Information for Surgeons on Assistive Technologies in Hip Arthroplasty

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INTRODUCTION

Despite total hip arthroplasty being hailed as the operation of the last century there may still be room for improvement![1] Complications such as dislocation and leg length discrepancy still affect patients and approximately 5% are dissatisfied with their outcomes. The use of robotic assisted arthroplasty surgery has increased over the last decade, mainly in knee arthroplasty but has now established a platform in hip arthroplasty. Robotic assisted surgery builds on the principles of computer navigation but is less reliant on the surgeon's accuracy for bone preparation and reaming. It differentiates itself by using a variety of control mechanisms which should deliver an increased level of precision and accuracy, providing alignment and placement of the prostheses depending on the system used.[2]

There are broadly three types of robots available: passive, semi-active and active. Passive robotic assistance is a system where alignment of the cutting jig is assisted but the bone cut is independent from the robot. A semiactive or semi-autonomous system is one where the robot aligns and controls the saw, but requires the surgeon to hold and initiate the saw cut. A fully active or autonomous system is one that does not require any input from the surgeon to perform the bone cuts. The latter two systems usually work within a defined haptic boundary, an area beyond which the system will not cut/ream or will shut down when the cutting device reaches this limit.

Robotic systems also vary in their modelling of the patient's limb with some using image-based techniques (plain radiographs, CT or MRI) whilst others are imageless and rely on surface mapping techniques, similar to most navigation systems, with intraoperative identification of landmarks. Image based technology requires preoperative imaging of the lower limb to aid preoperative planning and provisional implant alignment. The model created is then verified intraoperatively during registration of multiple predefined anatomical landmarks.

The majority of the current evidence for robotic assisted surgery is on the Stryker MAKO robot, which has been in clinical use for hip arthroplasty since 2010 with subsequent Food and Drug Administration (FDA) approval in 2015.[3] This is a semi active system with haptic boundaries and uses CT images to plan surgery, aid optimal version, offset (restoration of the hip centre) and inclination of the acetabular component. This system has been shown to be associated with improved component positioning and improved patient reported outcomes, but it is not clear whether this improvement is clinically significant to the patient, generally being less than the minimal clinically important difference (MCID).[4] The learning curve of the MAKO system in terms of achieving accurate implant positioning is zero, meaning the first is a good as the last, and 12 to 35 cases for achieving steady state theatre time and staff confidence.[4]

There are potential drawbacks to robotic assisted surgery within a public health system like the NHS in the United Kingdom (UK). The increased cost may be difficult to justify with no level one evidence for a clinically significant difference in outcomes.[4] The cost of each robotic system varies but can be considerable.[5] In addition, there is the cost and capacity for imaging, for those using image-based navigation. There are also intraoperative consumable packs for drapes and pins, which can vary from £500 to £1,000. Furthermore, there is an increase in theatre time to set up the system and perform the registration when compared to conventional manual surgery. Cost utility studies assessing the cost effeteness of robotic THA are limited especially in the UK healthcare system.[5] Early non-randomised data wound suggest units performing more than 50 cases per year were cost effective at 10 years follow up, due to the increased health related quality of life gain associated with robotic THA.[5] Cost effectiveness is currently being evaluated in the UK with the RACER2 study which will assess not only whether there is a clinically significant improvement in patient reported outcomes, but also whether this specific robotic technology is cost effective.[6] RACER is a NIHR funded multicentre, randomised control trial comparing MAKO robotic arm assisted surgery versus manual THA and is likely to complete recruitment in 2024.

The precision of implant alignment offered by robotic assisted surgery coupled with the opportunity to accurately size, adjust implant position and analyse soft tissue balance has enabled a reconsideration of what constitutes optimal implant alignment. The traditional concept of medialisation of the acetabular component and increasing femoral offset is now being challenged, with the ultimate aim to restore hip centre, offset, version and leg length.[7]

