasty.

Background

Clinical Need

Arthritis refers to inflammation of the joints, however, the term is commonly used to include a variety of joint disorders, including those resulting from degenerative disease, inflammatory disease, and post-traumatic damage.(10)

The 1990 Ontario Health Survey revealed that 18.5% of the population aged 16 years and over reported having arthritis. The prevalence of arthritis increased with age from 6.3% in those aged 16 to 24 years old to 51.2% for people aged 75 years and over.(11)

The most common type of arthritis is osteoarthritis which is a degenerative disorder characterized by destruction and loss of the articular cartilage together with changes in the underlying bone.(10) Estimates of the prevalence of osteoarthritis are imprecise due to difficulties associated with diagnosis.(10) There is no clear disease maker and there is heterogeneity in the nature of the disease. Hawker stated that prevalence studies indicated that in populations aged 65 years and over, 60 to 70% show signs of osteoarthritis based on radiographic assessment, and 33% have symptomatic osteoarthritis.(10)

While the mainstay of treatment is medical, there are patients in whom anti-inflammatory drugs become ineffective. For these patients, hip or knee replacement has become an important treatment option.

Hip arthroplasty is a surgical procedure used to replace all or part of the hip joint with an artificial device that re-establishes normal hip joint motion. Hip arthroplasty is indicated in cases of severe intractable degenerative arthritis. Knee arthroplasty is surgery involving the replacement of the knee joint with artificial components which re-establishes normal joint function. Knee arthroplasty is indicated in cases of severe knee fracture or degenerative arthritis unresponsive to medical therapy.

In 2000/2001, there were 8,078 total hip and 10,426 total knee replacement procedures in Ontario.(12) Compared to 1994/1995, there was a 15.6% increase (6,988 to 8,078) for total hip replacements and 52.4% increase (6,839 to 10,426) for total knee replacements.(12) The age standardized rate for total hip replacements was 62.1 per 100,000 population in 1994/1995 and 62.8 per 100,000 population in 2000/2001 (1.1% increase).(12) The age standardized rate for total knee replacements was 60.9 per 100,000 population in 1994/1995 and 81.8 in 2000/2001 (34.3% increase).(12)

Another aspect of clinical need is the nature of the surgery itself. For example, in knee replacement surgery, outcomes are affected by variations in surgical technique.(13) Incorrect positioning or orientation

of the implant, as well as improper alignment of the limb, may lead to accelerated implant wear and loosening in addition to suboptimal functional performance.(13) Stulberg et al.(13) suggested that alignment errors of no more than 3 degrees are associated with more rapid failure and less satisfactory functional results after total knee arthroplasty.

In the mid-1980s, cementless femoral components (not requiring bone cement to join the prosthesis to the bone) were introduced for hip arthroplasty. Problems associated with cementless femoral components included postoperative thigh pain, intraoperative fracture and failure of bony ingrowth.(14) It was subsequently realized that, not only should the implant fit the femur well, but the bone should also be shaped accurately to fit the implant.(14) In addition, the surgical instruments in use at that time were from the era when only cemented components were used. These instruments create a rough, irregular surface that is ideal for cement, but inaccurate for cementless applications.(14) The inaccuracies created gaps at the implant to bone junction that could lead to instability and decreased bony ingrowth.(14)

In revision total hip replacement surgery, a failing orthopedic implant, typically cemented, is replaced by removing the cement and fitting a new implant into a canal broached in the femur.(15) Removing cement can be time consuming and risky. Femoral canal preparation for a revision is difficult because there is less good bone left and the surgical manipulations are more delicate.(15) When errors occur, additional time is required to repair the damage, more blood is lost and the risk of infection increases.(15)

The Technology

Computer-assisted arthroplasty consists of navigation and robotic systems.

Davies(16;17) classified computer-assisted systems used for navigation or robotic-assisted arthroplasty into three broad categories:

Passive Robots

- Passive systems do not perform any actions on patients; they can assist surgeons during preoperative planning, surgical simulation or intraoperative guidance (navigation).
- Surgical navigation is a visualization system that provides positional information about surgical tools or implants relative to a target bone on a computer display (Figure 1).(18) Navigation uses three dimensional position sensors (optical or magnetic) to track the target bone and surgical tools or implants and creates a surgical plan.(18)
- Optical systems use cameras to obtain positional information which is usually based on infrared light from a dynamic reference frame attached to the target bones and surgical tools to be tracked. Most navigation systems for orthopedics use an optical sensor.(18)
- There are three types of surgical planning that involve navigation systems.(18)
    - Volumetric image based navigation uses preoperative images for planning. This is performed using computed tomography, magnetic resonance imaging, or ultrasound echography.
    - Fluoroscopic navigation. Fluoroscopic images are used to construct the guiding map used during the operation.
    - Imageless navigation. Intraoperative kinetic information about joints, morphological information about bones or both are used for planning and guiding maps.

Active Robots

- Most active robots have been developed for a specific task, such as hip surgery robots ROBODOC and the Computer Assisted Surgical Planning and Robotics system (CASPAR) (Figure 3). The tip of the robot carries a high-speed rotary cutter that can accurately ream out the femoral cavity for the stem of a particular hip implant.

- The ROBODOC system was designed as a preoperative planning computer workstation (ORTHODOC) based on computed tomography data input linked to a robotic arm with a high-speed burr that mills the femoral canal for the selected implant in the position chosen preoperatively on the computer workstation.(14)
- Of the three robotic-assisted arthroplasty devices under review, ROBODOC was the system most extensively described in the literature.

Synergistic Systems

- Davies defined a system as synergistic when "the surgeon's skills are combined with the robot's constraint capabilities to form a partnership that enhances the performance of the robot acting alone."(16) Synergistic systems provide the surgeon with low-force control within a central, predefined region, (e.g., ACROBOT is an active constraint robot for knee surgery) (Figure 4). This control strategy allows the surgeon to directly feel how much force the cutter exerts. Towards the edge of the low-force region, the robot impedance gradually increases until, at the limit of the permitted region, the control system switches into high-force position control. Therefore, the robot gives active constraint within an accurately pre-programmed area.

Potential advantages to navigation-assisted arthroplasty include(18):
- Reduction of errors in rotational and translational alignment of the prosthetic components and of the limb used with mechanical alignment systems.(19)
- Reduction of accelerated wear, component loosening and degraded functional performance as a result of incorrect positioning or orientation of implants.

Potential advantages to robotic-assisted arthroplasty include the following(15):

- Reduction of cement removal complications (for revision arthroplasty of a prior cemented implant), specifically cortical wall penetration and bone fracture
- Reduction of cement removal labour and time
- Improved position accuracy and fit of the new implant resulting from precise canal milling
- Reduction of bone sacrificed to fit the new implant
- Reduction of cumulative exposure to x-ray radiation caused by repeated use of the fluoroscopic arm
- Shortened hospital stay and operating time

Alternative Technologies

Alternative technologies for navigation and robotic systems used in computer-assisted arthroplasty are available, but each has limitations.

The alternative to navigation-assisted arthroplasty is a mechanical alignment system. Mechanical alignment systems help to improve the precision with which implants can be installed but errors in surgical alignment still occur.(19) In general, mechanical alignment systems are designed based on standardized bone geometry and optimal placement of the components may not be achieved when a patient's bones differ from the bone geometry that was assumed by the instrument designer.(19)

The alternative to robotic assisted arthroplasty is hand milling. Osteotomes (blades for cutting or chiselling bone) and flexible reamers (rotating drills used to shape or enlarge a hole) are difficult to manipulate and have the tendency to follow the pathway of the old canal.(15) New cement removal

technologies such as cement softening with ultrasonically driven tools or cement fracturing can lower complication rates, but are unlikely to significantly improve accuracy or shorten the procedure.(15)

Ontario Facilities Where Technology is Used

Navigation-assisted arthroplasty is used in at St. Joseph's Health Centre in London(20) and Kingston General Hospital.(21) It was recently reported that Kingston General Hospital offers all forms of joint replacements to patients suffering from bone, joint and soft tissue disease and has already performed approximately 250 computer-assisted procedures to date.(21)

The University Health Network reported use of computer-assisted navigation for spinal surgery, but not arthroplasty.(22)

Robotic-assisted arthroplasty is not currently used in Ontario.

Regulatory Status

The Health Canada licensing status of computer assisted navigation systems for hip or knee arthroplasty is as follows:

The OrthoPilot navigation system (Aesculap, Tuttlingen, Germany) is licensed by Health Canada as a class 2 device (License # 61231).
The SurgiGate navigation system (Medivision, Oberdorf, Switzerland) is not licensed by Health Canada.

