

Results of total hip replacement using the Robodoc surgical assistant system: clinical outcome and evaluation of complications for 97 procedures

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Abstract

Background A computerized robotic surgical system was developed from 1986 by the Thomas J. Watson Research Center. In 1992 the system unit Orthodoc[®] and the milling robot Robodoc[®] were first used on humans. We present the results achieved with Robodoc-assisted total hip arthroplasty in 97 hips.

Methods Between 1997 and 2002, 143 total hip replacements (128 patients) were performed using the Robodoc system. This is a consecutive series. Complete follow-up was possible in 97 hips at a mean follow-up period of 3.8 years.

Results Technical complications directly related to the robotic device occurred in nine cases (9.3%). The pre-operative Merle d'Aubigne score was determined at 8.1 points compared to a post-operative mean score of 16.2. There was no sign of femoral stem loosening on radiographs.

Conclusions Robotic-assisted total hip arthroplasty with the Orthodoc/Robodoc system achieves equal results as compared to a manual technique. However, there was a high number of technical complications directly or indirectly related to the robot. Copyright © 2007 John Wiley & Sons, Ltd.

Keywords total hip arthroplasty; robotic; outcome

Introduction

To improve the results for permanent fixation in cementless total hip replacement (THR), a computerized robotic surgical system was developed from 1986 by the Thomas J. Watson Research Center (IBM, USA) with Davis University in California (1). The company ISS (Integrated Surgical Systems, Sacramento, CA, USA) further developed a planning and robotic system, which consisted of the planning unit Orthodoc[®] and the milling robot Robodoc[®] (1). After clinical trials on dogs, in 1992 the system was first used on humans (1). The first clinical use in Germany took place in the summer of 1994 at the Berufsgenossenschaftliche Unfallklinik (BGU) in Frankfurt (2). In the subsequent 10 years the Robodoc system has sometimes received harsh criticism regarding the technique, results and complications caused by the system (3–10). Because of this, the French subsidiary, ISS SA (formerly IMMI) was brought into the French bankruptcy court and no further support was provided to its users. ISS filed with the U.S. Securities and Exchange Commission

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(SEC), stating that it had 'ceased operations and terminated all employees'. As a result, there are no systems remaining in clinical use in Europe. About 2 years later, ISS resumed operations and subsequently sold its assets to Novatrix Biomedical in June 2007 (11). There were reports about high accuracy and stability achieved by the technique (5,12–14); on the other hand, conflicting results have been reported regarding the amount of soft tissue problems and gait anomalies found (9,14–16).

In 1997 we introduced the Robodoc[®] robotic system for total hip arthroplasty (THA) in our institution. The rationale for the acquisition of such a system was first to optimize the implant size and orientation, and second to optimize the accuracy of the created cavity. We hoped thereby to gain a significant increase in primary stability and an improvement in long-term results. Optimized osteo-integration of the implant was a major goal and the resulting load transfer from implant to bone was thought to have a decisive effect on the durability of the prostheses. As a trauma hospital, we treat a comparatively high number of post-traumatic deformities, resulting in the need for THA. To monitor and analyse the results of this completely new technique, we enrolled all patients treated with the Robodoc for a clinical trial. The aim was to identify complications directly during the use of the robotic system as well as in the post-operative period. Retrospectively we then analysed these data and performed follow-up examinations, including scoring systems and radiographs.

As the Robodoc system is still in clinical use in India, South Korea and Japan and a FDA trial (17) is coming to an end, we thought it of value to report the results gained with the assistance of the Orthodoc/Robodoc system.

Patients

Between February 1997 and October 2002, 143 total hip replacements (128 patients) were performed using the Robodoc system. This was a consecutive series. No hip replacements using this system were performed after this time at our institution (see Figure 1).

- **Inclusion criteria:** considered for inclusion were all patients with an indication for cement-free THA.

Patients had to be able to give informed consent to the study.

- **Exclusion criteria:** age <18 years, revision THA, not able to give informed consent.

The mean age at the index procedure was 56 (median 59, range 19–75) years. 89 hip replacements were implanted in male patients (62%). The reason for THA in 76 (53%) patients was idiopathic arthritis of the hip, in 43 (30%) the arthritic deformity was due to a post-traumatic condition (mainly after fractured neck of femur in 23 (54%) cases). Eleven (8%) patients had dysplastic hips and in 13 (9%) osteonecrosis of the femoral head was the reason for THA (see Table 1). Pre-operative data included a general examination, measurement of range of motion, determination of leg length inequality and radiographs.

