



Robotics in total hip arthroplasty: a review of the evolution, application and evidence base

Jean-Pierre St Mart¹

En Lin Goh²

Zameer Shah³

- Robotic systems used in orthopaedics have evolved from active systems to semi-active systems.
- Early active systems were associated with significant technical and surgical complications, which limited their clinical use.
- The new semi-active system Mako has demonstrated promise in overcoming these limitations, with positive early outcomes.
- There remains a paucity of data regarding long-term outcomes associated with newer systems such as Mako and TSolution One, which will be important in assessing the applicability of these systems.
- Given the already high satisfaction rate of manual THA, further high-quality comparative studies are required utilizing outcome scores that are not limited by high ceiling effects to assess whether robotic systems justify their additional expense.

Keywords: complications; outcomes; robotic-assisted; total hip arthroplasty

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Introduction

Background

Long-term outcomes and survivorship of total hip arthroplasty (THA) are dependent on the accurate restoration of hip biomechanics, which is achieved through optimal component positioning.¹⁻⁹ It is evident that suboptimal component positioning leads to joint instability,⁹ increased wear,¹⁰ and poorer function.¹¹⁻¹⁴ Robotic-assisted orthopaedic surgery has the potential to improve the accuracy of component positioning in THA, thus, enhancing clinical outcomes.^{15,16} This review aims to summarize the

history and development of robotic technology in orthopaedic surgery, and discuss the evidence base surrounding its use.

Evolution of robotic surgery in orthopaedics

There has been an increased uptake of robotic surgery across different specialties since it was first introduced for neurosurgical biopsies in 1985.¹⁷ In orthopaedics, robotic systems are classified as passive, active (autonomous) or semi-active (haptic); of which, the latter two are most commonly used. With passive robotic systems, the surgeon retains control of the robot throughout the procedure. The da Vinci robot is one such example, although its use has been limited to upper limb orthopaedic procedures.¹⁸ Early robotic systems for THA were based on active technology, where the robot operated autonomously under surgical supervision without real-time guidance.¹⁹ The robot was programmed using pre-operative computed tomography (CT) to carry out bony preparation for component implantation once adequate surgical exposure was achieved intra-operatively. An instant shut-off switch was available to the surgeon if required.¹⁵ In recent years, semi-active robotic systems have become increasingly popular.^{15,20} These systems require the surgeon to guide the robotic arm for bony preparation via a haptic feedback mechanism that ensures minimal deviation from the pre-determined surgical plan. Additionally, these systems have the capability to provide real-time information on femoral preparation to allow corrections to be made intra-operatively.

First-generation robotic systems

ROBODOC

ROBODOC (Curexo Technology Corporation, Fremont, California, USA) was an active robotic system and the first robotic system used in THA.²¹ Since its inception, it has

been used in over 17,000 procedures.²² As part of the pre-operative phase, a CT scan of the patient was uploaded to the ORTHODOC workstation software to generate a three-dimensional (3D) virtual model of the patient's anatomy. This was used to plan and select the optimal design and size of the femoral component based on fit and fill for each patient.²⁰ The customized plan would then be transferred to the ROBODOC surgical system consisting of a five-axis robotic arm with a high-speed milling device.²¹ Post calibration and 'matching' of the pre-operative plan to the patient's anatomy, the robotic arm would then be used to mill out the proximal femur to accommodate the press fit femoral stem. Since this was a fully active system, once initiated, the only input allowed by the surgeon was an emergency stop. The acetabulum would then be manually reamed and standard instrumentation used for component implantation. Several modifications were made throughout its lifespan to address early complications associated with the original pin-based calibration system,^{21,23} which required insertion into the femur.^{24,25} In 2004, the holding company, Integrated Surgical Systems became financially insolvent after facing a class action lawsuit over complications associated with the system and was acquired by Curexo Technology Corporation.