The Stryker navigation system (hip and knee module) (Howmedica, Osteonics, Germany) is licensed by Health Canada as a class 3 device (License # 20516).

Navitrack system (total hip replacement) (Orthosoft, Montreal, Quebec) is licensed by Health Canada as a class 2 device (License # 39319, 62119, 62123).

Vectorvision 2 image guided surgery system (knee and hip software) (Brainlab, Heimstetten, Germany) is licensed by Health Canada as a class 3 device (License # 15417).

The Achieve system (Smith and Nephew, Memphis, United States) is licensed by Health Canada as a class 2 device (License # 60717).

The robotic systems used for hip or knee arthroplasty are ROBODOC (Integrated Surgical Systems, Davis, CA), the Computer Assisted Surgical Planning and Robotics system (CASPAR) (Universal Robot Systems Ortho, Germany) and ACROBOT (Imperial College London, United Kingdom). These robotic systems are not licensed by the United States Food and Drug Administration (USFDA) or Health Canada.

The ROBODOC project is reported to be under investigation through a multicentre study with concurrent controls in 3 sites in the United States.(14;23) These clinical trials, which began in December 2000, required a total of 188 patients at each site. At the conclusion of the trials, the manufacturer will seek USFDA clearance to market the ROBODOC system in the United States.(23)

In Germany, ROBODOC has been used for more than 4,500 total hip replacements since 1994.(6)

Literature Review

Objective

- To assess the effectiveness and cost-effectiveness of navigation or robotic-assisted hip and knee arthroplasty

Methods

Inclusion Criteria

- English language
- Primary data on the effectiveness or cost-effectiveness of navigation or robotic-assisted hip and knee arthroplasty obtained in a clinical setting, or analysis of primary data maintained in registries or databases
- Study design and methods clearly described
- Systematic reviews, randomized controlled trials (RCTs), non-randomized controlled trials and/or cohort studies that have more than 20 patients
- Cost-effectiveness studies.

Exclusion Criteria

- Studies that are duplicate publications (superseded by another publication by the same investigator group, with the same objective and data).
- Non-English articles
- Non-systematic reviews, letters and editorials
- Animal and in-vitro studies
- Case reports
- Studies that do not examine the outcomes of interest

Intervention

- Navigation or robotic-assisted hip or knee arthroplasty.
- Controls do not undergo navigation or robotic-assisted hip or knee arthroplasty but receive optimal medical management.

Literature Search

- Cochrane Database Of Systematic Reviews
- ACP Journal Club
- Database of Abstracts of Reviews of Effects
- International Network of Agencies for Health Technology Assessment
- EMBASE
- MEDLINE
- Reference sections from reviews and extracted articles

Outcomes of Interest

- Adverse effects
- Mobility
- Revisions
- Length of hospitalization
- Quality of life
- Economic analysis data

Results of Literature Review

The Cochrane and International Network of Agencies for Health Technology Assessment databases did not identify any health technology assessments on navigation or robotic-assisted hip or knee arthroplasty. A search of MEDLINE and EMBASE from January 1, 1996 to November 30, 2003 produced 367 studies, of which 9 met the inclusion criteria. The quality of the evidence in the included articles is presented below.

Quality of Evidence

Study Design	Level of Evidence	Number of Eligible Studies
Large RCT, systematic reviews of RCTs	1	2
Large RCT unpublished but reported to an international scientific meeting	1(g)	
Small RCT	2	2
Small RCT unpublished but reported to an international scientific meeting	2(g)	
Nonrandomized study with contemporaneous controls	3a	4
Nonrandomized study with historical controls	3b	1
Nonrandomized study presented at international conference	3(g)	
Surveillance (database or register)	4a	
Case series (multisite)	4b	
Case series (single site)	4c	
Retrospective review, modelling	4d	
Case series presented at international conference	4(g)	

g=grey literature

Navigation-Assisted Arthroplasty

The overall results of the navigation-assisted hip or knee arthroplasty studies are included in Table 1.

Navigation-Assisted Knee Arthroplasty

■ In 2003, a German, single centre, randomized controlled trial by Sparmann et al.(1) examined the outcomes of total knee arthroplasty (TKA) using an unnamed navigation system that was an imageless method designed by the authors and the manufacturer (Stryker Howmedica Osteonics, New Jersey) who funded the study compared to the conventional hand-guided technique.

No sample size calculation was reported. The authors stated that the aim was to compare 120 patients treated with and 120 without navigation guidance. During the study, 373 TKAs were performed. Inclusion criteria consisted of all patients who were scheduled for a primary TKA and for whom a condylar prosthesis was suitable. No exclusion criteria were specified because "the aim was to determine whether navigation systems can be used successfully in any situation."(1) However, Sparmann et al.(1) stated that 133 patients were excluded due to:

Primary hinged arthroplasty was required to treat 63 patients with severe deformity or instability
Revisions undertaken because of septic (n=23) or aseptic (n=43) loosening
Patients originally allocated to the hand guided group requested a navigated operation (n=4)

The characteristics of the patients in terms of age, sex, type of osteoarthritis (primary or post traumatic), rheumatoid arthritis, and other conditions were comparable at baseline, but no p values were provided.

There was a statistically significant difference between the two groups in the intraoperative deviation in the mechanical axis (alignment) ($p<0.0001$); postoperative frontal femoral axis (varus valgus deviation) ($p<0.0001$); sagittal femoral axis (navigation n=73, hand guided n=86) ($p<0.001$); and frontal tibial axis ($p<0.05$). There was no significant difference between the two groups for the postoperative sagittal tibial axis. (Level 1 evidence)

Complications in both groups of patients were as follows. No p values were provided.

Complications in the study groups.

	Navigated	Hand-Guided
Deep infection	1	0
Calf-vein thrombosis	1	1
Delayed would healing	3	1
Manipulation under anesthesia (undertaken if knees had not regained 90 degrees flexion within 12 days of surgery)	1	4

Reproduced with permission and copyright © of the British Editorial Society of Bone and Joint Surgery, and permission of the author; From: Sparmann M, Wolke B, Czupalla H, Banzer D, Zink A. Positioning of total knee arthroplasty with and without navigation support. Journal of Bone & Joint Surgery -British Volume 2003; 85(6):830-835.

Limitations to the study included:

- Navigation assisted arthroplasty was assessed in the short term only (postoperatively). The endpoints in the study were related to angle accuracy. To date, the long-term effects (e.g., implant longevity, need for revision, pain, functional performance) are unknown.
- There was no explanation as to the patient sample size chosen for the study.

■ In a single centre, prospective randomized study from the Czech Republic, Hart et al.(2) performed total knee arthroplasty and compared radiographic results from 60 patients who underwent the conventional technique and from 60 patients who underwent the OrthoPilot kinematic computed

tomography-free navigation system.

Hart et al.(2) stated that the patients were selected at random as they came for their first evaluation. No further details of the randomization procedure were reported. The indications for TKA were primary osteoarthritis in 78 cases and secondary osteoarthritis in 42 cases. Patients were followed for an average of 15 (range, 6 to 24 months).

Hart et al.(2) reported that the navigated implantation of the prosthesis lasted 10 to 15 minutes longer than the conventional procedure. There were no complications related to the use of the navigation system.

The results were expressed as the postoperative measured angles and are presented below and of five post-operative angle measurements, only one was statistically better in the navigation-assisted group. (Level 2 evidence)

Postoperative value of measured angles (mean and range)

Measured Angles	Conventional procedure (Degrees)	Navigation procedure (Degrees)	P value
Anatomic lateral tibiofemoral angle	174.9 (172-179)	174.3 (170-179)	>0.05
Anatomic lateral distal femoral angle	83.7 (81-87)	83.5 (76-88)	>0.05
Anatomic medial proximal tibial angle	89.2 (86-92)	88.9 (84-93)	>0.05
Anatomic posterior distal femoral angle	88.4 (84-91)	88.5 (82-93)	>0.05
Anatomic posterior proximal tibial angle	88.3 (84-92)	88.9 (82-91)	<0.001

Reproduced with kind permission of Springer Science and Business Media, and the author; From Hart R, Janecek M, Chaker A, Bucek P. Total knee arthroplasty implanted with and without kinematic navigation. International Orthopaedics 27(6):366-9, 2003.

Hart et al.(2) did not discuss the relevance (if any) of the statistically significant difference in the anatomic posterior proximal tibial angle between the conventionally and navigationally treated patients.

Limitations to the study by Hart et al.(2) were:

- Lack of a justification for the sample size of the study.
- Outcomes were postoperative measured angles. Long term results in terms of revision rate, pain, functional performance, implant survival are unknown.
- Statistical comparisons of the baseline patient characteristics between the study groups were not reported.
- Lack of discussion regarding any blinding of the researcher who measured postoperative angles.

