Development of new Robotic MSK surgical service within the NHS

A Best Practice Guide

British Orthopaedic Association

Royal College of Surgeons of England

THE ROYAL COLLEGE OF SURGEONS OF EDINBURGH

PREFACE

This guidance document has been developed by the RCS MSK RADAR Working Group on behalf of the BOA.

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INTRODUCTION

The utilisation of robotic-assisted surgery in Trauma and Orthopaedics is growing across the United Kingdom (UK) with multiple centres putting forward business cases to develop new robotic surgical programmes. For these centres, surgical teams will be embarking on robotic-assisted orthopaedic surgery for the first time within their NHS trusts and health boards. As with the introduction of any new surgical procedure, patient safety is paramount, and it is essential that individual hospitals have robust local protocols to enable the safe adoption of robotic-assisted surgery. Many NHS trusts will already have had experience with other surgical specialty robots, such as the DaVinci surgical system. This experience may have precipitated positive or negative perceptions around the financial and logistical implications involved. These will need to be addressed to enable a smooth introduction of MSK robotic surgery as it poses less operating environment and pathway disruption.

The Royal College of Surgeons of England (RCSEng) has established the Robotic And Digital Assisted suRgery (RADAR) advisory group to consider the benefits and issues around the implementation of robotic-assisted surgery in the UK. This includes the development of this guidance document to provide a practical tool kit for individual hospitals when setting up a new MSK robotic surgical service. Literature concerning the general implementation of robotics into the healthcare system, has highlighted the issues that need to be addressed, such as governance of new technology, surgical training, equity of access and public perception.[1,2] This document aims to provide comprehensive recommendations covering these areas relevant to MSK surgery. It aims to help the multidisciplinary robotic surgical team set-up and develop safe practice, before embarking on clinical cases for the first time. It is important to point out that this guidance document highlights areas of best practice. The responsibility for clinical governance lies with individual NHS trusts and health boards.

SETUP OF ROBOTIC GOVERNANCE AND PEER REVIEW GROUP

Prior to establishing a new robotic service, a governance peer review group should be created. Members should include surgeons, anaesthetists, operating team members (Scrub team, operating department practitioners [ODPs], industry representatives and hospital management). Procurement, radiology, hospital facilities and IT support may also be needed depending on the technology chosen (image-based or image-free robotic systems). This group should develop the business case, standard operating procedure (SOP) and necessary training for all intended users of a specific robotic system. Group membership may need to change among individual robotic systems.

It is recommended that surgeons with experience in computer navigation and/or robotic surgery are involved initially, as there is evidence that this results in flattening of the learning curve.[3] Collectively with the respective robotic vendor specialists, they should provide education and training to allow preparation for the first clinical cases. We highly recommend utilising senior robotic vendor specialists in the early phases of robotic adoption, to allow the surgeon and their team to transition through the learning curve as quickly as possible. It is appreciated robotic specialists are a commodity and cannot be present for all cases, however the orthopaedic surgeon should insist on their presence during the early phases.

Members of the working group from hospital procurement, with clinical input, will need to discuss with the robotic vendor the pricing of any new implants, including any required robot-specific consumables, and these will need to be included in the business case. Early review with the vendor of facilities for storage, pricing and other practical requirements is recommended. Data protection impact assessments and any data transfer processes will also need to be developed and reviewed by trust governance processes, and it is advised to start this process early as it may be time consuming.

EVIDENCE FOR MSK ROBOTIC SURGERY

When creating a business case, you may need the most recent literature as evidence to back your proposal. Other points of discussion can be integrated into the business case including reputational benefits, ability to attract highly skilled consultants as well as trainees and fellows, research opportunities and establishment of the hospital as a tertiary centre, hosting surgical teams. Recent systematic reviews and randomised controlled trials have shown the below potential benefits for MSK robotic surgery:

- Improved patient outcomes[4-8]
- Reduced length of stay [9-13]
- Improved Survivorship in registry data[14]
- Less soft tissue damage[15]
- Improved implant positioning [16,17]
- Reduced dislocation rates[18]
- Less physician stress and strain[19]

This body of evidence can be presented in the business case when discussing patient benefits and potential financial implications.

