Title:

A Prospective Cohort Study Comparing the Accuracy Of Component Positioning And Restoration Of Hip Biomechanics In Conventional Versus Robotic-arm Assisted Total Hip Arthroplasty

Authors:

Babar Kayani, Sujith Konan, Ahmed Magan, Fares S Haddad

Disclosures:

Nil

Abstract:

Objectives:

The primary objective of this study was to compare accuracy in restoring the native centre of hip rotation in patients undergoing conventional manual THA versus robotic-arm assisted THA. Secondary objectives were to determine differences between these treatment techniques for THA in achieving the planned combined offset, cup inclination, cup version, and leg-length correction.

Methods:

This prospective cohort study included 50 patients undergoing conventional manual THA and 25 patients receiving robotic-arm assisted THA. All operative procedures were undertaken by a single surgeon using the posterior approach. Two independent blinded observers recoded all radiological outcomes of interest using plain radiographs. Patients in both treatment groups were well-matched for age, gender, body mass index, laterality of surgery, and ASA scores.

Results:

Correlation coefficient was 0.92 (95% CI: 0.84 - 0.95) for intra-observer agreement and 0.88 (95% CI: 0.82-0.94) for inter-observer agreement in all study outcomes. Robotic THA was associated with improved accuracy in restoring the native horizontal ($p<0.001$) and vertical ($p<0.001$) centres of rotation, and improved preservation of the patient's native combined offset ($P<0.001$) compared to conventional THA. Robotic THA improved accuracy in positioning of the acetabular cup within the combined safe zones of inclination and anteversion described by Lewinnek et al ($p=0.02$) and Callanan et al ($p=0.01$) compared to conventional THA. There was no difference between the two treatment groups in achieving the planned leg-length correction ($p=0.10$).

Conclusion:

Robotic-arm assisted THA was associated with improved accuracy in restoring the native centre of rotation, better preservation of the combined offset, and more precise acetabular cup positioning within the safe zones of inclination and anteversion compared to conventional manual THA.

Clinical relevance:

Robotic-arm assisted THA enables improved preservation of native hip biomechanics compared to conventional manual THA.

Introduction:

Total hip arthroplasty (THA) is a highly successful surgical procedure that is performed in over 90,000 patients in England and Wales each year [1]. The procedure has well established middle- to long-term clinical outcomes and implant survivorship is greater than 90% at minimum of 10 years follow-up [2]. Accurate implant positioning and restoration of native hip biomechanics in THA are important technical objectives that affect residual acetabular bone stock, abductor function, joint stability, soft tissue injury, impingement, bearing surface wear, and long-term implant survival [3-9]. In conventional THA, the surgeon uses preoperative radiographic templating, surgical alignment guides, and intraoperative anatomical landmarks to guide acetabular reaming and implant positioning. However, this manual technique is highly dependent on surgical experience [10] with 38-47% of acetabular implants being inserted outside of the desired ranges for cup inclination and cup version with conventional THA [10-13]. Suboptimal implant positioning outside of these safe ranges may increase hip instability, accelerate wear of the acetabular surface, and reduce implant survivorship [4,8-10].

Evolution in surgical technology has led to the development of robotic-arm assisted THA. This technique uses a preoperative CT scan of the pelvis and proximal femur to create a patient-specific computer-aided design (CAD) model for surgical planning. The surgeon is able to use this CAD model to virtually select the implant size and positioning to achieve the desired bone coverage, centre of rotation, cup version, cup inclination, femoral offset, and leg-length correction [14,15]. An intraoperative robotic arm guides acetabular reaming through a planned haptic tunnel to preserve acetabular bone stock and then guides acetabular cup positioning to execute the preoperative plan to a high degree of accuracy [15]. Preliminary cadaveric studies and clinical trials have shown robotic THA may help to reduce manual errors in implant positioning and improve short-term functional outcomes compared to conventional THA [14-17].

Optimising clinical outcomes, functional results, and long-term implant survivorship in THA is dependent on a complex triad of interactions between the patient, surgeon, and implant. Robotic-arm assisted surgery influences all three variables independently and produces a complex three-way interaction effect that determines accuracy in achieving the preoperative plan and restoring native hip biomechanics in THA [16,17]. The primary objective of this study was to compare accuracy in restoring the native centre of hip rotation between patients undergoing conventional manual THA versus robotic-arm assisted THA. Secondary objectives were to determine differences between these treatment techniques for THA in achieving the planned combined offset, cup inclination, cup version, and leg-length correction.