■ Jenny and Boeri(4) conducted a single site case-control study to examine a non image based navigation system (OrthoPilot, Aesculap, Germany) approach for total knee prostheses in 100 patients compared to 100 patients undergoing the conventional surgeon-controlled operative technique. The patients were matched according to age, gender, body mass index, preoperative coronal mechanical femorotibial angle, and severity of the preoperative degenerative changes. All patients had a complete radiologic examination in the first 3 months after the index procedure.

The mean operative time was 110 minutes (standard deviation 20 minutes) in the navigated group and 98 minutes (standard deviation 21 minutes) in the conventionally treated group.

The number of prostheses in the desired angular range, as determined by the radiographic results, were significantly better in navigation-treated patients compared to conventionally treated patients. (Level 3 evidence)

Limitations to the study by Jenny and Boeri(4) were:

- Retrospective study design.

- Short term accuracy results. Long term results for total knee prostheses are unknown. Jenny and Boeri stated "the follow-up of the navigated prostheses is currently too short to know if clinical outcome or survival rates will be improved. Longer follow-up is required to determine the respective advantages and disadvantages of both techniques."
- Angles were measured by an observer (Jenny) who was unable to be blinded to the type of instruments used because the presence or absence of the rigid body fixation holes was obvious.

■ Jenny and Boeri(5) conducted a single site, case-control study to examine a non image based navigation system (OrthoPilot, Aesculap, Germany) approach for unicompartmental knee prostheses in 30 patients compared to 30 patients undergoing the conventional surgeon-controlled operative technique. The patients were matched according to age, gender, body mass index, preoperative coronal mechanical femorotibial angle, and severity of the preoperative degenerative changes. All patients had a complete radiologic examination in the first 3 months after the index procedure.
No complications were reported to have occurred. All navigation procedures were performed completely and no conversion to the conventional technique was required. The mean operative time increased from 67 to 86 minutes due to the use of the navigation system.

The number of unicompartmental prostheses in the desired angular range, as determined by the radiographic results are presented below and demonstrate improved short term outcomes for navigation-treated patients compared to patients who received conventional treatment. (Level 3 evidence)

Radiographic results: number of prostheses in the desired angular range.

	Navigated N=30	Conventional N=30	P Value
Coronal femorotibial mechanical angle	26	20	>0.05
Coronal orientation of femoral component	27	19	<0.02
Sagittal orientation of femoral component	27	19	<0.02
Coronal orientation of tibial component	26	19	<0.05
Sagittal orientation of tibial component	28	21	<0.02
Satisfactory implanted prosthesis	18	6	<0.01

Reproduced with kind permission of Springer Science and Business Media; From: Jenny JY, Boeri C. Unicompartmental knee prosthesis implantation with a non-image-based navigation system: rationale, technique, case-control comparative study with a conventional instrumented implantation. Knee Surgery, Sports Traumatology, Arthroscopy 2003; 11(1):40-45.

Limitations to the unicompartmental knee prostheses study by Jenny and Boeri(5) were:
- Retrospective study design.
- Short term accuracy results. Long term results for unicompartmental knee prostheses are unknown. The authors stated "the follow-up of the navigated prostheses is currently too short to know if clinical outcome or survival rates are improved. Longer follow-up is required to determine the respective advantages and disadvantages of both techniques."
- Angles were measured by an observer (Jenny) who was unable to be blinded to the type of instruments used because the presence or absence of the rigid body fixation holes was obvious.

Navigation-Assisted Total Hip Arthroplasty

■ In a Level 2 evidence, single centre study from Belgium, Leenders et al.(3) assessed whether the variability of the abduction angle of acetabular cups (hollow portion of the pelvis into which the head of the thigh bone fits) could be reduced with the use of computer navigation (SurgiGate system, Medivision, Switzerland) compared to the free hand method for total hip arthroplasty (THA).

The abduction angles of 150 consecutive THAs were assessed. Group A consisted of 50 patients who underwent a computed tomography based computer navigation THA. Group B consisted of 50 patients

who underwent a free-hand method. Leenders et al.(3) stated that a randomized system was used to determine which patients would undergo the navigation procedure. The authors included a third group of patients, Group C which consisted of the last 50 patients who underwent THA using the free-hand method in the period before the authors started using computer navigation for hip surgery (historical controls).

All cups were placed by the same surgeon and all were uncemented, metal-backed cups. All three patient groups were comparable with regard to mean age, sex, and indication for surgery (osteoarthritis, subcapital fracture, avascular necrosis). Osteoarthritis was the main indication in all three groups.

The authors reported that the difference in variability of cup abduction angle in Group C versus Group A was statistically significant in favour of the navigation group ($p<0.001$). There was also a significant difference when Group C was compared to Group B ($p<0.0001$), in favour of Group B. There was no significant difference in variability of cup abduction angle between Groups A (navigation) and B (free hand concurrent control) ($p>0.05$).

Limitations to the study by Leenders et al. were:

- There was no justification for the sample size used in the study.
- The study was reported to be randomized between Groups A and B. All analyses that examined Group C compared to Groups A or B were not based on prospective randomized groups. The authors provided no rationale for inclusion of a historical control group in the study.
- The authors stated that 150 THAs were assessed in a prospective manner. In fact, only 100 cases were assessed in a prospective manner.
- No discussion about the lack of significance between Groups A and B in terms of variability of cup abduction angle. The only part of the study that may be considered prospective, randomized, and controlled is the comparison between groups A and B; and it is not known if the study was powered to determine whether differences between the groups were statistically significant.
- Only short-term effects (abduction angle) were studied.

Summary of Navigation-Assisted Arthroplasty

- Five studies were identified that examined navigation-assisted arthroplasty.
- A Level 1 evidence study from Germany found a statistically significant difference in alignment and angular deviation between navigation-assisted and free-hand total knee arthroplasty in favour of navigation-assisted surgery. However, the endpoints in this study were short-term. To date, the long-term effects (need for revision, implant longevity, pain, functional performance) are unknown.(1)
- A Level 2 evidence short-term study found that navigation-assisted total knee arthroplasty was significantly better than a non-navigated procedure for one of five postoperative measured angles.(2)
- A Level 2 evidence short-term study found no statistically significant difference in the variation of the abduction angle between navigation-assisted and conventional total hip arthroplasty.(3)
- Observational studies of navigation-assisted total knee arthroplasty and unicompartmental knee arthroplasty have been conducted. Two studies reported that "the follow-up of the navigated prostheses is currently too short to know if clinical outcome or survival rates are improved. Longer follow-up is required to determine the respective advantages and disadvantages of both techniques."(4;5)

Robotic-Assisted Arthroplasty

The overall results of the robotic-assisted hip or knee arthroplasty studies are listed in Table 2.

Robotic-Assisted Total Hip Arthroplasty

■ A Level 1 evidence, German, randomized controlled study by Honl et al.(6) assessed the outcomes of robotically assisted, cementless, primary total hip implantation compared with those of conventional manual implantation of the same type of prosthesis. Honl et al.(6) reported that the prosthesis used in the study was "S-ROM" (DePuy, Leeds, United Kingdom). To be included in this study, subjects had to have osteoarthritis of the hip joint. One hundred and fifty-four patients were randomly assigned to undergo either conventional manual implantation (n=80) or robotic-assisted implantation (n=74) of the same type of prosthesis. A sample size calculation was not reported. The authors stated that the purpose of the study was to provide objective information on the differences in clinical outcome between robotic-assisted and conventional manual implantations of the same type of total hip prostheses.

The robotic implantations were performed with ROBODOC along with the ORTHODOC planning computer. ORTHODOC transformed computed tomography scans, carried out according to the manufacturer's specified protocol, into three-dimensional reconstructions in order to plan the implantation of the prostheses. For implantations performed with the conventional manual approach, a preoperative planning sketch was drafted using radiographic templates and limb lengths.

All patients were examined clinically and radiographically before the operation as well as at 3, 6, 12, and 24 months postoperatively. Functional hip scores according to the Harris and Merle d'Aubigne systems and the Mayo clinical score were determined preoperatively and at the identified postoperative intervals. Blinding of the investigators was not reported.

There were no significant baseline differences between the 2 groups with regard to age, sex, weight, height, or preoperative functional hip scores.