MODEL FOR ROBOTIC SURGICAL TRAINING

The robotic vendor should organise cadaveric laboratory training for any surgeons wishing to use their technology. This may include a formal accreditation document, either provided by the vendor or the hospital and is essential to providing a safe and efficient adoption. Tips and troubleshooting in the early phase of introducing robotic technology is best undertaken outside a 'live' theatre setting.
The theatre staff will need training on how to set up the robot, the procedural workflow and consumables needed such as disposable drapes, sensors and new trays for the specific kit. Training days for all scrub staff should be organised and simulation of the procedure carried out. This training should cover set up, registration of robot, new devices, robot positioning, troubleshooting workflows and procedures in the event of surgical or medical emergency.

Radiology staff may also need training and a calibration process may be required for relevant imaging equipment. An SOP for requesting, obtaining and uploading imaging should be developed, with input from surgeons, administration staff, radiographers and radiologists, along with any DPIA required. This should also include agreements on reporting obligations. A pertinent consideration is whether reporting of CT utilised for pre-operative planning should be performed, checking for incidental findings or tumours. This is often discussed at a Trust-level and at present there is insufficient evidence in the literature to suggest a particular approach. The potential benefit of discovering sinister pathology should be weighed against the added workload for Radiology and all stakeholders should be involved in decision making.

Robotic-assisted surgery is not currently part of surgical training curricula in the UK but this is being developed. Therefore, trainees' exposure to robotic surgery and its principles is recommended via training organised either by the respective robotic vendors or other professional organisations. This guide will be updated with future courses when available. Technical and non-technical skills are important components for instigating robotic surgery within the NHS. Clear communication with robotic vendor specialists and team working is needed to allow efficient surgical workflow. Many scenarios and decisions on philosophies around implant alignment and functional component positioning[20] can be discussed pre-operatively and could represent a useful teaching tool. Surgical assistants and scrub team need to be aware of robotic camera and sensor positioning and sterility throughout the procedure.

ACQUIRING PROCEDURAL COMPETENCY AND TROUBLESHOOTING

The introduction of any new technology mandates a comprehensive understanding of the risks involved and troubleshooting strategies to prevent potential errors. The learning curve in robotic assisted arthroplasty is not associated with achieving the desired accuracy.[3,6,8] It is linked to acquiring procedural competency and familiarity with the new equipment and technology, streamlining the operation and improving surgical confidence. It is therefore of paramount importance for the surgical team to be proficient with the surgical procedure prior to commencing robotic surgery. Furthermore, troubleshooting and recovery workflows should be in place and can be developed collectively with the industry representatives. Each robotic system will have workflows on how to correct a malfunction in the system or solutions in case the array moves, or re-registration is needed. These documents will need to be studied and available during cases. Should all options fail, albeit rare, there may be a need to convert to manual procedure, with which the arthroplasty surgeon is likely to have extensive experience, owing to contemporary practice and current training curricula. The surgical team should also ensure that conventional instruments and more complex prostheses are available and sterile prior to the commencement of the case. If available, surgeons should initially take the opportunity for dual operating with a colleague experienced in robotics. This will ensure that all necessary steps are taken to protect patient safety.

PROCEDURE SPECIFIC ROBOTIC SURGICAL SKILLS DEVELOPMENT

Surgeons and their teams are encouraged to visit robotic surgery centres of excellence to observe best practice and optimal surgical workflow. Host surgeons will act as preceptors. This is a valuable opportunity for the wider surgical team to observe other elements of robotic surgery such as set-up, positioning, equipment and theatre workflow both between cases and during the case, as well as learning from potential pitfalls, and considering critical safety set-ups that may have evolved. All high volume robotic centres in the UK have learnt greatly from these visits and they are highly recommended for all staff aspiring to adopt robotic surgery.

EMERGENCY SAFETY PROTOCOLS AND STANDARD OPERATING PROCEDURES

Safety protocols to cover medical and/or surgical situations will usually be in place in theatres already but may need updating for robot specific complications before embarking on the first clinical case. Safety protocols should also be in place for robotic equipment failure and steps to be taken in the event of such failure to protect patient safety.

The respective robotic vendors supply specialist technicians as support during cases initially and then some robots allow surgeons to control intra operative machines without support. In the early cases support should be present to help with decision making and troubleshooting until the full team (including surgeon and appropriate theatre staff) are comfortable and sufficiently experienced. We highly recommend asking for senior specialist support from each vendor as this makes the process less stressful and more efficient.

ROBOTIC SURGICAL CHECKLIST

The WHO surgical safety checklist must be followed for robotic-assisted surgery. Further consideration should be given to an intraoperative multidisciplinary checklist designed to detect any adverse intraoperative events. Debrief of the surgical team upon completion of the case will be critical to highlight any potential lessons learnt during each robotic-assisted case and allow reinforcement of good practice. Any adverse event or incident should undergo root cause analysis in accordance with local governance procedures.