Methods:

Patient selection:

This study included 75 patients with symptomatic hip osteoarthritis undergoing primary THA between September 2016 and January 2018. This included 50 patients undergoing conventional manual THA and 25 patients receiving robotic-arm assisted THA. Patients were allocated to their respective treatment groups based on availability of the robotic device within the hospital on the day of surgery. All operative procedures were performed by the senior author who is a high-volume arthroplasty surgeon with extensive experience in conventional manual THA and previous cadaveric training on robotic-arm assisted THA. The robotic group was the first cohort of patients to undergo robotic-arm assisted THA by the operating surgeon. All surgical procedures were performed using the ~~minimally-invasive~~ posterior approach in the lateral decubitus position under general anaesthetic. Informed consent was obtained from all study patients. Institutional review board approval was obtained prior to commencement of the study.

Inclusion criteria:

Inclusion criteria for this study included the following: diagnosis of primary osteoarthritis or secondary osteoarthritis secondary to osteonecrosis or rheumatoid arthritis; patient undergoing primary THA; patient between 18-80 years of age; and patient suitable to have the planned study implants. Exclusion criteria included the following: patients in whom the planned hip biomechanics were in a different position to the contralateral side (E.g. developmental dysplasia of the hip or protrusio acetabuli); patient required revision surgery following previously failed THA; patient under 18 years or over 80 years of age; patient was immobile or had other neurological condition affecting musculoskeletal function; and patient not suitable to have the planned study implants (E.g. patient required dual mobility cup or cemented implants). Patients undergoing conventional manual THA and robotic-arm assisted THA were well matched for baseline demographic characteristics (table 1).

Preoperative imaging and templating:

All study patients underwent routine preoperative standing pelvic radiographs and CT scan of the pelvis and proximal femur. In both treatment groups, preoperative templating was performed using both imaging modalities by the operating surgeon to guide femoral osteotomy site, implant size, implant position, and leg-length correction. Preoperative templating on the plain anteroposterior pelvic radiograph was performed using Traumacad software (Traumacad, Petach-Tikva, Israel). In all study patients, preoperative CT scans were loaded into a software programme (MAKOplasty® total hip application; Mako surgical corporation, Kalamazoo, MI, USA) to create patient-specific CAD models. Preoperative templating was performed to restore the native centre of rotation and combined offset to that of the contralateral side. Planned acetabular cup inclination was 40 degrees and anteversion was 20 degrees in both treatments groups. In all study patients, preoperative templating was performed to fully correct for any pre-existing leg-length discrepancy.

Surgical technique:

Conventional manual THA was performed using the standard handheld reaming technique with manual implantation of the acetabular cup. Implant position was guided by both preoperative templating and intraoperative anatomical landmarks. Sequentially larger acetabular reamers were used to remove residual cartilage until the ~~true floor~~ desired acetabular depth was reached and the underlying subchondral acetabular bone exposed. The transverse acetabular ligament, anterior and posterior acetabular walls, and sciatic notch were used as fixed intraoperative anatomical landmarks to guide final anteversion of the acetabular component. An external alignment guide was attached to the cutting-edge reamer handle to ensure accurate cup version and alignment and confirm position within 40 ± 10 degrees of abduction and 15 ± 10 degrees of anteversion.

Robotic-arm assisted THA used the RIO robotic arm interactive orthopaedic system (Mako surgical, Kalamazoo, MI, USA) to guide acetabular bone reaming and acetabular implant positioning. Three reference pins were inserted into the iliac crest for attachment of the fixed pelvic array. Checkpoints were inserted just superior to the posterior-superior acetabular rim and greater trochanter, and a fixed ECG lead attached to the patella tendon of the operated leg for intraoperative assessment of leg-length inequality. The position of the pelvis was confirmed by registering and verifying the position of patient-specific anatomical landmarks displayed onscreen. Intraoperative measurements in the coronal plane as described by Murray et al [18] were displayed throughout the procedure. A surgeon-controlled robotic arm was used to guide acetabular bone resection within the boundaries of the haptic tunnel and control final cup position to within 3 degrees of the preoperative plan. No further adjustments to the position of the acetabular cup were performed.