Historically, predefined “safe” zones of acetabular component orientation have been used (Lewinnek and Callanan) to guide cup positioning. Notwithstanding this, there has been an evolution of ideas beyond these descriptions, primarily driven by reports that most dislocations occur within the perceived “safe zones”.[8] It is therefore of paramount importance for the arthroplasty surgeon to acquire a comprehensive understanding of the spine-pelvis-hip axis and the clinical implications. The most prevalent method to ascertain spinopelvic stiffness is the change in sacral slope from sitting to standing (delta SS), with a delta SS < 10 indicating a stiff spinopelvic construct.[7] It has recently been suggested that measuring the delta SS from a flexed seated position rather than relaxed seated to standing may represent a more accurate and reproducible method.[9] Other key parameters the arthroplasty surgeon should comprehend, and measure are the Pelvic Incidence, Pelvic Tilt, Combined Anteversion and Lumbar Lordotic Angle.[7]

Two classification systems that provide guidance in relation to acetabular cup positioning based on the individual spinopelvic motion have been described by Stefl et al[10] (normal mobility or hypermobile, stuck sitting, stuck standing and kyphotic) and Vigdorchik et al[11] (1A––normal spinal alignment and normal mobility, 1B––normal spinal alignment and stiffness of the spinopelvic construct, 2A––flatback deformity and normal mobility, and 2B––flatback deformity and stiffness of the spinopelvic construct). “Stuck standing” patients are at risk of posterior instability and the arthroplasty surgeon should consider increasing the offset, and/or inclination and anteversion. Conversely “stuck sitting” patients are at risk of anterior dislocation and removal of posterior osteophytes, decreasing cup anteversion or anteversion and increasing femoral offset should be considered.

Accurate pre-operative planning and execution lies at the core of applying the principles of functional implant positioning and in this vein, robotic THA can have a pivotal role. The latest version of the most widely used software (MAKO 4.0) includes a virtual range of motion (vROM) tool, enabling pre-operative and intra-operative feedback regarding impingement and the effect of changes in component positioning. It remains to be seen whether functional component positioning translates to better outcomes, reduced complications (dislocations) and improved implant survival.

It is important to remember that these new technologies are instrument platforms that open up new alignment possibilities due to the higher degree of precision and enabling surgical workflows, but the outcome and success of each of these surgical philosophies should be assessed separately from the delivery system or assisted technology itself. With the increased precision and reproducibility of hip arthroplasty surgery however, robotic systems have the potential to allow us to identify the optimal alignment/orientation of the implant to improve the outcomes of our patients.

THE EVIDENCE FOR ROBOTIC ARM-ASSISTED HIP ARTHROPLASTY

Robotic assisted surgery hip arthroplasty

Knowns

- Improves precision of component positioning
- Has a short learning curve
- Associated with improved patient reported outcomes but whether these are clinically meaningful remains to be established

Unknowns

- Whether it offers clinically significant functional benefits
- Optimal component positioning tailored to the individual spinopelvic mobility.
- Survival advantage of robotic assisted THA over manual
- The cost-effectiveness in a National Health Care system

In a recent meta-analysis of studies comparing semi-active Robotic Arm-assisted THA versus manual THA, authors identified 17 studies that satisfied the inclusion criteria and reported the learning curve of robotic surgery (n=4), component positioning accuracy (n=13), functional outcomes (n=5), complications (n=10) or implant survival (n=4).[4]

- Four studies reported the learning curve, out of which two utilised CUSUM analysis to establish an inflexion point for proficiency. This ranged from 12 to 14 cases in terms of surgical time and staff confidence. However, optimisation of the surgical workflow was reported to continue up to the first 35 cases.
- There was consistent evidence that robotic THA resulted in a significantly greater percentage of acetabular component positioned within the safe zones: between 77% and 100% of acetabular components were within Lewinnek's safe zone as compared to 30% to 82% with manual THA. When applying the stricter Callanan's zone, 75% to 94% of robotic THAs were within the safe zone compared to 36% to 94% when using manual THA. Quantitive synthesis of the data revealed a significantly greater number of cases of acetabular component placements in the safe zones compared with the manual THA group [Odds ratio 5.71 (95% CI 4.10 to 7.94); $p < 0.001$].

