A review of the evolution of Robotic Assisted Total Hip Arthroplasty

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Abstract

Total Hip Arthroplasty (THA) is currently a very successful operation but continues to evolve, as we try to perfect the techniques and improve outcomes for our patients. Robotic Hip Surgery (RHS) began with the 'active' ROBODOC system in the 1980's. There were drawbacks associated with the original ROBODOC and most recently, the MAKO robot was introduced with early promising results. One of the limiting factors of conventional THA currently is the human factor in surgery. RHS aims to tackle this by promising a reproducible and reliable method of component positioning. We have reviewed the literature surrounding the technology and discuss the pros and cons of these systems.

Introduction

Total Hip Arthroplasty (THA) has been a successful operation since its introduction half a century ago (1, 2). Each decade has its own area of focus for improving outcomes for THR. In the 1970's, it was the bearing surfaces. The 1980's it was the cemented versus uncemented debate, which continues to this day. The 1990's introduced newer bearing surfaces including metal-on-metal, ceramic-on-ceramic and resurfacing arthroplasties with the preservation of bone stock. At the start of the new millennium, two major topics developed in THA. Firstly, the early failure of large bearing metal-on-metal hip implants and secondly, the role of minimally invasive hip arthroplasty and alternative approaches to the hip. As we come towards the second decade of this millennium, robotic assisted surgery has become the new hot topic.

Jacofsky and Allen in their review quote Roger Bohn that every industry; from aviation to manufacturing to financial services to firearm safety to military activity has followed 5 phases of development (3). These phases are i) consideration of the industry as an ''art'' by experts in the field ii) development of ''rules plus instruments'' iii) development of ''standardized procedures and templates'' iv) automation v) computer integration. At present, surgery is at the third stage. It could only be a matter of time before we enter the fourth stage, and the use of robots is routine in surgery. Paraphrasing Moors Law from the 1970s, computing power will double every two years and it is now hard to imagine that robotics will not play an increasing role in healthcare in the near future.

However, important questions remain as to whether this new technology at present will lead to improved outcomes in patients undergoing hip arthroplasty surgery. This review will discuss the history of robotic hip surgery and the evidence currently available surrounding this area.

Methods

We performed a literature review searching Medline, Embase, Ovidsp, Cochrane library, pubmed database and google scholar pertaining to adults using the following keywords: 'Robotic hip surgery', 'Robotic orthopaedic surgery', 'Computer assisted hip surgery', 'Robotic arthroplasty', 'Computer assisted Orthopaedic Surgery'.

Types of Robot

In the field of hip surgery, robotic surgery can be passive, active or semi-active. Passive robots complete a task that is continuously under the control of the surgeon with no feedback loops. An example of this, is the Da Vinci robot, which is a passive remote telemanipulator. Active robotic hip surgery systems perform the bony preparation for implantation of the components based on pre-determined programming. Semi-active robots require the surgeon's involvement but has haptic feedback loops present i.e. it is able to communicate with the surgeon in real-time.

Haptics provide tactile feedback that facilitates the pre-operative plan to be implemented in the operating room. It can be auditory, tactile and visual or a combination of all. Historically, the active robot only had applications for the femur and the semi-active options for the acetabulum. However, with improved technology and developments, some now offer guidance for both femoral and acetabular preparations.

On review of the literature, 4 major systems for robotic hip surgery were found. These include Robodoc (THINK surgical, Inc., Fremont, CA, USA), CASPAR (Universal Robot Systems Ortho, Germany), ACROBOT (COMPANY), and the RIO MAKO ROBOT (Stryker, FL, USA). Only the ROBODOC and the RIO MAKO robot remain in widespread clinical use.

ROBODOC – The first active surgical robot assistant

Computer Assisted Orthopaedic Surgery (CAOS) and Robotic Hip Surgery (RHS) entered into clinical practice in the early 1990's in the form of 'Robodoc'(4, 5). William Bargar in the 1980's started making custom implants using computer-assisted design/computer-assisted manufacturing (CAD/CAM) technology based on computer tomography (CT) imaging. In the same campus, Howard Paul was investigating joint replacements on canines. It was the joint collaboration of Bargar and Paul that resulted in the first active robotic surgical system called the ROBODOC (incidentally named after the then popular film Robocop)(6).