Thirteen of the robotic assisted procedures had to be stopped prior to completion of the reaming process, resulting in a failure rate of 18% (13/74).(6) These patients were subsequently excluded from the study. For nine patients, the system automatically shut off and would not resume even after four attempts to restart it. For four patients, software as well as hardware problems prevented the start of robotic reaming. Exclusion of the 13 patients left 61 patients who underwent robotic-assisted surgery. Table 3 tracks the distribution of patients at different time points during the study by Honl et al.(6)

For 16 of the 61 patients who underwent successful robotic-assisted surgery, the system shut down during the milling process.(6) For 3 other patients, bone motion exceeded the limit allowed by the ROBODOC system and this resulted in the reference pins having to be implanted for surgery again.

The immediate postoperative radiographs showed a significantly larger angle (indicating misalignment) between the femur and the shaft of the prosthesis in those patients who had the manual procedures compared with those who had the robotic implantations ($p<0.001$). The patients' limb lengths were assessed 6 months postoperatively. The group treated with robotic implantation had significantly less discrepancy in leg length than the group treated with manual implantation ($p<0.001$).

The results for the functional hip scores at different assessment time points are presented in Table 4. Three months postoperatively, there were no significant differences in the hip scores between the 2

groups. Six months postoperatively, the Mayo score and Merle d'Aubigne score were significantly better in the robotically treated group, whereas the difference in the Harris scores was not statistically significant. At 12 months, only the Harris and Mayo scores were significantly better in the robotically treated group. At 24 months, there were no significant differences in the functional hip scores between the 2 groups, although patients in the group treated with manual implantation had lower scores than those treated with the robot-assisted implantation.

Honl et al.(6) concluded that robotic-assisted arthroplasty had advantages in terms of preoperative planning and the accuracy of the procedure. For example, limb length equality and mean angle between the femur and the shaft of the prosthesis were better with the robotic-assisted procedure.

Disadvantages of robotic-assisted arthroplasty were the higher revision rate (8/61 compared to 0/78 patients, $p<0.001$), the higher dislocation rate (11/61 compared to 3/80 patients, $p<0.001$), and the longer duration of surgery (mean 107.1 [standard deviation 29.1] compared to 82.4 [23.4] minutes, $p<0.001$). At 24 months, there was no statistically significant difference in the functional hip scores for patients who underwent robotic-assisted and manual implantations. The use of the robotic reamer required that all soft tissue at the reamer's starting point be cut.(6) In addition, the reamer cut into some layers of the base of the tendon of the abductor muscles. However, Honl et al.(6) stated that the part of the muscle attachment that had to be removed to approach the joint was always carefully repaired. The authors speculated that the "greater number of dislocations in the group treated with robotic implantation was probably related to the insufficiency of the patients' abductor muscles in that group".(6) However, Honl et al. did not explicitly discuss whether the insufficiency of the patients' abductor muscles was de novo or as a result of the procedure. The authors supported their speculation by stating that during the nine revisions approximately 6 to 12 months following robotic implantations, it was found that the gluteus medius and maximus muscles did not have any attachment to the greater trochanter.(6) Honl et al.(6) stated that abductor muscle function was assessed in all patients preoperatively, as well as at 3, 6, 12 and 24 months however, no muscle abductor function data was reported to compare the two patient groups at baseline, 3, 6, and 12 months after surgery. In contrast to the speculation by Honl et al.(6), at twenty-four months, there was no statistically significant difference in abductor muscle function between the two patient groups, $p>0.05$.(6)

Honl et al. suggested that the extent of muscle detachment produced by robotic-assisted arthroplasty depends on the type of prosthesis.(6) Table 5 lists the implants supported by ROBODOC as reported by the manufacturer. A retrospective analysis by Honl et al.(6) of the planning sketches for different prostheses (S-ROM, Osteolock and ABG) revealed that the "so-called anatomic prosthesis" (ABG) has advantages with respect to this problem. Honl et al. concluded that reaming for the "so-called anatomic ABG prosthesis" will not encroach as much on the insertion of the abductor muscles on the greater trochanter part of the femur, as compared to reaming for the S-ROM and Osteolock prostheses. On the basis of the results of the study, the robot program for the S-ROM prosthesis was altered by the authors to protect the area of the muscle base of the greater trochanter as much as possible.(6) Honl et al.(6) stated that "the new software improves the intraoperative situation, although the clinical results of this modification are not yet available."

Honl et al.(6) revealed that one reason for the general lack of robotic-assisted arthroplasty studies is that, in most centres, the robotic and manual approaches are used to implant different types of prostheses.

Limitations to the study by Honl et al.(6) were as follows:

- Lack of sample size calculation
- Lack of information regarding the blinding of the follow-up investigators assessing patient outcomes
- Large number of patients who failed to complete the procedure and lack of information whether intent-to-treat analysis was used

■ In a Level 3 evidence, prospective, observational, controlled study from Japan, Hagio et al.(7) compared the risk of intraoperative embolism between patients undergoing cementless total hip replacement (THR) by ROBODOC compared to manual femoral milling. Hagio et al.(7) hypothesized that robotic milling, by excavating the femoral canal precisely, should reduce the risk of pulmonary embolism during cementless THR. Hagio et al.(7) stated that rasping the intra-medullary canal of the femur can increase the intra-femoral pressure due to entry of fat and bone marrow into the blood, which may then migrate to the lungs. The objective of the study was to compare the risk of intraoperative embolism between study and control group using transesophageal echocardiography and hemodynamic monitoring. A total of 71 patients (75 hips) with osteoarthritis of the hip were included in the study. Forty-six patients (50 hips) underwent cementless THR with preparation of the femoral canal using ROBODOC. Twenty-five patients (25 hips) underwent conventional cementless THR. No pharmacological prophylaxis for thromboembolism was given to the patients. However, Hagio et al.(7) stated that in both groups of patients during surgery, a bandage was tightly wrapped around the lower extremity of the operated side as prophylaxis against thromboembolism.

Echocardiographic findings divided into 4 grades (from Pitto et al.(24)):

Grade 0: No emboli.
Grade 1: A few fine emboli.
Grade 2: A cascade of small emboli or embolic masses with a diameter <5mm.
Grade 3: Small emboli mixed with embolic masses having a diameter ≥5 mm.

In both groups, no embolic events were detected during incision of the hip, dislocation of the joint or osteotomy of the femoral neck, or at the end of the operation.

In the manually milled group, 9/25 hips had a grade 2 or greater embolic event during preparation of the femur. No patient in the ROBODOC group had such an event. The frequency and severity of embolic events during preparation of the femur between the two groups differed significantly.

Frequency and severity of events in the two patient groups
Data presented as: Number (%) of hips

	ROBODOC			Manual			P value
	Grade 1	Grade 2	Grade 3	Grade 1	Grade 2	Grade 3	
Preparation of the femur	4 (8%)			16 (64%)	8 (32%)	1 (4%)	<0.001
Implantation of stem	18 (36%)			17 (68%)	4 (16%)	1 (4%)	<0.001
Relocation of hip joint	29 (58%)	4 (8%)		13 (52%)	11 (44%)	1 (4%)	<0.001

From: Pitto RP, Kossler M, Kuchle JW. Comparison of fixation of the femoral component without cement and fixation with use of a bone-vacuum cementing technique for the prevention of fat embolism during total hip arthroplasty. A prospective, randomized clinical trial. Journal of Bone and Joint Surgery (Am) 1999; 81:831-843.

Overall, the incidence of events of greater than Grade 2 during hip relocation was lower with ROBODOC (4/50) than with manual surgery (12/25).

Hagio et al.(7) also evaluated hemodynamic changes at each stage of THR. The data from the two patient groups were combined and divided into two groups based on the grade of embolic events: ≤Grade 1 or ≥Grade 2 on echocardiography. At all the stages of THR in the group of patients with ≥Grade 2 embolic events, blood gas and arterial oxygen saturation were significantly lower than in patients with ≤Grade 1 embolic events, $p<0.03$ to 0.0004. However, there was no significant difference between the two groups of patients for heart rate or systolic blood pressure.

Hagio et al.(7) concluded that the ROBODOC may reduce the amount of fat and bone marrow introduced into the venous system during femoral preparation resulting in a low incidence of severe events (≥Grade 2) during stem insertion and hip relocation.

Limitations to the study by Hagio et al. included:

- Hagio et al.(7) reported that it is difficult to define clearly the nature of echogenic particles. Pitto et al.(24) reported that Grade 1 events also occurred when the infusion via the central venous catheter was a maximum flow. Hagio et al.(7) also observed grade 1 events when infusion via the peripheral venous catheter was at maximum flow.
- Pitto et al.(24) used transesophageal echocardiography to study patients who underwent THR. Among patients who underwent cemented THR, there was severe embolic events (≥Grade 2) in 10% during preparation of the femoral canal, 85% during stem insertion and 75% during reduction.(24) Among those who underwent cementless THR, there were severe embolic events in 15% during femoral preparation and 0% during stem insertion and reduction.(24) The stem design that was used by Pitto et al.(24) was different from the stem design used by Hagio et al.(7) Different stem designs and/or instruments used in femoral preparation may affect the generation of embolic particles.