GRADUATED APPROACH: SIMPLE CASES FIRST

The surgical team should plan to do straightforward cases initially, on the least comorbid patients (e.g., ASA I-II, low BMI), to take pressure off the list and give the best chance of being completed successfully and safely in a timely fashion. It should be possible to introduce robotic cases without losing productivity, i.e. still maintaining a 4-joint list, if this is routine with conventional cases. This should form part of the structured development plan for the robotic surgical teams with the recognition that the initial training and implementation phase may entail additional time and costs. Surgeons with navigation and robotic experience can be invaluable in this early phase of development. Research has shown that the learning curve is low with robotic surgery however (6 to 12 cases in knee replacement surgery[3,4,21] and 12 to 35 in total hip replacement procedures[22]).

CONSENTING PATIENTS

Patients should be counselled appropriately, with a full informed consent process, as per any other surgical procedure. Patients should be informed that robotic assistance will be used, and what this involves for a given system, including the perceived advantages and disadvantages over conventional techniques, including any relevant evidence, as appropriate.
Should an image-based robotic system be used, the patient should be informed about the need for CT and additional radiation. However, in some centres, CT scans are routinely performed prior to elective conventional arthroplasty to aid with surgical planning and accurately delineating the individual anatomy.[23]

Verbal, written and web-based resources (robotic vendor sites, YouTube) can be used to help explain that the robotic arm is a tool used and controlled by the surgeon, rather than the robot being autonomous. Some patients can be apprehensive if this is not explained fully, and time should be provided to answer any additional questions. The focus should be on the patient, and you need to elicit the views and attitudes towards potential robotic surgery, which vary widely between individuals.

The surgeon will need to disclose their experience with the robotic system, whether a new or unfamiliar implant is required, and the available evidence base. The surgeon must give full disclosure of how many cases have been performed and where the surgical team is on their learning curve and the experience with conventional techniques in case they need to convert to the conventional approach. They should highlight the slight differences in procedure risks with different incisions for pin sites and higher fracture risk due to pins[24]. The surgeon's and patients' preference will need to be discussed as over time the demand may shift and all positive and negative aspects should be discussed as part of an informed consent. Rare but catastrophic sequelae must not be omitted.

MAINTENANCE OF ROBOTIC SURGICAL PRACTICE & AUDIT OF CLINICAL OUTCOME PLUS FUTURE RESEARCH

For a trained robotic surgeon to maintain good clinical outcomes, they will need to maintain an adequate volume of robotic-assisted cases annually with audit of activity and outcomes.

Prospective audit of the robotic surgical cases and their outcomes should be used to benchmark outcomes, identify and highlight any potential problems and learning points. The National Joint Registry dataset does not collect sufficient outcome data for safe governance of new robotic systems and additional data collection is recommended.

Recent work has been performed looking at how best to record the effect robotic technology will have on NHS practice. The consensus meeting for the RoboCOS study[25] in the UK led to the agreement of a 10-item core outcome set including:

- Patient Level
  - o Treatment effectiveness
  - o Overall quality of life
  - o Disease-specific quality of life
  - o Complications (Including mortality)

- Surgeon Level
  - o Precision/accuracy
  - o Visualisation

- Organisation
  - o Equipment failure
  - o Standardisation of operative quality
  - o Cost effectiveness

- Population
  - o Equity of access

Robotic systems vary in the data that underlies their safety and clinical effectiveness. The core dataset above is currently recommended for all robotic procedures, but is particularly important for new, emerging or unproven technologies. Small case series alone, especially single centre, are inadequate to identify patient safety risks. These principles have been established in the IDEAL consensus and the introduction of new technologies such as new robotic systems needs to be underwritten by robust clinical data collection.[26] With the ever-growing number of vendors and robotic devices in contemporary orthopaedic practice, it is vital to ensure high-quality evidence is generated for each system individually.

We also recommend recording prospective data from the robot and potentially signing up to available studies (such a RADICAL, ongoing randomised trials or collaborative studies) and using the data collection sheets provided in appendix 1 and 2 for UKA/TKA and THA procedures. Robotic surgery is a valuable tool in the research armamentarium and could lead to the generation of invaluable data within the UK to help answer questions on the best techniques and philosophies for future arthroplasty surgery. Furthermore, such a strategy will ensure an efficient workflow of robotic surgical cases, and lead to a more cost-effective robotic surgical programme.

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