ROBODOC (THINK surgical, Inc., Fremont, CA, USA) was the first surgical robot in hip arthroplasty that had widespread use. It was originally produced by Integrated Surgical Systems. A class-action lawsuit was filed in 2004 in Germany against ROBODOC following some patients who developed complications. The company was then acquired by Curexo technology which later became Think surgical Inc. The company now has FDA approval for its next generation active ROBODOC system called TSolution One(7).

It has been used worldwide for over 17,000 THAs since 1994(8). It is a system that assists surgeons to pre-operatively plan the type of femoral implant, as well as machine mill the femoral canal to press-fit the chosen uncemented implant. This is an 'active' system in that it performs actions, based on pre-operative planning instructions. It has an ORTHODOC workstation (the 'brains') with a ROBODOC surgical robot arm with a high-speed milling device (the 'effector') (9).

To function, the ROBODOC needs calibration markers on the patient to map the anatomical co-ordinates which are fed back to a computer then looped back to the robotic arm. This process, known as calibration involved placing fiducials (radiographic markers) on patients. The original ROBODOC system used a pin based system. Originally these fiducials were titanium screws that were inserted into the greater trochanter and into the femoral condyles before a CT scan is taken under local anaesthetic. This was an additional procedure for the patient associated with complications including fractures, knee pain, nerve injury, and broken metalwork (10, 11). During the hip replacement surgery, the surgeon has to expose and identify these pins to the ROBODOC. It then recognizes the position of these fiducials and places them in context of the patients bony anatomy (12).

Due to the drawbacks, in 1999 Robodoc introduced surface marking calibration techniques using optical sensors placed in the operating room and probes placed on bony landmarks on the patient known as the DigiMatch Technique. This eliminated the need for the surgical pins. Nakamura et al compared their results with the conventional locator pin based registration to the DigiMatch technique and concluded the DigiMatch technique was safe and effective though they noted the DigiMatch group had a longer duration of surgery compared to the pin based system of 146 and 121 minutes respectively (13). Their group also validated the accuracy of the DigiMatch technique with post-operative CT scanning and component positioning. After registration the femur was rigidly fixed to the ROBODOC with a clamp placed at the level of the lesser trochanter making it ready to mill the femoral canal actively.

The landmark paper for Robodoc published by its co-inventor Bargar et al produced promising results (14). This paper introduced the results of the FDA approved multicentre randomized controlled trial of 136 hip replacements in the USA between 1994 and 1995. The results showed comparable Harris hip scores (HHS) for patients having a hip replacement using the Robodoc and the control group. Complications were not different, except that in the control group there were three femoral fractures and zero in the Robodoc group. There was also greater surgical time and increased blood loss in patients undergoing the Robodoc hip. However, the ROBODOC achieved more accurate alignment and fixation of the femoral stem.

The additional German study of 900 hip replacements also corroborated well with the initial FDA approved trial (14).

Recently, Bargar et al has published his single-surgeon fourteen-year follow-up results of the randomized clinical trials showing that there were no failures for stem loosening and a small (but clinically not significant) improvement in functional scores (8). The authors attribute the improved functional scores to more accurate component positioning, however accept this is less than the minimal clinically important difference (MCID). This conclusion however is debatable and open to criticism of inventor bias.

Other studies have demonstrated that ROBODOC leads to improved component positioning and reduced leg length discrepancies (15, 16). Hananouchi et al have carried out DEXA studies comparing ROBODOC hip replacements to conventional hip replacements. The results suggest that robotic milling is effective in facilitating proximal load transfer and minimizing bone loss with uncemented stems (17). This could have the potential benefit of reducing stress shielding in the future though long-term studies are required to confirm this. Furthermore, Robodoc has also been quoted to be useful in revision arthroplasty, particularly in removal of the distal cement plug (18). A prospective randomized controlled trial using short uncemented femoral stems, concluded that RAS using the ROBODOC lead to increased accuracy of stem alignment and leg length equalities but also reduced intraoperative femoral fracture risk compared to standard THA's (19).