■ In Austria, Bach et al.(8) conducted a prospective, observational, controlled, three-dimensional gait analysis of 25 patients who underwent robotic-assisted THA using ROBODOC and 25 patients who were treated with conventional cementless THA using the transgluteal approach. Patients were recruited consecutively. No sample size calculation was reported. Gait analysis was conducted 6 months after surgery and consisted of: pelvic tilt (sagittal plane), pelvic obliquity (frontal plane), hip flexion/extension (sagittal plane), and hip abduction/adduction (frontal plane). (Level 3 evidence)

Pelvic and hip motion parameters did not differ significantly in patients who underwent ROBODOC or conventional THA, p=0.3 to 0.9.

Limitations to the study by Bach et al. were:

- Outcome measured at only one time point (6 months after surgery).
- Sample size was not justified.
- It was not reported whether a blinded investigator was used for the gait analysis of the patients at 6 months after surgery.

Robotic-Assisted Total Knee Arthroplasty

■ In Germany, Siebert et al.(9) conducted a cohort study to compare outcomes of TKA between 69 patients (70 TKAs) undergoing robotic surgery using CASPAR and 52 patients who were historical controls and underwent manually operated surgery.

The authors reported that the full range of motion seemed to be regained more quickly for the majority of robotic TKA patients. However, these observations were not quantified. To restore full motion, the knee joints of 7 patients in the robotic group and 2 patients in the manual group had to be mobilized under general anesthesia.

The authors stated that no major adverse events directly related to CASPAR were noted.(9)

One patient who was undergoing CASPAR had to convert to a manual technique due to a defective registration marker.(9)

The first follow-up examinations at 3 and 6 months did not show any visible change of the initial implant position in either group. Siebert et al.(9) stated that Knee Society scores did not differ significantly in patients treated with the robotic or manual technique. No further details were provided by the authors.

Postoperative tibiofemoral alignment between the two patient groups revealed a much broader variation of angles after manual TKA compared to the robotic technique ($p<0.0001$). (Level 3 evidence)

Limitations to the study by Siebert et al.(9) were:
- The patient groups used different implants.
- Use of historical controls.
- The results were a brief, qualitative report.
- Long-term results are unknown.

Summary of Robotic-Assisted Arthroplasty
- One Level 1 evidence study from Germany revealed that there was no statistically significant difference between functional hip scores at 24 months post implantation between patients who underwent robotic-assisted (ROBODOC) primary hip arthroplasty and those that were treated with manual implantation.(6)
- Robotic-assisted arthroplasty had advantages in terms of preoperative planning and the accuracy of the intraoperative procedure.(6)
- Patients who underwent robotic-assisted hip arthroplasty had a higher subsequent dislocation rate and more revisions.(6)
- One Japanese observational study (Level 3 evidence) found that the incidence of severe embolic events of greater than Grade 2 during hip relocation was lower with ROBODOC than with manual surgery.(7)
- One observational study from Germany (Level 3 evidence) compared outcomes of TKA between patients undergoing robotic surgery using CASPAR and patients who were historical controls. Brief, qualitative results suggested that there was much broader variation of angles after manual TKA compared to the robotic technique and that there was no difference in knee functional scores or implant position at the 3 and 6 month follow-up.(9)

- One Austrian observational study (Level 3 evidence) found that there was no significant difference in gait analyses of patients who underwent robotic-assisted THA using ROBODOC compared to patients who were treated with conventional cementless THA.(8)

Consultation with Ontario Experts

A discussion with experts in the field revealed that robotic-assisted arthroplasty is not currently under investigation in Ontario. However, navigation-assisted arthroplasty is used at some facilities in Ontario and, to date, garners greater interest among orthopedic surgeons than robotic systems.

An expert in the field stated stated:

- Navigation-assisted arthroplasty is an evolving field with continually changing software and techniques.
- One cannot generalize the results for one navigation system to other systems as the system-to-system accuracy may vary.
- Few studies have assessed the efficacy of enhancements to a single system or compared the efficacy of one system to another.
- "Despite these shortcomings, research on the use of computer-assisted arthroplasty should continue in a few centres as this technique holds great promise in improving the accuracy and outcomes of THR/TKR and would be a logical addition to allow safe minimal incision/access total joint replacement surgery".

Economic Analysis

Literature Review

No cost-effectiveness analysis and no economic analyses in general of navigation or robotic-assisted arthroplasty were identified.

Bargar et al.(14) stated that the expected purchasing cost of the ROBODOC system was estimated to be approximately $600,000 US. It is unclear from Bargar et al.(14) if this includes the cost of the ORTHODOC system.

There were no reports in the literature of the purchasing cost of a navigation-assisted arthroplasty device.

A manufacturer of a navigational system quoted a price of $95,000 CDN for the navigational system (including hardware and basic setup equipment), $40,000 CDN per software package (for knee or hip), and $30,000 CDN for instruments (for knee or hip).

An expert in the field estimated that the cost of navigation systems varies depending on the system and software required but may range from $250,000 to $400,000 CDN.

An expert in the field stated that training for navigation systems requires a one to two day seminar where the surgeons can familiarize themselves with the system. This is followed by a moderate learning curve where the system is actually used by both the surgeons and nursing staff. Many systems may also require an additional person (computer programmer) in the operating room to oversee the navigation system. For a fluoroscopic navigation system, an intraoperative image intensifier and radiology technician is required. For a volumetric image based system requiring preoperative imaging, a CT scan (or MRI, ultrasound) and time for preoperative planning of the

surgeon is an additional cost. Imageless systems avoid the need for preoperative images and intraoperative fluoroscopy, but may still require a programmer to operate the navigation system.

Existing Guidelines Regarding Use of the Technology

There are no current guidelines specifically regarding the use of navigation or robotic-assisted arthroplasty.

Summary and Conclusion

Summary of Findings on Effectiveness

Navigation-Assisted Arthroplasty

- Five studies were identified that examined navigation-assisted arthroplasty.
- A Level 1 evidence study from Germany found a statistically significant difference in alignment and angular deviation between navigation-assisted and free-hand total knee arthroplasty in favour of navigation-assisted surgery. However, the endpoints in this study were short-term. To date, the long-term effects (need for revision, implant longevity, pain, functional performance) are unknown.(1)
- A Level 2 evidence short-term study found that navigation-assisted total knee arthroplasty was significantly better than a non-navigated procedure for one of five postoperative measured angles.(2)
- A Level 2 evidence short-term study found no statistically significant difference in the variation of the abduction angle between navigation-assisted and conventional total hip arthroplasty.(3)
- Observational studies of navigation-assisted total knee arthroplasty and unicompartmental knee arthroplasty have been conducted. Two studies reported that "the follow-up of the navigated prostheses is currently too short to know if clinical outcome or survival rates are improved. Longer follow-up is required to determine the respective advantages and disadvantages of both techniques."(4;5)

Robotic-Assisted Arthroplasty

- Four studies were identified that examined robotic-assisted arthroplasty.
- A Level 1 evidence study revealed that there was no statistically significant difference between functional hip scores at 24 months post implantation between patients who underwent robotic-assisted primary hip arthroplasty and those that were treated with manual implantation.(6)
- Robotic-assisted arthroplasty had advantages in terms of preoperative planning and the accuracy of the intraoperative procedure.(6)
- Patients who underwent robotic-assisted hip arthroplasty had a higher dislocation rate and more revisions.(6)
- Robotic-assisted arthroplasty may prove effective with certain prostheses (e.g., anatomic) because their use may result in less muscle detachment.(6)
- An observational study (Level 3 evidence) found that the incidence of severe embolic events during hip relocation was lower with robotic arthroplasty than with manual surgery.(7)

- An observational study (Level 3 evidence) found that there was no significant difference in gait analyses of patients who underwent robotic-assisted total hip arthroplasty using robotic surgery compared to patients who were treated with conventional cementless total hip arthroplasty.(8)
- An observational study (Level 3 evidence) compared outcomes of total knee arthroplasty between patients undergoing robotic surgery and patients who were historical controls. Brief, qualitative results suggested that there was much broader variation of angles after manual total knee arthroplasty compared to the robotic technique and that there was no difference in knee functional scores or implant position at the 3 and 6 month follow-up.(9)

Conclusion

Computer-assisted arthroplasty using navigation systems is considered to be in the investigational stage. To date, studies have only assessed short-term outcomes; long-term effectiveness (need for revision, implant longevity, pain, functional performance) has not been demonstrated. This is important because a Level 1 study that examined robotic-assisted arthroplasty compared to manual implantation concluded that despite advantages in surgical accuracy, the long-term effects included a higher revision and dislocation rate. Furthermore, at 24 months after surgery, there was no difference between the patients who underwent robotic-assisted and manual implantation in terms of functional hip scores.

