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1 **A review of the evolution of Robotic Assisted Total Hip Arthroplasty**

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4 **Short title:** A review of the evolution of Robotic Assisted Total Hip Arthroplasty

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19 **A review of the evolution of Robotic Assisted Total Hip Arthroplasty**

20

21 **Abstract**

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

30

31

32 **Introduction**

33

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

44

45 Jacofsky and Allen in their review quote Roger Bohn that every industry; from aviation to
46 manufacturing to financial services to firearm safety to military activity has followed 5 phases
47 of development (3). These phases are i) consideration of the industry as an "art" by experts
48 in the field ii) development of "rules plus instruments" iii) development of "standardized
49 procedures and templates" iv) automation v) computer integration. At present, surgery is at

50 the third stage. It could only be a matter of time before we enter the fourth stage, and the
51 use of robots is routine in surgery. Paraphrasing Moors Law from the 1970s, computing power
52 will double every two years and it is now hard to imagine that robotics will not play an
53 increasing role in healthcare in the near future.

54

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

59

60 **Methods**

61

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

66

67

68

69 **Types of Robot**

70

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

78

79 Haptics provide tactile feedback that facilitates the pre-operative plan to be implemented in
80 the operating room. It can be auditory, tactile and visual or a combination of all. Historically,
81 the active robot only had applications for the femur and the semi-active options for the

82 acetabulum. However, with improved technology and developments, some now offer
83 guidance for both femoral and acetabular preparations.

84

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

89

90

91 **ROBODOC – The first active surgical robot assistant**

92

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

100

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

107

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

114

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

125

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

136

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

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

147

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

154

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

166

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

172

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

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

180

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

184

185 Another factor limiting the widespread use currently are the costs involved. The costs of
186 robotic arthroplasty have a varied range but initial purchase costs of Robodoc include
187 \$635,000 with \$130,000 annual service costs (23, 24). Finally the literature suggest a surgical
188 learning curve with the Robodoc. Sugano et al note this is particularly relevant to an active
189 surgical robot which is not under the direct control of the surgeon, even though there is a
190 'kill switch' (9).

191

192

193 **CASPAR**

194

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

201

202

203 **ACROBOT**

204

205 Due to the disadvantages associated with the active robotics, more accepting devices such as
206 the ACROBOT (Acrobot Ltd, London, UK) were developed. The surgical arm is moved by the
207 surgeon which is limited to stay within a pre-determined surgical field by pre-operative CT
208 planning. In the literature, there is only one clinical study involving ACROBOT that noted the

209 use in hip resurfacings (25). The Acrobot was sold to Stanmore Implants Worldwide and
210 subsequently, some of the technology was acquired by Mako.

211

212

213 **Mako – A semi-active robot**

214

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

219

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

232

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

241 used, sized pre-operatively. The real cup is also inserted through the haptic tunnel with the
242 monitor displaying real-time information.

243

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

248

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

257

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

267

268 The increased duration of surgery associated with RHS increases the risk to patient of
269 periprosthetic joint infections as well as anaesthetic risks. It also places a burden on theatre
270 utilization. As above noted, with increasing experience, the surgical time can be reduced from
271 80 minutes for the surgeons first 35 cases to 69 minutes after 70 cases (29).

272

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

283

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

290

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

296

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

299

300 Tsai et al carried out a CT based study postoperatively of RHS patients, with unilateral
301 arthroplasties who underwent hip arthroplasty with RHS and compared these models to
302 patients who had conventional hip surgery (36). They conclude that there was significantly
303 less variation in the orientations of components in the RHS group compared to the non RHS
304 group and demonstrated reproducibility with RHS. Another recent CT based study conclude

305 that the post-operative Mako THR component positioning accurately correlated with the pre-
306 operative template (for length, offset, anteversion and inclination) (37).

307

308

309

310 **Is there a Problem that needs addressing?**

311

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

320

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

326

327 There is widespread data in the literature suggesting that experience and surgical volume
328 improve component positioning accuracy (43-45). However, even in experienced hands, there
329 is a range of component positioning. In one study by Padgett et al, the results of a single hip
330 surgeon over 40 consecutive hip arthroplasty cases revealed a mean cup abduction angle of
331 42.1° but with a range of 23° to 57° with an intra-observer and inter-observer variability less
332 than 0.3° (46). A similar variability has been demonstrated in anteversion of the femoral
333 component (47). Other studies confirm that even in high volume arthroplasty units, there is
334 a significant number of mal-positioned components radiographically (48, 49).

335

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

345

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

351

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

356

357

358

359 **Conclusion**

360

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

364

365 The Mako system can be equated to the release of the first iPhone (Apple Inc, Cupertino,
366 California, USA). It is revolutionary change to everything that has been around so far.
367 Analogous to the current iPhone X that has facial recognition and Siri, the Mako robot will

368 continue to develop and may one day become semi-autonomous. This has already been
369 shown to be possible in other systems when in 2016, the Smart Tissue Autonomous Robot
370 (STAR) has sown two pieces of pig's intestine together (51). Ultimately however, we still
371 require the surgeon to be in control analogous to the current situation where we would not
372 yet be comfortable travelling in a non-piloted aeroplane. A wider more philosophical question
373 raised would be whether robotic surgery could one day replace surgeon involvement
374 completely.

375

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

382

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

387

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

392

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

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