Opponents of the Robodoc raised concerns with potential thermo-necrosis caused by the robotic milling arm despite the irrigation systems that were in place. Nogler et al have demonstrated in-vitro studies that the temperature could get up to 172^{o}C without irrigation so note that care needs to be taken when using the robotic mill (20). However, there were no clinical studies demonstrating these concerns.

Honl et al performed a prospective randomized controlled trial and demonstrated unfavourable results for the ROBODOC. They showed in their 154-patient trial, the ROBODOC had higher dislocation rates. They attributed this to intra-operative muscle damage caused by the robotic mill. There was also a higher revision rate and longer duration of surgery with

Robodoc. Furthermore, 18% of the patients had failed attempts of robotic implantations due to the failure of the computer system (15). The complication of registration failure has been noted and has been quoted to occur as high as 10% of the time (11, 21).

In addition to the above, other disadvantages of RHS include increased radiation to the patient (for the CT scan). The pre-operative planning CT subjects the patient to three times the radiation of a usual plain hip radiograph series (22).

Another factor limiting the widespread use currently are the costs involved. The costs of robotic arthroplasty have a varied range but initial purchase costs of Robodoc include $635,000 with $130,000 annual service costs (23, 24). Finally the literature suggest a surgical learning curve with the Robodoc. Sugano et al note this is particularly relevant to an active surgical robot which is not under the direct control of the surgeon, even though there is a 'kill switch' (9).

CASPAR

Another example of an active surgical robot includes CASPAR (Universal Robot Systems Ortho, Germany). The literature on Caspar is mainly restricted to articles in German. One often quoted paper by Siebel et al compared 36 CASPAR robotic assisted and 35 conventional total hip arthroplasties with an 18-month follow-up. They noted that with CASPAR the average duration of surgery and blood loss was greater. The Caspar robotic system is no longer available in clinical use.

ACROBOT

Due to the disadvantages associated with the active robotics, more accepting devices such as the ACROBOT (Acrobot ltd, London, UK) were developed. The surgical arm is moved by the surgeon which is limited to stay within a pre-determined surgical field by pre-operative CT planning. In the literature, there is only one clinical study involving ACROBOT that noted the use in hip resurfacings (25). The Acrobot was sold to Stanmore Implants Worldwide and subsequently, some of the technology was acquired by Mako.

Mako – A semi-active robot

Disadvantages of the active robot lent itself to the rise of the semi-active robot - the Mako robot (Stryker, FL, USA). The Mako robot uses a Robotic Arm Interactive Orthopaedic (RIO) system. FDA approval was given in 2008 for knee arthroplasty and hip arthroplasty in 2010. By the start of 2017, Stryker sales data indicate that 20,000 Mako THA's were performed (26).

The Mako system has a planning stage whereby the patient undergoes a pre-operative CT scan to generate a 3-D model of the pelvis and proximal femur. The surgeon then templates the components in the optimal position virtually. The Surgeon proceeds to perform the surgery with the robotic arm (RIO) system using standard surgical tools. During the surgery, three pins are inserted into the thickest portion of the iliac crest. A further pin is inserted into the intertrochanteric ridge as well as a checkpoint smaller screw into the greater trochanter. Femoral registration is completed by touching 32 required points on the proximal femur with a probe (similar to the DigiMatch technique of the Robodoc). Being able to template the centre of rotation of the femoral head and the hip joint, including other para-meters pre-operatively, the robot can guide the surgeon to perform the neck osteotomy at the pre-templated level. The femur is prepared with broaches and the anteversion is measured of the final broach in place.

Acetabular registration occurs using a pelvic checkpoint screw inserted outside the acetabulum. 32 registration points are also taken here. When performing the acetabular reaming, the robotic arm is constrained by a conical virtual haptic tunnel. The Mako system works on a principle of 'active constraint'. It prevents the surgeon from straying from the desired pre-operative templated components by haptic feedback (auditory beep, visual colour changes on the screen and tactile vibrations). The computer screen shows in real-time the cup anteversion and inclination as well additional useful information such as distance to the centre of rotation (COR) templated and the real-time COR. A single acetabular reamer is used, sized pre-operatively. The real cup is also inserted through the haptic tunnel with the monitor displaying real-time information.