CASPAR

CASPAR (Universal Robotic Systems Ortho, Germany) was an active robotic system that utilized similar pre-operative CT planning to ROBODOC to mill the proximal femur and guide implant insertion. This system had several prevailing issues; notably, variable precision of implantation and poorer post-operative outcomes,^{26–29} which highlighted the challenges associated with early robotic systems. This system is no longer in use since Universal Robotic Systems Ortho, the company behind it, went out of business.³⁰

ACROBOT

ACROBOT (The Acrobot Co. Ltd, London, UK) was developed with the aim of addressing issues associated with ROBODOC and CASPAR.¹⁹ As with the aforementioned systems, pre-operative CT-based software was used to create a surgical plan. This was then mapped to the patient's anatomy using a non-invasive anatomical registration method with the robotic arm subsequently guided by the surgeon to perform bony resection under haptic feedback.³¹ This system was advantageous as it could achieve the same level of accuracy as its predecessors without a significant time delay.³² This system was sold to Stanmore Implants Worldwide and the technology was purchased by Mako as part of a confidential patent infringement settlement in 2013.¹⁹

New-generation robotic systems

Mako

Mako (Stryker Corporation, Kalamazoo, MI, USA) is a semi-active robotic system that has been used in more than 20,000 THAs.^{15,33,34} Similar to earlier systems, pre-operative CT imaging is used to generate a 3D model of the native hip joint. An initial plan is created using selected CT landmarks and superimposed onto the 3D reconstruction. The surgeon is then able to fine-tune this to ensure optimal templating of component size and alignment, thus allowing the desired restoration of hip biomechanics, bone coverage, component positioning and leg-length correction.¹⁵ In contrast to earlier systems, the robotic arm is not fully automated but based on haptic feedback, so the surgeon retains partial control. There are currently two Mako software paths available: the enhanced and express femoral workflows. The enhanced workflow requires the full mapping and matching of both the proximal femur and acetabulum to the pre-operative 3D plan. This is performed by the registration of 32 surface points on both the acetabulum and femur, making it possible to calculate offset and hip length throughout the operation via pelvic and greater trochanteric checkpoints. For this workflow, initial femoral canal preparation and measurement of stem version allows subsequent adjustment of planned acetabular component positioning prior to reaming and cup placement. This is based on the theory of combined version as described by Ranawat and Dorr.^{35,36} Although the femur is prepared manually, the level of the neck cut can also be marked as indicated by the Mako software prior to resecting. For acetabular preparation, the surgeon reams using the robotic arm guided by haptic feedback. This prevents the surgeon from straying from the surgical plan. The same haptic-guided robotic arm is used to implant the acetabular component with the Mako software monitor displaying real-time information thus ensuring the cup is well seated. This ensures that over-reaming is restricted to 2.3 mm and cup orientation to within 5° of the surgical plan.³⁴ The express workflow uses the robotic arm for acetabular preparation only but allows limb-length discrepancy and offset to be calculated with similar accuracy to the enhanced workflow using similar pelvic and femoral checkpoints.

TSolution One

TSolution One is an active robotic system that incorporated the technology developed for ROBODOC. In addition to active femoral canal preparation, this system provides guided acetabular reaming and assisted cup implantation with the robotic arm. This system has since gained FDA approval, although the effectiveness of this system is yet to be determined due to the lack of available studies.^{19,37}

Operating system platforms

Open platforms

ROBODOC and CASPAR were open platforms. This meant that they provided compatibility with different implant companies and designs, which enabled the surgeon to tailor implant choice to the patient's anatomy. However, the capability of the open platform to incorporate configurations for multiple implant choices resulted in a lack of design specificity and biomechanical data to predict optimal implant positioning.^{30,38}

Closed platforms

Mako is a closed platform, which currently limits the acetabular component to the Trident cup and the stem choice to either the cemented Exeter or uncemented Accolade II stem (Stryker, Mahwah, New Jersey, USA). As such, surgeons may have to use an alternative implant compared to their usual practice. As the long-term outcomes relating to this system become clearer, surgeons will need to decide whether the risks and benefits of such a robotic system outweigh those associated with implant choice.^{33,39}