Computer-assisted arthroplasty using robotic systems is considered to be in the investigational stage and short-term outcomes seem promising. A Level 1 study revealed that there was no statistically significant difference between functional hip scores at 24 months post implantation between patients who underwent robotic-assisted primary hip arthroplasty and those that were treated with manual implantation. Robotic-assisted arthroplasty had advantages in terms of preoperative planning and the accuracy of the intraoperative procedure, however, patients had a higher dislocation rate and more revisions. Additional study is required to further address long-term effectiveness since it was suggested that the use of different prostheses may produce less muscle detachment in primary hip arthroplasty.

The current large investigative studies of robotic-assisted arthroplasty underway in the United States to develop information for FDA licensing are awaited with interest. The robotic-assisted technology is not yet licensed by Health Canada or the USFDA.

Health Systems Implications

Navigation Systems

- Increased precision may lead to decreased revision rates
- Decreased revision rates may lead to increased recruitment at younger ages (diffusion pressure)
- Distribution/access concerns (distortion of referral patterns)
- May not be enough resources and services immediately available to efficiently handle all existing and new eligible patients

Robotic Systems

- Not licensed by Health Canada
- Unlikely uptake in future due to undesirable outcomes

Glossary

Osteotome: A chisel-like device to cut bone

Osteotomy: The surgical cutting of a bone

Trochanter: One of the bony prominences near the upper portion of the femur (thigh bone) to which muscles are attached. The lateral prominence is called the greater trochanter (to which the abductor muscles are attached) and the medial prominence is called the lesser trochanter (to which the psoas tendon is attached).

References

1. Sparmann M, Wolke B, Czupalla H, Banzer D, Zink A. Positioning of total knee arthroplasty with and without navigation support. Journal of Bone & Joint Surgery -British Volume 2003; 85(6):830-835.

2. Hart R, Janecek M, Chaker A, Bucek P. Total knee arthroplasty implanted with and without kinematic navigation. International Orthopaedics 2003; 27(6):366-369.

3. Leenders T, Vandevelde D, Mahieu G, Nuyts R. Reduction in variability of acetabular cup abduction using computer assisted surgery: A prospective and randomized study. Computer Aided Surgery 2002; Vol 7(2):-106.

4. Jenny JY, Boeri C. Total knee prosthesis implantation with a non-image based navigation system: rationale, technique, case-control comparative study with a conventional instrumented implantation. Techniques in Orthopaedics 2003; 18(2):160-166.

5. Jenny JY, Boeri C. Unicompartmental knee prosthesis implantation with a non-image-based navigation system: rationale, technique, case-control comparative study with a conventional instrumented implantation. Knee Surgery, Sports Traumatology, Arthroscopy 2003; 11(1):40-45.

6. Honl M, Dierk O, Gauck C, Carrero V, Lampe F, Dries S et al. Comparison of robotic-assisted and manual implantation of a primary total hip replacement. A prospective study. Journal of Bone & Joint Surgery - American Volume 2003; 85-A(8):1470-1478.

7. Hagio K, Sugano N, Takashina M, Nishii T, Yoshikawa H, Ochi T. Effectiveness of the ROBODOC system in preventing intraoperative pulmonary embolism. Acta Orthopaedica Scandinavica 2003; Vol 74(3):-269.

8. Bach CM, Winter P, Nogler M, Gobel G, Wimmer C, Ogon M. No functional impairment after Robodoc total hip arthroplasty. Gait analysis in 25 patients. Acta Orthopaedica Scandinavica 2002; Vol 73(4):-391.

9. Siebert W, Mai S, Kober R, Heeckt PF. Technique and first clinical results of robot-assisted total knee replacement. Knee 2002; Vol 9(3):-180.

10. Hawker G. Epidemiology of Arthritis and Osteoporosis. In: Williams JI, Badley EM, editors. Patterns of Health Care in Ontario: Arthritis and Related Conditions. Toronto: Institute for Clinical Evaluative Sciences; 1998. p. 1-10.

11. Badley EM, Webster GK, Rasooly I. The impact of musculoskeletal disorders in the population: are they just aches and pains? Findings from the 1990 Ontario Health Survey. Journal of Rheumatology 1995; 22(4):733-739.

12. Canadian Institute for Health Information (CIHI). Total Hip and Total Knee Replacements in Canada, 2000/01. 2003.

13. Stulberg SD, Loan P, Sarin V. Computer-assisted navigation in total knee replacement: Results of an initial experience in thirty-five patients. Journal of Bone & Joint Surgery - American Volume 2002; Vol 84(SUPPL. 2):-98.

14. Bargar WL, Bauer A, Borner M. Primary and revision total hip replacement using the ROBODOC(TM) system. Clinical Orthopaedics & Related Research 1998; Issue 354:82-91.

15. Taylor RH, Joskowicz L, Williamson B, Gueziec A, Kalvin A, Kazanzides P et al. Computer-integrated revision total hip replacement surgery: concept and preliminary results. Medical Image Analysis 1999; 3(3):301-319.

16. Davies B. A review of robotics in surgery. Proceedings of the Institution of Mechanical Engineers 2000; Part H - Journal of Engineering in Medicine 2000; 214(1):129-140.

17. Davies BL, Harris SJ, Lin WJ, Hibberd RD, Middleton R, Cobb JC. Active compliance in robotic surgery--the use of force control as a dynamic constraint. Proceedings of the Institution of Mechanical Engineers 1997; Part H - Journal of Engineering in Medicine. 211(4):285-292.

18. Sugano N. Computer-assisted orthopedic surgery. Journal of Orthopaedic Science 2003; 8(3):442-448.

19. Delp SL, Stulberg SD, Davies B, Picard F, Leitner F. Computer assisted knee replacement. Clinical Orthopaedics & Related Research 1998;(354):49-56.

20. Anonymous. Computer-assisted total hip arthroplasty. http://www arthritisnetwork ca/research_programs/diagnostics asp [2004 Available from: URL:http://www.arthritisnetwork.ca/research_programs/diagnostics.asp

21. Bryan B. KGH robotic assisted research gains two ORs. Hospital News 2004.

22. Foley KT, Simon DA, Rampersaud YR. Virtual fluorosccopy: computer-assisted fluoroscopic navigation. Spine 2001; 26:347-351.

23. Integrated Surgical Systems. Robodoc. Integrated Surgical Systems [2003 Available from: URL:www.robodoc.com/eng/robodoc.html

24. Pitto RP, Kossler M, Kuchle JW. Comparison of fixation of the femoral component without cement and fixation with use of a bone-vacuum cementing technique for the prevention of fat embolism during total hip arthroplasty. A prospective, randomized clinical trial. Journal of Bone and Joint Surgery (Am) 1999; 81:831-843.