Nawabi et al performed a cadaveric study and validated the accuracy of the Mako robot and confirmed the robotic system provided superior accuracy compared to manual implantation in terms of desired component positioning (27). This group also noted that the leg lengths were reconstructed to within 1mm using the robot.

Kamara et al performed a retrospective cohort review and compared 3 groups of patients (28): The first 100 patients fluoroscopic assisted anterior approach THAs, the first 100 robotic assisted THAs and a control group of the last 100 standard THAs. The results showed that component positioning in the target zone was achieved in 76% of the standard THAs, 84% in the fluoroscopic assisted anterior approach but 97% in robotic assisted THAs. This paper also notes the learning curve associated with the Mako robot is minimal. The authors conclude that robotic techniques deliver significant and immediate improvement in the precision of the acetabular component.

In contrast, a prospective collected data series of 105 consecutive RHS, Redmond et al concluded that there is a significant learning curve with the Mako robot (29). They noted there was a significant decrease in acetabular component mal-positioning and operative time with increasing experience ($p<0.05$). The group also noted that in five percent of the cases, there were technical problems associated with the fixation of the femoral screw for navigation. The screw that was inserted into the posterior border of the greater trochanter loosened in osteoporotic bone. This affected the intra-operative feedback on leg length and offset (29). This was picked up by the surgeon but emphasised the fact that the he or she cannot ‘switch off’ during robotic surgery.

The increased duration of surgery associated with RHS increases the risk to patient of periprosthetic joint infections as well as anaesthetic risks. It also places a burden on theatre utilization. As above noted, with increasing experience, the surgical time can be reduced from 80 minutes for the surgeons first 35 cases to 69 minutes after 70 cases (29).

Similar to the ROBODOC, RAS with the Mako RIO system has significant costs associated with the technology. Reported costs for the platform include $793,000 which does not include the annual servicing and maintenance costs (30). Supporters of Mako point out that this technology does not expose the surgeon to have to learn new techniques of exposure nor alter his surgical technique significantly. It does not expose the surgeon to radiation like fluoroscopic assisted THAs. Furthermore, although there is a small increased radiation to the patient for the pre-operative CT scan, it could be argued that the patient does not require an early post-operative radiograph as the surgeon has intraoperative imaging of final component positioning. This could help mitigate the difference in radiation doses to the patients associated with RHS.

The Mako robot can provide a 'virtual safety barrier' for the surgeon to prevent errors in component positioning. The haptic feedback allows the pre-operative plan to be implemented in the operating room. The Mako robot has been validated in Domb et al's matched-pair controlled study. They showed 100% of the RHS were within the Lewinnek's safe zone compared to 80% of conventional hip surgeries (31). This has been corroborated with Malchau's et al series (32).

In a multi-centre trial, 119 patients underwent robotic hip surgeries. The results showed that the inclination and version of the acetabular components were within the commonly accepted limits in 100% of the cases (33). The same group published their data showing that in RHS with Mako, acetabular component positioning was within 4 degrees of the planned position in 95% of the cases (32).

Intra-operative data on RHS for the acetabular position produced accurate and reliable data when compared to postoperative radiograph analysis of component positioning (34, 35).

Tsai et al carried out a CT based study postoperatively of RHS patients, with unilateral arthroplasties who underwent hip arthroplasty with RHS and compared these models to patients who had conventional hip surgery (36). They conclude that there was significantly less variation in the orientations of components in the RHS group compared to the non RHS group and demonstrated reproducibility with RHS. Another recent CT based study conclude that the post-operative Mako THR component positioning accurately correlated with the pre-operative template (for length, offset, anteversion and inclination) (37).

Is there a Problem that needs addressing?

Hip arthroplasty is already a one of the most successful surgical procedures available throughout healthcare. Success of hip arthroplasty can broadly be divided into three factors. These are patient factors, surgeon factors and implant factors. One of the surgeon factors affecting success includes component positioning. Based on the UK registry data, the most common reason for revision hip surgery within the first year following the primary arthroplasty remains dislocation (38). Bozic et al confirm that the most common indication of revision hip surgery is dislocation giving rise to nearly one quarter of all revision hip surgeries (39). An important cause of dislocations remains component positioning.