Component positioning

There is a growing body of evidence that robotic THA systems improve component alignment.¹⁵ Previous active systems have focused on femoral canal preparation using a robotic milling arm prior to manual insertion, whilst more recent semi-active systems such as Mako favour acetabular preparation and insertion using a robotic arm incorporating haptic feedback. In addition, the enhanced workflow capability offers the option of optimizing combined version as described above.^{34,36,40}

Femoral side

Bargar et al noted that the ROBODOC group had significantly better stem positioning compared to the manual group,²¹ which has also been confirmed by other studies.^{23,41,42} Furthermore, manual THA was associated with greater deviation in femoral anteversion from the pre-operative plan, which correlated weakly with higher vertical seating of the stem and increased risk of femoral fracture. Cadaveric and lab-based studies of CASPAR have suggested improved accuracy of femoral preparation over a manual approach, although this may be influenced by the type of stem used.^{43–46} However, the effectiveness of CASPAR in a clinical environment has been questioned. One study showed a significantly lower accuracy of post-operative femoral stem anteversion compared with pre-operative planning.²⁹ This highlights the importance of correlating experimental data with clinical outcomes, when appraising new technology. Although the Mako system relies on manual femoral broaching, the enhanced

femoral workflow path allows intra-operative calculation of the trial femoral stem version. This allows femoral stem retroversion to be detected and corrected towards a target of 15° anteversion if required.⁴⁷

Acetabular side

Several studies have evaluated Mako's ability to improve placement of the acetabular component. This has been based on previous studies noting the Lewinnek safe zones and subsequent Callanan modification as essential parameters for successful THA.^{9,48} Illgen et al reviewed 300 manual and robotic-assisted THAs.⁴⁹ In their study, the robotic group had improved acetabular component placement within the Lewinnek safe zones compared to the manual group. Subsequent studies have demonstrated a higher likelihood of placement of the acetabular component within the Lewinnek and Callanan safe zones with Mako.^{50–52}

Preservation of bone

Given the rising incidence of revision arthroplasty, bone stock preservation is an important consideration in primary THA.²⁰ Short stems are advantageous over long stems as they conserve more bone, thus providing more favourable conditions for future revision.⁵³ However, meticulous preparation of the femoral canal is required due to the lack of diaphyseal fit in order to reduce the risk of stem malalignment, incorrect stem sizing, and intra-operative fracture.⁵⁴ One advantage of the ROBODOC was its compatibility with short metaphyseal-fitting stems. A cadaveric study by Lim et al noted improved fit, better seating and a reduced risk of intra-operative fracture with ROBODOC compared to manual rasping.⁵⁵ This was corroborated by a clinical study which confirmed more accurate implantation of short femoral stems using ROBODOC's milling system compared to manual methods.⁵⁶ Preservation of acetabular bone stock in primary THA is essential in ensuring proper stability of cementless acetabular components as well as for considering future revision surgery.^{57,58} The haptic feedback of the Mako robotic arm ensures acetabular over-reaming is restricted to no more than 2.3 mm of the pre-operative CT plan.³⁴ A study by Suarez-Ahedo et al suggested that this accuracy led to a greater preservation of bone stock compared to conventional THA.⁵⁸

Limb-length discrepancy

Limb-length discrepancy (LLD) is associated with patient dissatisfaction and is the most common reason for litigation after THA.^{59,60} The ability of robotic systems to potentially minimize LLD is advantageous. A ROBODOC study noted that LLD was significantly reduced in THAs where the femoral canal was prepared with robotic assistance compared to being manually rasped. This was despite the

manual implantation of all femoral stems.²³ A prospective study by Nakamura et al with a minimum five-year follow-up noted that, although there was no significant difference in LLD between the ROBODOC-assisted (75 hips) and hand-rasped THAs (71 hips), the ROBODOC group had significantly less variance in LLD.⁴¹ Furthermore, Lim et al noted significantly smaller LLD with ROBODOC compared to manual THA.⁵⁶