Patients in both treatment groups received the Accolade II femoral stem (Stryker, Mahwah, NJ, USA) and trident acetabular shell (Stryker, Mahwah, NJ, USA). In both treatment groups, the femur was prepared manually. Hip stability was tested through the full range of movement and leg-length discrepancy checked clinically before selection and insertion of final femoral stem and head sizes.

Study outcomes:

All study outcomes were recorded by two independent fellowship-trained surgeons that were blinded to the treatment group and to each other's findings. Radiological outcomes were recorded using standing anteroposterior pelvic radiographs at 6 weeks after surgery. Measurements were recorded twice by each observer at 28 days apart to assess for intra-observer agreement. Magnification was corrected on postoperative radiographs using the implanted acetabular cup size as the reference value. The postoperative radiograph was used to calculate the contralateral femoral head size and this was used as the reference for correcting magnification on the preoperative radiograph. Accuracy in achieving the planned centres of horizontal and vertical rotation were assessed using the method described by Meermans et al [19] [Figure 1]. Outliers were defined as displacement of the horizontal centre of rotation more than 5mm medially or by displacement of the vertical centre of rotation by more than 3mm superiorly [3]. Acetabular cup inclination ~~and version were~~ was calculated using the method described by Murray et al [18] and cup version assessed using a cross-table lateral radiograph using the technique described by Woo et al [30]. Combined offset was calculated by summating the value of the acetabular offset and femoral offset as described by Flecher et al [20]. Leg-length discrepancy was calculated with plain anteroposterior pelvic radiographs using the technique described by Woolson et al [21]. This technique compares the distances from the vertex of the lesser trochanters to a line transecting through the inferior aspect of the acetabular teardrops on each side. Accuracy of the Traumacad system for measuring radiological parameters has previously been reported [28,29].

Sample size calculation:

The primary outcome measure was set as accuracy in restoration of the native horizontal centre of rotation, which affects the postoperative abductor lever arm, polyethylene wear and long-term implant survivorship [4,5]. In a previous cadaveric study, root mean square error in restoring the planned horizontal centre of rotation in conventional THA was 2.0 mm (error range; -1.6 to 3.1 mm) and 1.5 mm (error range; -3.2 to 0.9 mm) in robotic-arm assisted THA [15]. The minimally clinically important difference in this study was set at 5 mm [3]. Assuming similar errors values for accuracy in restoring the horizontal native centre of rotation in this study and using a superiority design, 72 patients were required to detect a minimal clinically important difference with a power of 90% and alpha value of 0.5. To account for 5% rate of sample size attrition at 6 weeks follow-up, a total of 75 patients were recruited into the study.

Statistical analysis:

Statistical analysis for inter- and intra-observer agreement on all study outcomes were performed using the intraclass correlation coefficient test for absolute agreement using the 2-way random effects model. Independent t-tests were used to compare demographic characteristics and study outcomes found to be normally distributed, whilst the Mann-Whitney U test was used for continuous outcomes found not to be normally distributed. Categorical outcomes were compared using Fisher's exact test. Statistical significance was set at $p < 0.05$ for all analyses and all statistical analysis was performed using SPSS software version 24 (SPSS Inc., Chicago, IL).

Results:

~~Interclass~~ Correlation coefficient was 0.92 (95% CI: 0.84 - 0.95) for intra-observer agreement and 0.88 (95% CI: 0.82-0.94) for inter-observer agreement in all study outcomes suggesting good agreement between the two independent observers in the outcomes recorded. Patients in both groups were well matched for the planned centres of hip rotation, combined offset, and leg-discrepancy correction (table 2).

Robotic THA was associated with improved restoration of the native horizontal ($p<0.001$) and vertical ($p<0.001$) centres of rotation compared to conventional THA (Table 3). Robotic THA had reduced outliers from both the predefined horizontal (4% vs 28%, $p<0.001$) and vertical (4% vs 20%, $p<0.001$) centres of rotation. Accuracy in achieving the combined offset was improved in patients undergoing robotic THA compared to conventional THA ($p<0.001$) (table 3).