- There was conflicting evidence whether robotic assisted THA resulted in better functional outcomes when compared to manual THA. Three studies reported differences in postoperative functional scores between robotic versus manual THA. Domb et al[12] demonstrated a statistically significant difference in Harris hip score, Forgotten Joint Score, Veterans RAND 12-Item Health Survey (VR-12), and 12-Item Short Form Survey (SF-12) score between robotic and manual THA. Bukowski et al[13] also reported that robotic THA resulted in significantly better Harris hip scores and UCLA scores but no significant difference in SF-12 or WOMAC scores. Meta-analysis of functional outcome data from four of these studies with the exclusion of one study, demonstrated robotic THA resulted in a significantly better Harris hip score compared to manual THA in the short- to mid-term follow-up (difference 3.05 (95% CI 0.46 to 5.64); p = 0.020). Notwithstanding this, the above difference does not exceed the MCID, hence the clinical benefit is not clear.
- Importantly there was no difference in leg length discrepancy, superficial and deep infection, wound dehiscence, or overall complication rates, but there was a trend [OR 0.61 (95% CI 0.30 to 1.24)] towards a lower overall complication rate associated with robotic surgery at short-term follow up.

In summary, robotic arm-assisted THA demonstrated improved accuracy of component positioning and patient-reported outcomes. The learning curve of RATHA for operating time was between 12 and 35 cases. Future well-powered studies comparing robotic and manual THA should report on the implant alignment/offset and balancing techniques utilised to enable better comparisons on which techniques maximise patient outcomes.

The caveat for the literature quoted above is that studies may be system specific, and the results cannot be extrapolated among different systems. This could potentially make generalisation about the overall benefit of robotic assisted technology difficult.

CURRENT STUDIES ON ASSISTIVE TECHNOLOGIES:

The HELLO study: the primary outcome is to assess surgical complications (Bournemouth).
Conventional THA versus MAKO robotic arm assisted THA: The primary aim is to assess the reproducibility of the planned pre-operative centre of rotation of the hip joint (UCL Hospitals NHS Foundation trust, London).
Multi-centre pragmatic trial (RACER2: NIHR HTA, Warwick / Birmingham).

SUMMARY

In summary, early data for robotic assisted THA surgery is promising but does not support the routine use of robotics for all patients at the current time. In the spirit of responsible innovation, it is essential that we continue to collect data on surgical outcomes of using new technologies to allow comparison with existing standards of care. It is also essential, specifically for hip surgery, that the target alignment, offset and version philosophy employed are recorded. This will enable a comprehensive assessment of implant positioning targets and the robotic technology. Finally, patients undergoing surgery with new technologies should be consented appropriately. The framework below may be of benefit in this regard.

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THE EVIDENCE FOR ROBOTIC ARM-ASSISTED HIP ARTHROPLASTY

Theme	Sub-theme Discussion before surgery	Sub-theme Discussion after surgery
1. New procedure details	1.1 Statement that the procedure/device is new 1.2 Details about what makes the procedure/device new	
2. Conflict of interest	2.1 Statement of any relevant conflict of interests	
3. Reasons for the innovation	3.1 Expected benefits, risks and/or consequences of the new procedure/device 3.2 Reasons why the new procedure/device is believed to be appropriate for the patient	3.1 Actual benefits, harms and/or consequences experienced 3.2 Changes to which types of future patients the new procedure/device is suitable resulting from the benefits, harms and/or consequences experienced
4. Choice of treatment alternatives	4.1 Existence/availability of treatment alternatives 4.2 Freedom to choose the new procedure/device or alternative care	
5. Unknowns	5.1 Statement that there are unknowns about the new procedure/device in the context of relevant evidence 5.2 Possibility that the new procedure/device may be modified, stopped or changed to an alternative	5.2 Actual modifications to the new procedure/device, or explanation of why it was stopped or changed to an alternative 5.3 Unexpected benefits, harms and/or consequences
6. Expertise with the innovation	6.1 Statement that the surgeons' level of skill in the new procedure/device may not be the same as standard care 6.2 Description of surgeons' level of skill in the new procedure/device	
7. Governance, oversight & accountability	7.1 Relevant approvals in place for the introduction of the new procedure/device in the context of national and/or international regulatory guidance 7.2 Details of how patient safety is monitored 7.3 Relevant processes in place if anything goes wrong	