Information for Surgeons on Assistive Technologies in **Knee Arthroplasty**

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INTRODUCTION

Robotic assisted knee arthroplasty surgery has increased over the last decade, building on the principles of computer navigation. It differentiates itself by using a variety of control mechanisms which should deliver an increased level of precision and accuracy, providing either jig placement or actual bone cuts themselves depending on the system used.

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 or will shut down when the cutting blade reaches this limit. The use of haptic control has been shown to result in less soft tissue disruption in total knee replacement surgery.

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, and the model created is then verified intraoperatively during registration of multiple anatomical landmarks.

The majority of the current evidence for robotic assisted surgery is on the Stryker MAKO robot, which has been in clinical usage since 2006. This is a semi active system with a haptic boundary and uses CT images of the hip, knee and ankle to plan knee arthroplasty surgery, with those of the hip and ankle aiding assessment of the mechanical axis. This system has been shown to be associated with improved implant alignment, early pain relief and range of motion. There is a trend towards improved patient reported outcomes, but these may not clinically significant, generally being less than the minimal clinical important difference. 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 seven to 10 cases for achieving steady state theatre time and staff confidence.

There are potential drawbacks to robotic assisted surgery within a public health system like the NHS. The increased cost may be difficult to justify with no level one evidence for a clinically significant difference in outcomes. The cost of each robotic system varies but can be considerable. In addition, there is the cost and capacity for the 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. There have been several cost utility studies suggesting that robotic assisted surgery is cost-effective but whether this increased cost is justifiable in the NHS is unclear at the current time. Cost effectiveness is currently being evaluated in the UK with the RACER and UCLH studies 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. RACER is a NIHR funded multicentre, randomised control trial comparing MAKO robotic arm assisted surgery versus manual total knee arthroplasty and will probably close to recruitment in 2023.

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 mechanical alignment of the knee was influenced by the potential for surgical error with jig based measured resection, coupled with less forgiving implant designs and poorer grade polyethylene meant that an alignment target of +/-3 degrees became the historic standard and compromise. Non mechanical alignment concepts are now more frequently employed with a deliberate strategy to deviate from a Hip Knee Ankle (HKA) of zero, depending on the patient’s preoperative constitutional alignment.

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 knee arthroplasty surgery however, robotic systems have the potential to allow us to identify the optimal alignment strategy.

THE EVIDENCE FOR ROBOTIC ARM-ASSISTED KNEE ARTHROPLASTY

Robotic assisted surgery knee arthroplasty

Knowns
- Improves precision of implant alignment
- Has a short learning curve
- Robotic arm assisted medial unicompartmental knee arthroplasty has a higher early to mid term survivorship compared to manual

Unknowns
- Whether robotics offers clinically significant functional advantage
- The optimal alignment and balance of the knee arthroplasty
- Long term survival advantage of robotic assisted TKA over manual
- Whether new systems which match the outcome of the MAKO system – each will need to be evaluated
- The cost-effectiveness in a National Health Care system

TOTAL KNEE ARTHROPLASTY

In a recent meta-analysis of studies comparing semi-active Robotic Arm-assisted TKA (RATKA) versus manual TKA (mTKA),16 studies satisfied the inclusion criteria and reported the learning curve of RATKA, component positioning accuracy (n=6), alignment and balancing techniques (n=7), functional outcomes (n=7), or complications (n=5).

- Two studies reported the learning curve using CUSUM analysis to establish an inflexion point for proficiency, in terms of surgical time and staff confidence which ranged from 7 to 11 cases and there was no learning curve for component positioning accuracy.

- There was a significantly lower difference between planned component position and implanted component position for robotic surgery, and there was narrower spread for RATKA compared with the mTKA group (Femur coronal: mean 1.31, 95% confidence interval (CI) 1.08–1.55, p<0.00001; Tibia coronal: mean 1.56, 95% CI 1.32–1.81, p<0.00001). Suggesting RATKA is more precise.

- Three studies reported using different alignment and balancing techniques between mTKA and RATKA, two studies used the same technique for both groups and two studies did not state the methods used in their RATKA groups.

- RATKA resulted in better Knee Society Score compared to mTKA in the short-to-mid-term follow up (95%CI − 1.23 to − 0.51, p=0.004), but these differences may not be clinically significant.

- Importantly there was no difference in arthrofibrosis, superficial and deep infection, wound dehiscence, or overall complication rates.

In summary therefore RATKA demonstrated improved accuracy of component positioning and patient-reported outcomes. The learning curve of RATKA for operating time was between 7 and 11 cases. Future well-powered studies on RATKAs however should report on the knee alignment and balancing techniques utilised to enable better comparisons on which techniques maximise patient outcomes.

UNICOMPARTMENTAL KNEE ARTHROPLASTY

In a recent meta-analysis comparing MAKO Robotic Arm-assisted UKA (RAUKA) versus manual UKA (mUKA), 14 articles satisfied the inclusion criteria and were included for analysis. The papers analysed include one on learning curve, five on implant positioning, six on functional outcomes, five on complications, six on survivorship, and three on cost.

- The learning curve was six cases for operating time and zero for precision.

- There was consistent evidence of more precise implant positioning with MAKO RAUKA.

- There was a lower overall complication rates associated with MAKO RAUKA (OR 2.18 (95% confidence interval (CI) 1.06 to 4.49); p = 0.040) but no difference in re-intervention or infection.

- There was however no difference in Knee Society Score (KSS; mean difference 1.64 (95% CI -3.00 to 6.27); p = 0.490), or Western Ontario and McMaster Universities Arthritis Index (WOMAC) score (mean difference -0.58 (95% CI -3.55 to 2.38); p = 0.700).

- MAKO RAUKA was shown to be a cost-effective procedure, but this was directly related to volume.

The caveat for the all the literature quoted above is that the studies may be system specific and the results can not be extrapolated between the different systems making generalisation about the overall benefit of robotic assisted technology difficult.

CURRENT STUDIES ON ASSISTIVE TECHNOLOGY

IMako Uni vs conventional TKR Edinburgh: (TRAKER)

MAKO Bi-Uni vs TKR Strathclyde: (TRUCK, NIHR EME)

MAKO Uni vs Conventional University of Strathclyde / Glasgow

MAKO TKR with Orthosensor vs manual TKR, Newcastle (ROAM)

London, UCLH - Inflammatory response & tissue damage

Multi-centre pragmatic trial (RACER: NIHR HTA, Warwick / Birmingham)

London UCLH: Mechanical alignment vs functional alignment

London UCLH: Functional alignment cementless vs cemented TKA study

Exeter: Varus alignment study measured resection vs kinematic alignment.

SUMMARY

In summary the early data for robotics is promising but does not support the routine use of robotics or other technologies for routine care of knee arthroplasty patients at the current time. In the spirit of responsible innovation that it is essential that we continue to collect data on the outcome of surgery using new technologies to allow comparison with existing standards of care. It is also essential specifically for knee surgery that the target alignment philosophy employed is recorded to allow distinction between this and the technology used for implantation to be assessed. Finally, patients undergoing surgery with new technologies should be consented appropriately. The framework below may be of benefit in this regard.