Although a cadaveric THA study has demonstrated the accuracy of measurement of leg lengths using Mako software compared to CT scans,⁶¹ there are still questions about whether this extrapolates to a reduction in LLD or planned limb-length correction compared to traditional techniques. Kayani et al noted that the Mako was more accurate at restoring the patient's native centre of rotation and offset, but there was no difference in planned limb-length correction compared to manual THA.⁶² Two recent systematic reviews concluded no significant difference in limb-length discrepancy between robotic and manual THR.^{63,64}

Clinical outcomes

Functional outcomes

There is a limited amount of data evaluating functional outcomes including patient-reported outcome measures (PROMs) for robotic THA. Most data available are based on active robotic systems which are now obsolete. For ROBODOC, the majority of studies reported similar functional outcome scores between robotic THA and manual THA after three years of follow-up.^{21,23,25,56} However, Nakamura et al noted marginally improved Japanese Orthopaedic Association scores in the robotic THA group compared to the manual THA group at two and three years follow-up, although this was not sustained after five years.⁴¹ A long-term study of patients undergoing surgery with ROBODOC by Bargar and colleagues found that the robotic THA group had significantly improved pain and function scores compared to the manual THA group. There were no significant differences in wear or revisions for loosening noted.²² One study evaluated the effectiveness of CASPAR compared to the conventional techniques.²⁸ In this study, the authors reported similar Harris Hip Scale (HHS) and Health Status Questionnaire (HSQ) scores between the two groups after 18 months of follow-up. However, the Merle d'Aubigné–Postel score was significantly less, and hip abductor function significantly poorer in the CASPAR group. More recently, several studies have evaluated outcomes associated with the Mako robotic system. Perets et al documented improvements in function, pain and patient satisfaction scores with this system after two years.⁶⁵ These findings were supported by a subsequent study comparing Mako and manual THAs, which showed significantly better functional scores with Mako.³

Complications

A prevalent issue with robotic-assisted THA has been the high rate of technical complications resulting in conversion to the manual approach.^{23,25} Two studies estimated that technical complications associated with ROBODOC were as high as 18%.^{23,25} A recent study of Mako reported technical complications in 1.4% of cases,⁵⁰ which may suggest improvements in the reliability of newer robotic systems. Nevertheless, it is evident that technical issues such as pelvic array loosening, acetabular registration failure, repetitive reaming, and arduous cup implantation occur more frequently during the learning phase, which has important implications for training.⁵² Another important complication to consider is the rate of dislocations. Honl et al reported that the ROBODOC group had a significantly higher dislocation rate than the manual group at 18%.²³ Meanwhile, Nakamura et al documented a similar rate of dislocations between the ROBODOC and manual groups, which was attributed to better retraction and preservation of the hip abductors.⁴¹ Illgen et al noted dislocations were significantly reduced using Mako (0%) compared to manual THA.⁴⁹ Several studies of ROBODOC have suggested that robotic THA may confer an advantage in reducing the risk of intra-operative fracture.^{21,41} This can be attributed to greater accuracy of femoral canal preparation by milling the proximal femur using the robotic arm rather than manually rasping. Several studies have reported a higher rate of heterotopic ossification associated with ROBODOC and CASPAR.^{28,41} Data regarding intra-operative blood loss are inconclusive. Siebel et al noted that there was significantly greater blood loss with CASPAR.²⁸ Subsequently, Illgen et al found that blood loss was significantly lower with Mako.⁴⁹ In terms of component positioning, Kong et al reported unacceptable cup positioning, LLD and offset in 10% of cases.⁵² Other less common robotic complications that have been described in the literature include nerve injury, infections and femoral fissures.^{23,28} A systematic review compared the complication rate of five robotic studies with manual THA.⁶³ The five studies reviewed related to the ROBODOC and CASPAR systems only. They noted a higher intra-operative complication rate but a similar post-operative complication rate in manual compared to robotically assisted THA. Overall complication rates were higher in the manual THA group. A more recent meta-analysis including Mako results also noted that robotic THA had less frequent intra-operative complications but more post-operative dislocations and revisions compared to manual THA.⁶⁴ Overall, there were no differences between the groups in terms of total number of complications. The authors noted a possible trend of reduction in complications with newer robotic-assisted THA systems such as Mako and improved surgical technique. However, the higher rate of technical issues during the learning phase with all systems highlights

the importance of having a surgeon with sufficient hip arthroplasty experience overseeing the procedure.