Robotic THA was associated with improved accuracy of cup positioning within the combined safe zones of inclination and anteversion described by Lewinnek et al ($p=0.02$) and Callanan et al ($p=0.01$) compared to conventional THA (figure 2-5). Robotic and conventional THA groups were well-matched for preoperative leg-length discrepancy ($p=0.91$). There was no difference between the two treatment groups in achieving the planned leg-length correction ($p=0.10$) (table 3). No complications were reported in either treatment group within the 6 weeks postoperative follow-up period.

Discussion:

This study showed that robotic-arm assisted THA was associated with improved accuracy in reproducing the planned centre of rotation, better restoration of the native combined offset, and improved precision of cup positioning within the combined safe zones of Lewinnek et al and Callanan et al compared to conventional manual THA. There was no difference between the two treatment techniques for achieving the planned correction to any pre-existing leg-length inequality.

Improved accuracy in reproducing the patient's native centre of restoration and combined offset in the robotic group are important findings as previous studies have shown that these are associated with better preservation of acetabular bone stock, improved abductor lever arm function, enhanced patient reported outcome scores, and longer implant survival in THA [3-9]. In robotic THA, surgeon-controlled errors in achieving these technical objectives are reduced as acetabular bone reaming is confined to the boundaries of the haptic tunnel and final acetabular cup positioning is guided by the robotic arm [22]. Our findings are consistent with Nawabi et al who performed a cadaveric study with 12 conventional THAs on one side and 12 robotic THAs on the contralateral side, and found reduced root mean square errors in achieving the planned horizontal and vertical centres of rotation in the robotic group [15]. Kanwande et al reviewed outcomes in 27 patients undergoing robotic THA and showed accurate restoration of the horizontal and vertical centres of rotation were achieved in 81.5% of cases [14]. The authors reported that the centre of rotation was shifted superiorly by a mean of 0.9 ± 4.2 mm and medially by 2.7 ± 2.9 medially, which are similar to the findings of the robotic group in this study.

Adverse outcomes have been reported in patients in which the centre of rotation is displaced superiorly by greater than 3mm or medially by greater than 5mm [3]. Robotic-arm assisted surgery helped to reduce these outliers, which may clinically help to better preserve abductor muscle function, improve the gait cycle, and decrease the long-term risk of aseptic loosening compared to conventional THA [6,7]. Lachiewicz et al followed 83 patients with juvenile rheumatoid arthritis undergoing cemented THA and found medial or superior displacement of the centre of rotation by greater than 5 mm was associated with progressive radiolucencies and acetabular migration [8]. Karcachilios et al reviewed outcomes in 95 THAs and found that displacement in the centre of rotation greater than 2mm increased the risk of acetabular loosening at 12-18 years of follow-up [9]. Robotic-arm assisted surgery to improve the accuracy of acetabular bone reaming and cup positioning to restore the native centre of rotation may also reduce the need for intraoperative adjustments such as an extended offset head to lateralise the centre of rotation. This may lead to eccentric loading patterns, greater torsional forces at the liner-shell and bone-implant interface, and increased risk of aseptic acetabular implant loosening [23]. Importantly, our study showed improved accuracy in restoration of the native centre of restoration and combined offset in the robotic THA group but it is unknown how these will translate to differences between the two groups in relation to functional recovery, clinical outcomes, and long-term implant survivorship.

Dislocation is the primary indication for revision THA and accounts for 33% of all acetabular cup revisions [24,25]. Many surgeons use “safe zones” to guide acetabular cup inclination and version to improve the accuracy of cup positioning and reduce the risk of dislocation. The most commonly adopted safe zones are those of Lewinnek et al (inclination 30°–50°; anteversion 5°–25°) [26] and Callanan et al (inclination 30°–45°; anteversion 5°–25°) [10]. However, intraoperative identification of these safe zones within the three-dimensional configuration of the pelvis is challenging owing to pelvic tilt, hip flexion contractures, obesity, and distorted anatomy from the disease process [11]. Surgeons undertaking conventional THA use preoperative radiological templating, intraoperative anatomical landmarks, and alignments guides but these have varying degrees of accuracy and reproducibility [11], which may lead to inadvertent manual cup positioning outside of the planned safe zones [10,11,13]. In robotic-arm assisted THA, preoperative CT scan and patient-specific CAD model of the pelvis and proximal femur are used to identify specific anatomical points that enable the software to determine the intraoperative position of the patient. This software uses the patient’s anterior/posterior pelvic tilt in the supine position during CT scan to account for the pelvic tilt. All acetabular cup positioning angles are on the functional (coronal) plane of Murray, which is more accurate than the anatomical plane. Intraoperative bone registration enables the surgeon to intraoperatively confirm the acetabular bony anatomy of the CT scan prior to acetabular reaming and cup positioning [22]. This may have helped to improve accuracy of precision within the safe zones of Lewinnek et al and Callanan et al observed within the robotic group in this study.