Component malalignment can lead to not just hip dislocation but also hip impingement, early wear, edge loading, periprosthetic fractures and revision surgery (40, 41). Revision surgery has a cost most importantly to the patient but also gives rise to a significant financial burden to the healthcare economy (42). Therefore, technology which helps reduce the burden of revision hip surgery and promotes better outcomes is warranted.

There is widespread data in the literature suggesting that experience and surgical volume improve component positioning accuracy (43-45). However, even in experienced hands, there is a range of component positioning. In one study by Padgett et al, the results of a single hip surgeon over 40 consecutive hip arthroplasty cases revealed a mean cup abduction angle of 42.1^{o} but with a range of 23^{o} to 57^{o} with an intra-observer and inter-observer variability less than 0.3^{o} (46). A similar variability has been demonstrated in anteversion of the femoral component (47). Other studies confirm that even in high volume arthroplasty units, there is a significant number of mal-positioned components radiographically (48, 49).

The early results with the Mako robot seems to promise more consistent component positioning in total hip arthroplasty. However, care must be taken in reaching conclusions that this would automatically lad to better outcomes and function. There is a need for more robust studies with longer term follow up of patients with a focus on patient reported outcome measures and other functional assessments. Currently the data does confirm that robotic hip surgery adds to the operative time and there is a significant cost implication factor. It is important not to rush into the next 'orthopaedic fad'. New technology needs to be assessed thoroughly to prevent repeating history with examples such as the large metal on metal THRs.

Ultimately, uptake especially initially depends on costs and health-care economics. In today's healthcare economics with austerity measures, this will be a significant factor limiting its widespread use. Proponents of robotic surgery however argue that although there are relatively high initial set up costs involved, there may be an overall cost saving element to the healthcare economy if the predictions of reduced revisions with RHS are true (50).

Finally, the role of RHS could be expanded providing a more controlled training opportunity for the junior surgeons who will learn and practice inserting the component in the correct place. Furthermore, it could be used in conjunction with simulation tools in the university as a training opportunity with virtual reality technology.

Conclusion

As Redmond notes in their results, though the surgeon relies on the computer generated information on hip measurements, the surgeon should still pay close attention to the anatomic landmarks to ensure the robotic system is providing accurate information (29).

The Mako system can be equated to the release of the first iPhone (Apple Inc, Cupertino, California, USA). It is revolutionary change to everything that has been around so far. Analogous to the current iPhone X that has facial recognition and Siri, the Mako robot will continue to develop and may one day become semi-autonomous. This has already been shown to be possible in other systems when in 2016, the Smart Tissue Autonomous Robot (STAR) has sown two pieces of pig's intestine together (51). Ultimately however, we still require the surgeon to be in control analogous to the current situation where we would not yet be comfortable travelling in a non-piloted aeroplane. A wider more philosophical question raised would be whether robotic surgery could one day replace surgeon involvement completely.

In the current era, the greatest weakness of arthroplasty surgery is the human factor which includes human error. Trying to implant perfectly positioned components, one hundred percent of the time, in every patient, in a biological environment, where there is diversity in anatomy and pathology seems only attainable with the innovation of robots. As Dorr et al quotes 'Improving human performance in surgery will be done by machines in the operating room just as it is in every other human endeavour outside surgery' (52).

In one of the few level 1 studies, a recent meta-analysis of the first 30 years' experience of robotic surgery across different surgical specialities, the authors from Imperial college conclude that robotic surgery contributed positively to some perioperative outcomes but longer operative times and costs remained a downfall (53).

Finally, it is worth noting that current robotic platforms do not allow for the assessment of spino-pelvic plane dynamics. As discussed, RHS allows us to consistently place the acetabular component at the '40/20' position, however, this may not be applicable to all patients and data is emerging that this 'one rule fits all' may not apply to hip surgery(54).

In conclusion, as orthopaedic surgeons, we must critically appraise all new technology and support the use providing there is sound robust evidence backing it.

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