25. Pransky J. Surgeons' realizations of RoboDoc. Industrial Robot 1998; 25(2):105-108.

Appendix

Table 1 Studies Assessing Navigation-Assisted Hip or Knee Arthroplasty

Study	Type & Size	Objective & Methods	Outcome
Sparmann et al.(1) Germany 2003	Randomized controlled trial. 120 patients treated with navigation 120 patients treated without navigation	Objective: to compare 120 patients treated with and 120 treated without navigation guidance Inclusion criteria: all patients who were scheduled for a primary total knee arthroplasty Bone angles measured in both groups	There was a statistically significant difference between the two groups in the intraoperative deviation in the mechanical axis (alignment) ($p<0.0001$); postoperative frontal femoral axis (varus valgus deviation) ($p<0.0001$); sagittal femoral axis (navigation n=73, hand guided n=86) ($p<0.001$); and frontal tibial axis ($p<0.05$). There was no significant difference between the two groups for the postoperative sagittal tibial axis. Limitations Short -term outcomes. Long-term effects (pain, revision, functional assessment, implant survival) unknown. No justification for sample size chosen.
Leenders et al.(3) Belgium 2002	Randomized controlled trial. Group 1: 50 patients who underwent total hip arthroplasty (THA) using free hand method in period before authors started using computer navigation (historical controls). Group 2: 50 patients who underwent a computed tomography based computer navigation THA. Group 3: 50 patients who underwent a free hand method after the authors had begun using the computer navigation method (concurrent controls).	Objective: To examine whether the variability of the abduction angle of acetabular cups could be reduced with the use of computer navigation compared to the free hand method for THA. Osteoarthritis was the main indication in all 3 groups.	The difference in variability of cup abduction angle in group 1 versus group 2 was statistically significant in favour of the navigation group ($p<0.001$). There was also a significant difference when group 1 was compared to group 3 ($p<0.0001$), in favour of group 3. There was no significant difference in variability of cup abduction angle between groups 2 and 3 ($p>0.05$). Limitations No explanation for the chosen sample size Use of historical controls Lack of discussion as to why there was no significant difference between groups 2 and 3 in terms of variability of cup abduction angle Only short-effects were studied
Jenny and Boeri (4) France 2003	Case-control study 100 patients non image based navigation system for <u>total knee replacement</u> 100 patients undergoing conventional surgeon controlled operative technique	Objective: to assess the number of prostheses in the desired angular range after total knee replacement, as determined by radiographic results. Patients matched according to age, gender, body mass index, preoperative coronal femorotibial mechanical angle, and severity of the preoperative degenerative changes.	The number of prostheses in the desired angular range, as determined by the radiographic results, were significantly different between the conventionally and navigation-treated patients ($p<0.05$). Coronal femorotibial mechanical angle Coronal orientation of the femoral component Sagittal orientation of femoral component Coronal orientation of tibial component Sagittal orientation of tibial component Satisfactory implanted prosthesis Limitations Retrospective study design. Short term accuracy results. Long term results for total knee prostheses are unknown. Authors stated “the follow-up of the navigated prostheses is currently too short to know if clinical outcome or survival rates will be improved. Longer follow-up is required to determine the respective advantages and disadvantages of both techniques.” Angles were measured by an observer (Jenny) who was unable to be blinded to the type of instruments used because the presence or absence of the rigid body fixation holes was obvious.
Jenny and	Case-control study	Objective: to assess the number of	There was a statistically significant difference in the number of prostheses in the desired angular

Boeri (5) France 2003	30 patients underwent conventional surgeon controlled operative technique for unicompartmental knee prostheses. 30 patients underwent non image based navigation system.	prostheses in the desired angular range after unicompartmental knee prostheses, as determined by radiographic results. Patients matched according to age, gender, body mass index, preoperative coronal femorotibial mechanical angle, and severity of the preoperative degenerative changes.	range between the navigation and conventionally treated patients for: Coronal orientation of the femoral component Sagittal orientation of femoral component Coronal orientation of tibial component Sagittal orientation of tibial component Satisfactory implanted prosthesis Limitations Retrospective study design. Short term accuracy results. Long term results for total knee prostheses are unknown. Authors stated "the follow-up of the navigated prostheses is currently too short to know if clinical outcome or survival rates will be improved. Longer follow-up is required to determine the respective advantages and disadvantages of both techniques." Angles were measured by an observer (Jenny) who was unable to be blinded to the type of instruments used because the presence or absence of the rigid body fixation holes was obvious.
Hart et al.(2) Czech Republic 2003	Prospective cohort study 60 patients who underwent the conventional technique for total knee arthroplasty 60 patients who underwent imageless navigation	Objective: to compare postoperative measured angles between patients undergoing a conventional versus navigation procedure. Indications for primary total knee arthroplasty were primary osteoarthritis in 78 patients and secondary osteoarthritis in 42 cases.	The only statistically significant difference between the two patient groups was for the anatomic posterior proximal tibial angle ($p<0.001$). There was no statistically significant difference between the two study groups for the following angles measured postoperatively: Anatomic lateral tibiofemoral angle Anatomic lateral distal femoral angle Anatomic medial proximal tibial angle Anatomic posterior distal femoral angle Limitations No justification for sample size of study. Long term results in terms of revision rate, pain, functional performance, implant survival are unknown. Statistical comparisons of the baseline patient characteristics between the study groups were not reported. Lack of discussion regarding any blinding of the researcher who measured postoperative angles.

Table 2 Studies Assessing Robotic-Assisted Hip or Knee Arthroplasty

Study	Type & Size	Objective & Methods	Outcome
Hagio et al.(7) Japan 2003	ROBODOC vs. manual femoral milling for cementless total hip replacement (THR). Prospective, observational, controlled. 71 patients with osteoarthritis of the hip. (75 hips). 46 patients (50 hips) underwent cementless THA with preparation of the femoral canal using ROBODOC. 25 patients (25 hips) underwent conventional cementless THA .	To compare risk of intraoperative embolism between study and control group via transesophageal echocardiography and hemodynamic monitoring. Echocardiographic findings divided into 4 grades (from Pitto et al.(24)): **Grade 0**: No emboli. **Grade 1**: A few fine emboli. **Grade 2**: A cascade of small emboli or embolic masses with a diameter <5mm. **Grade 3**: Small emboli mixed with embolic masses having a diameter ≥5 mm. All patients underwent primary hip arthroplasty via a posterolateral approach using a 2 pin based ROBODOC procedure. Distal pin implanted in the lateral condoyle. Tapered stem implant (VerSys Fiber Metal Taper) Separate measurements were made during preparation of the femur, insertion of the stem and relocation of the hip.	In both groups no embolic events were detected during incision of the hip, dislocation of the joint or osteotomy of the femoral neck, or at the end of the operation. In the manually milled group, 9/25 hips had a grade 2 or greater embolic event during preparation of the femur. No patient in the ROBODOC group had such an event. The frequency and severity of embolic events during preparation of the femur between the 2 groups differed significantly. No. (%) of hips: **ROBODOC** / **Manual** / **P value** **Gr. 1 Gr. 2 Gr. 3 Gr.1 Gr.2 Gr.3** Preparation of the femur 4 (8%) 16(64%) 8(32%) 1(4%) <0.001 Implantation of stem 18(36%) 17(68%) 4(16%) 1(4%) <0.001 Relocation of hip joint 29(58%) 4(8%) 13(52%) 11(44%) 1(4%) <0.001 Overall the incidence of events of ≥Gr. 2 during hip relocation was lower with ROBODOC (4/50) than with manual surgery (12/25). "Only a few patients complained of postoperative knee pain". **Limitation:** Stem design and/or instruments used in femoral preparation may affect the generation of embolic particles.
Honl et al.(6) Germany 2003	ROBODOC vs. manual implantation for primary total hip replacement. Prospective, randomized controlled. 154 patients randomly assigned to undergo ROBODOC (n=74 patients) of an S-ROM prosthesis or manual implantation (n=80) of same prosthesis.	To compare the functional hip scores of patients undergoing robotic and manual hip replacement preoperatively, 3, 6, 12, and 24 months after surgery. The scores used were the Harris, Merle d'Aubigne and Mayo clinical scores. Radiographs were also taken at these intervals. "modularity of S-ROM prosthesis can be used optimally in 3D preoperative planning for robotic surgery". Cementless cup.	13/74 (18%) attempted ROBODOC implantations had to be converted to manual implantations as a result of failure of the system. Duration of robotic procedures was longer than manual procedures - mean(SD): 107.1(29.1) min vs. 82.4(23.4) min, p<0.001. Limb-length equality [mean discrepancy: ROBODOC 0.18(0.30) cm vs. manual 0.96(0.93) cm, p<0.001]. Varus-valgus orientation of the stem (mean angle between the femur and shaft of the prosthesis): ROBODOC 0.34(0.67) degrees vs. manual 0.84(1.23) degrees, p<0.001. No intraoperative complications were observed in either group. The rate of nerve palsy was 4 hips (7%) in the ROBODOC group and 1 hip (1%) in the manual group, p=0.04. At 12 months, nerve function returned in all hips. By 24 months: no difference was noted between the groups with regard to any of the three scores. Dislocation was more frequent in ROBODOC (11/61 patients) vs. manual (3/80), p<0.001. Recurrent dislocation and pronounced limping were indications for revision surgery in 8/61 patients treated with ROBODOC and 0/78 patients treated manually (excluding 2 with revision for infection), p<0.001. Rupture of the gluteus medius tendon was observed during all revision operations. Authors' conclusion ROBODOC had advantages in terms of preoperative planning and accuracy of intraoperative procedure.