Clinical application

Learning curve

The learning curve is defined as the rate of a surgeon's progress in gaining experience or new skills.⁶⁶ This is typically described as the number of cases needed to achieve a steady state of outcomes. A variety of surrogate outcomes have been used to assess the learning curve associated with robotic THA including operating time, component positioning and intra-operative complications. Earlier studies evaluating the ROBODOC system have reported mixed results. While Bargar et al and Nakamura et al suggested that a significant learning curve was present,^{21,41} Honl et al subsequently refuted this.²³ It is important to emphasize that the contrasting findings from earlier work may be due to differences in study design and sample size. Recent studies evaluating the Mako system suggest a learning curve of 12–35 cases based on operating time.^{52,67,68} However, there is also substantial evidence that there is no learning curve with regard to component positioning with this system.^{52,68} It would therefore be reasonable to conclude that the learning curve associated with newer robotic systems for THA is more closely related to the familiarity of the surgical team with such technology.

Cost-effectiveness

Robotic technology is associated with high front-end costs, which include the robotic system, operational costs, disposables, pre-operative imaging, and implants.²⁰ These costs vary widely and are dependent on choice of system, manufacturer license agreements and individually negotiated pricing structures primarily based on each hospital's surgical volume. When first introduced, the ROBODOC system price offering varied between US\$635,000 and \$1.5 million. In some cases this cost is subsidized by implant manufacturers in order to increase sales of their implants.⁶⁹ The annual maintenance fees for most robotic systems is between \$40,000 and \$150,000.⁷⁰ This potentially includes software upgrades which can otherwise be an extra financial burden. Alternative payment structures include leasing models on a case-by-case payment structure. Charges are then based on company-specific implants and disposables required per case. The costs of disposables alone can vary from \$750 to \$1300.^{70,71} In addition both active and semi-active systems require pre-operative CT scans which are an additional \$260 each.⁷⁰ The cost of implants has previously been estimated to represent between 15% and 87% of surgical costs without taking into consideration additional expenses of robotic technology.⁷² There is also likely to be significant variation

between open and closed platforms, the latter potentially having increased pricing due to a lack of competition. Chen et al recently analysed the increased cost associated with robotic systems compared to manual THA.⁷⁰ They noted that using the Mako system added 12.2% and 6.1% respectively to the cost of each THA if 100 and 300 cases were performed, assuming a five-year robotic system life span. Under the same pricing structure, they suggested similar figures of 13.9% and 6.6% for 100 and 300 THAs respectively performed with TSolution One robot. Potential financial burdens to offset the cost of robotic technology include the costs saved on revision surgery and readmission for post-operative complications. For robotic TKA surgery the readmission rate has been reported to be a 5% lower than for conventional techniques.⁷¹ Chen et al equated this to a 4% decrease in overall cost of primary TKA using a robotic system compared to traditional instrumentation.⁷⁰ However, studies regarding robotic THA have been less favourable, with higher revision and similar post-operative complication rates having been reported.^{21,23} Chen et al equated this to a 20.3% increase in cost when using robotic THA compared to manual techniques.⁷⁰

Discussion

Early active robotic systems focusing on femoral canal preparation demonstrated theoretical advantages in terms of better fit and potentially lower iatrogenic fracture rate for uncemented stem implantation. However, improved stem fit did not equate to better outcomes nor a reduction in dislocation rates and other complications. Technical unreliability with active systems was a significant issue, resulting in manual conversion in up to 18% of cases.²³ Newer semi-active systems such as Mako allow for greater operating guidance whilst still maintaining the benefits of robotic precision for both acetabular reaming and cup placement. Further benefits include intra-operative calculations of hip length, offset and combined version, and the ability to make the relevant component adjustments accordingly. This semi-active system therefore shows a higher degree of accuracy in terms of component positioning compared to previous active systems.