Our findings are consistent with those of Domb et al who found that cup positioning within Lewinnek’s safe zone was achieved in 50/50 (100%) robotic THAs compared to 40/50 (80%) conventional THAs (p=0.001) [16]. The authors also reported that cup positioning within Callanan’s safe zone was achieved in 46/50 (92%) robotic THAs but only 31/50 (62%) conventional THAs (p=0.001). Illgen et al conducted a retrospective study on three groups of patients undergoing THA by one surgeon, and found implant positioning within Lewinnek's safe zones in 30% of the first 100 consecutive conventional THAs, 45% of the next 100 consecutive conventional THAs, and 77% in the first 100 consecutive robotic THAs (P<0.001) [17]. The authors reported robotic THA was associated with an additional 71% improvement in accuracy of acetabular implant positioning compared to manual THA in the first year of use (p<0.001). In our study, robotic-arm assisted THA was performed with intraoperative referencing to confirm acetabular cup inclination of 40 degrees and anteversion of 20 degrees. Despite this, there was a range of values achieved for both acetabular cup inclination and version in the robotic group, which likely reflects the limitations of recording these outcome measures on plain radiographs compared to CT scans.

Patient-specific rotation of the pelvis in the sagittal plane may also change the functional orientation of the acetabulum during activities of daily living [31]. Generalised safe zones for implant positioning may therefore not provide optimal stability in all patients. Preoperative simulation analysis has recently gained momentum as an avenue for assessing the relationship of the spine, pelvis, and femur through a range of exercises, which enables patient-specific safe zones to be established. Robotic technology may offer an avenue for surgeons to execute these individualised preoperative plans with greater precision than conventional manual techniques."

In this study, there was no difference between the two treatment groups in accuracy of correcting any pre-existing leg-length discrepancy but these results should be interpreted with caution. Firstly, conventional THA showed a much larger range in postoperative leg-length discrepancies than robotic THA suggesting that robotic technology led to more reliable and controlled corrections than conventional THA. Secondly, the operating surgeon is a high-volume arthroplasty surgeon who performs several intraoperative clinical tests and trials with various implant sizes to assess leg-length discrepancy before definitive implantation. Thus, the accuracy with the conventional technique for this surgeon may not be transferrable to other surgeons with less experience. Overall, both techniques were effective at restoring leg-length discrepancy to within acceptable limits and any observed differences are likely to be subclinical [27].

The main strengths of this study were that this was a single surgeon study assessing a comprehensive range of radiological parameters that affect clinical outcomes and implant survivorship. Outcomes were recorded by blinded observers using standardised techniques with high inter-observer agreement on all outcomes. However, there are also are several limitations that need to be considered when interpreting the findings of this study. Firstly, radiological analyses were performed using plain radiographs, which may have led to inaccuracies in data collection and increased scatter in the study outcomes recorded. Postoperative CT scan would have enabled more accurate assessment of radiological outcomes. Secondly, robotic technology was not used to guide femoral preparation or stem insertion, which may have affected the observed study outcomes in the robotic group. Thirdly, changes in hip biomechanics were not correlated to clinical and functional outcomes in study patients. Fourthly, this study included a relatively small sample size of patients undergoing robotic THA that may have increased the risk of type 2 error.

Conclusion:

Robotic-arm assisted THA was associated with improved accuracy in restoring the native centre of rotation, better preservation of the combined offset, and improved precision in achieving cup positioning within the combined safe zones of Lewinnek et al and Callanan et al. These outcomes are established technical objectives for optimising clinical outcomes and increasing implant survivorship in THA. There was no difference between conventional manual THA and robotic-arm assisted THA for achieving the planned leg-length correction.

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