			Disadvantages were high revision rate; higher dislocation rate; and longer duration of surgery. "This technology must be further developed before its widespread usage can be justified". **Limitations:** Authors stated that the extent of muscle detachment produced by robotic milling depends on the type of prosthesis. A retrospective analysis of the planning sketches for different prostheses revealed that so called anatomic prostheses (e.g., ABG) have pronounced advantages with respect to this problem (over S-ROM and Osteolock). On the basis of the results of the study, the robot program for the S-ROM prosthesis was modified in order to protect the area of the muscle base as much as possible. "The new software improves the intraoperative situation, although the clinical results of the modification are not yet available". Lack of sample size calculation Lack of information regarding the blinding of the investigators assessing patient outcomes Lack of information whether intent-to-treat analysis was used.
Siebert et al.(9) Germany 2002	CASPAR vs. manually operated historical controls. 69 patients with 70 total knee arthroplasty (TKAs). 52 patients formed the manually operated historic control group.	To compare outcomes of TKA surgery between patients undergoing robotic surgery (CASPAR) and manually operated surgery. LC Search Evolution knee system was used for all patients in the robotic group since this was the first knee implant system geometry that was loaded into the planning software. All patients in the historic manual control group received NexGen implants.	Full range of motion seemed to be regained more quickly for the majority of robotic TKA patients. However, these observations were not quantified. To restore full motion, the knee joints of 7 patients in the robotic group and 2 patients in the manual group had to be mobilized under general anesthesia. "No major adverse events directly related to CASPAR were noted." One CASPAR patient converted to a manual technique due to a defective registration marker. Three patients had superficial skin irritations at the pin sites. The first follow up examinations at 3 and 6 months did not show any visible change of the initial implant position in either group. Knee Society scores did not significantly differ in patients treated with the robotic or manual technique. No further details were provided. Postoperative tibiofemoral alignment between the two patient groups revealed a much broader variation of angles after manual TKA compared to the robotic technique ($p<0.0001$). **Limitations:** Use of a historical control group with different implants. Mainly qualitative results. Long-term results unknown
Bach et al.(8) Austria 2002	ROBODOC vs. conventional cementless total hip arthroplasty Observational, controlled. 25 patients underwent total hip replacement by means of ROBODOC. 25 patients treated with conventional cementless total hip replacement.	To use 3 dimensional gait analysis to assess the kinematics of the pelvis and hip performed 6 months after surgery. Consecutive series of patients. Preoperative diagnosis of osteoarthritis in all patients. Duraloc cup and Osteoloc stem. Transgluteal approach.	Pelvic and hip motion did not differ significantly in patients who underwent ROBODOC or conventional total hip arthroplasty ($p=0.3$ to 0.9). Authors conclusion: This study suggests that the ROBODOC procedure did not impair hip abductor function more than the conventional method. **Limitations:** Endpoint measured at only one time point (6 months after surgery). No sample size calculation was reported; sample size was not justified. It was not reported whether a blinded investigator was used for the gait analysis of the patients at 6 months after surgery.

Table 3 Patient Distribution at the Different Assessment Time Points
From Honl et al.(6)

	Pre Operative	3 Months	6 Months	12 Months	24 Months
Robotic Procedure					
Followed	61(100%)	58(95%)	53(87%)	50(82%)	51(84%)
Excluded*	0	0	3(5%)	9(13%)	9(15%)
Not found†	0	3(5%)	5(8%)	2(3%)	1(2%)
Manual Procedure					
Followed	80(100%)	72(90%)	76(95%)	71(89%)	69(86%)
Excluded*	0	2(3%)	2(3%)	2(3%)	2(3%)
Not found†	0	6(8%)	2(3%)	7(%)	9(11%)

*Patients requiring revision surgery were secondarily excluded.
†Patients who refused the request to return for clinical examination are considered "not found". (Six of the missing nine patients treated with manual implantation reported that they were doing well during a telephone interview at twenty-four months).

Table 4 Functional Hip Scores at the Different Assessment Time Points
From Honl et al.(6)

	Merle d'Aubigne Points Mean (SD)		P Value	Mayo Points Mean (SD)		P Value	Harris Points Mean (SD)		P Value
	Robotic	**Manual**		**Robotic**	**Manual**		**Robotic**	**Manual**	
Preoperative	9.7 (2.1)	10.1 (1.9)	0.37	27.7 (15.6)	28.1 (11.5)	0.39	44.4 (12.9)	47.6 (11.5)	0.87
3 months	9.7 (1.9)	10.1 (1.8)	0.26	45.8 (11.6)	49.6 (12.5)	0.67	52.6 (12.3)	51.7 (10.6)	0.08
6 months	13.0 (2.8)	12.6 (3.4)	0.04	63.6 (15.0)	56.0 (16.8)	0.01	74.4 (16.4)	68.3 (18.7)	0.06
12 months	15.7 (2.2)	14.4 (2.6)	0.23	73.1 (7.3)	62.8 (14.3)	<0.001	85.9 (12.0)	73.2 (16.9)	<0.001
24 months	15.7 (2.2)	14.9 (2.1)	0.06	73.1 (7.3)	65.5 (9.1)	0.07	85.9 (12.0)	83.6 (11.9)	0.06

Table 5 Implants Supported by ROBODOC as Reported by Integrated Surgical Systems
(From http://www.robodoc.com/eng/supported_implants.html)

Aesculap™	Biomet™	DePuy™(a Johnson & Johnson Company)	Endoprothetik™	Stryker Howmedical Osteonics™	Zimmer™
Antega™	Ranawat/Burstein™	AML™	SL-Plus™	Osteolock™	VerSys Fiber Metal Midcoat-Standard and LM™
Plasmacup™		AMLA Replica-A™		ABG	VerSys Beaded Metal Midcoat-Standard and LM™
		AMLA Bentom-A™		ABG II	VerSys Fiber Metal Taper-Standard and LM™
		S-ROM™		Meridian™	Anatomic™
		Vision 2000™		Duracon™ Knee	Trilogy™ Acetabular Systems
				Scorpio™ Knee	NexGen Knee
					LPS Flex

Above information from Integrated Surgical Systems at http://www.robodoc.com/eng/supported_implants.html (accessed January 2004)

Figures

Figure 1 The OrthoPilot navigation system
(1 Computer, 2 Monitor, 3 Infrared camera, 4 Localizers)

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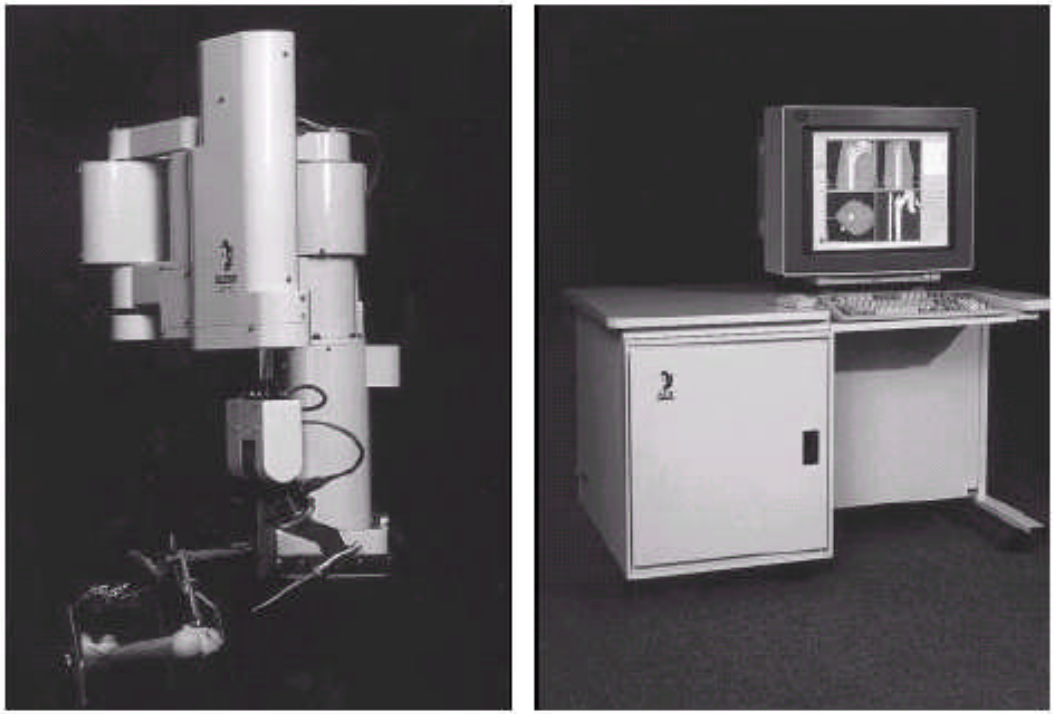

Figure 2 ROBODOC and ORTHODOC computer workstation.
(ROBODOC [left], ORTHODOC [right])

From Pransky(25)

Figure 3 The ACROBOT system

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