The higher complication rates in certain comparative studies with fully active systems compared to manual THA highlights the risks of using robotic technology which could potentially overshadow their benefits.^{23,28} The semi-active system Mako has demonstrated more favourable outcomes, however, with similar overall complication rates compared to manual THA.⁶² Specific complications such as blood loss and dislocation rates appear reduced in robotic THA using this semi-active system but increased in previous fully active systems. In terms of dislocation rates this may be due to the dependency of these

preceding active systems on manual acetabular preparation and implantation.^{3,28} Potential soft tissue damage with certain active systems may have also been a contributing factor.²⁸

Although robotic innovation is an exciting development in hip arthroplasty, it has yet to demonstrate superior functional outcome scores or improved patient satisfaction compared to conventional THA. This lack of difference is perhaps a testament to the already great success of the latter. Any potential improvement in functional outcome is likely to be narrow, and therefore measured outcome scores used should enable 'good' and 'excellent' differences to be clearly defined.²⁰ Unfortunately, the majority of robotic studies so far have utilized outcome scores such as the HHS and Merle d'Aubigné–Postel score which are limited in this regard by their high ceiling effects.^{20,73,74} This may contribute to previous robotic studies showing little difference in functional scores compared to manual THA. Of note, one study demonstrated poorer scores and abductor function in the robotic group although this active system is no longer in use.²⁸ Recent functional outcome data for Mako, however, are encouraging, although long-term follow up is required.^{3,65}

One potential issue with closed systems like Mako is the limited variation of compatible prostheses. Surgeons wishing to embrace this technology may therefore have to change their preferred implant choice. As a result, a learning curve relating to new implant usage may be introduced, independent of robotic technology. One argument, however, is that reduction in variation may reduce overall implant costs, which could potentially offset some of the upfront costs of robotic technology. A recent study by Boylan et al noted that adoption of a single preferred vendor for hip and knee arthroplasty reduced costs by 23% per case in the first year.⁷⁵ Despite the potential learning curve with new unfamiliar implants, there was no difference in short-term quality metrics in this study, although higher-volume surgeons were more reluctant to change implant.

Most robots currently used in THA are closed systems. This not only limits the comparison of individual robotic systems with manual implantation of different implants, but also prevents, in most cases, the evaluation of different robotic systems utilizing the same implant. Any long-term comparisons between such technologies should take into account that differences in outcome measures and survivorship may be due to individual prosthesis design as well as the additional accuracy that robots provide. Whether one of these factors has a greater impact in the long term may be difficult to establish even with registry data.

Although previous active systems appear redundant, in the future there may be a resurgence of interest with the TSolution One system. This fully active system is based on the legacy of the ROBODOC, but unlike its predecessor

allows preparation and component implantation of the acetabulum in addition to femoral preparation. This theoretical improved accuracy in combined component version may potentially address previous concerns of increased dislocation compared to manual techniques in previous active systems.²³ Outcome studies, however, have yet to be published.

Conclusion

Although robotic-assisted THA is associated with lower complication rates and superior radiographic outcomes compared to conventional THA, short- and long-term functional outcomes remain equivocal.^{63,64} It must be noted that this evidence is based upon limited data from a handful of studies, the majority of which are based on previous robotic systems that are now redundant. The results of the newer semi-active system, Mako, are promising, with greater accuracy of implant positioning relating to the safe zones, restoration of hip offset, and native centre of rotation.^{49,62} Further work is necessary to establish whether these improvements lead to a significant reduction in complications and improved long-term outcomes. The variation in technical failures, surgical complications and outcome measures between systems highlights the importance of appraising the merits of each system individually to fully quantify the true benefits and risks of robotic THA.

AUTHOR INFORMATION

¹Department of Trauma and Orthopaedics, King's College Hospital, London, UK.

²Oxford Trauma, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK.

³Department of Trauma and Orthopaedics, Guy's and St Thomas' NHS Foundation Trust, London, UK.

Correspondence should be sent to: Jean-Pierre St Mart, Department of Trauma and Orthopaedics, King's College Hospital, Denmark Hill, London, SE5 9RS, UK.
Email: jstmart@nhs.net

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