In three cases (2.1%) the robotic operation had to be stopped due to a technical fault of the robot and a conventional THA had to be performed; these patients were excluded. One patient developed a septic loosening (*Staphylococcus epidermidis*) and had to be revised. At follow-up, 23 patients (25 hips) could not be traced. Overall, 14 patients (15 hips) refused to take part in any further follow-up regarding this study. Two patients died of unrelated causes. All these cases had to be excluded from the study, leaving 85 patients (97 hips). The eventual follow-up rate is therefore 68% of implanted hip replacements.

There was no statistical difference ($p > 0.05$) in the group of all patients and the group that completed the study protocol. In the group of 97 patients with complete follow-up, statistical differences were detectable in the group with post-traumatic arthritis compared to patients with non-traumatic arthritis for the items age (50 vs.

Table 1. Aetiology of arthritis in all procedures and patients who completed the study protocol

Aetiology of arthritis	n (%)	Follow-up completed n (%)	χ^2
Ideopathic	76 (53)	56 (58)	n.s.
Post-traumatic	43 (30)	26 (27)	n.s.
Dysplasia	11 (8)	7 (7)	n.s.
Osteonecrosis	13 (9)	8 (8)	n.s.
Sum	143 (100)	97 (100)	

n.s., not significant.

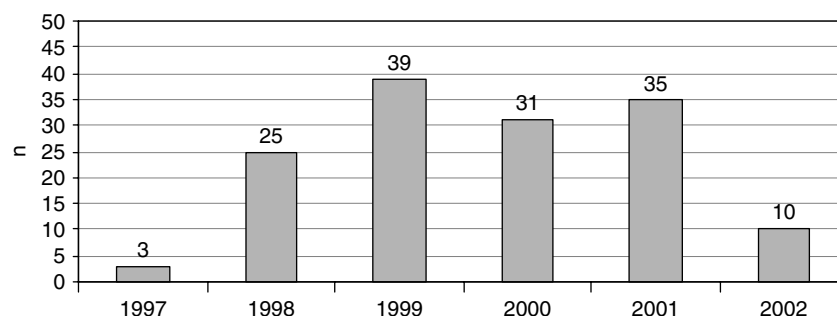


Figure 1. Robotic-assisted THA performed per year over the study period (n = 143 hips)

61 years) and number of previous procedures ($p < 0.05$). Although the rate of technical complications was 16% in post-traumatic vs. 9% in non-traumatic arthrosis, the difference was not statistically significant.

Methods

A modified transgluteal approach, as described by Bauer (18) was used in all cases. As a first step, two reference markers in the form of titanium pins were implanted at the medial femoral condyle and the trochanter major, respectively (the pinless version of the Robodoc system was not used in this study). This was performed under local anaesthesia 1 day before the intended THA. After this, a CT scan, with approximately 80 slices of the proximal femur and 10 slices of the distal femur, was taken and transferred to the Orthodoc planning station. With a colour-coded three-dimensional (3D) graphical display, the planned prostheses was chosen from an electronic catalogue and positioned by the surgeon. Positioning was possible in all directions, including rotation; the accuracy was stated by ISS as 0.1 mm axially and 1° rotationally (19). The data were then transferred to the Robodoc.

After manual implantation of the acetabular component, the femur was fixated and the reference markers were digitized with the robotic system for matching with the CT data. The path to the femoral canal had to be completely free of soft tissues to allow the required working space for the robotic arm. Detection of significant movement of the femur relative to the robot during the procedure led to an immediate stop; the reference points had to be sought again and the milling had to be re-started. During the milling procedure, the milling process could be visualized on a graphical display; milled bone particles were removed using high-pressure irrigation. After that, the femoral component was manually inserted and the procedure finished with placement of two wound drainages and wound closure in anatomical layers. For the acetabular component, the cement-free Osteoloc system (Howmedica, Rutherford, New Jersey, USA) was used in all cases. The femoral component consisted of a cement-free implanted ABG II prosthesis (Howmedica) in all cases.

The surgeon filled out a sheet detailing the intra-operative problems and complications, divided by surgical, technical and anaesthesiological issues. Single-shot antibiotic prophylaxis (Cefuroxime i.v.) was used in all cases; no antithrombotic pneumatic device was used intra-operatively. All patients received anti-thrombosis stockings and subcutaneous low-molecular weight heparin in the post-operative period. Ossification prophylaxis consisted of twice-daily 50 mg indomethacin for 10 days. In 31 (32%) cases this had to be terminated, due to side-effects.

Follow-up examination took place on average 3.8 (range 2.9–5.3) years after the index procedure. The protocol for follow-up included a clinical examination, the Merle d'Aubigne Score–Postel hip score, radiographs

(pelvic view, 43 × 35 cm; axial Lauenstein projection, 20 × 40 cm) with comparison to direct post-operative radiographs and examination of signs of osteolysis and loosening under determination of the Gruen (20) and DeLee-Charnley (21) zones. The follow-up examination and data exploration were performed by an independent examiner (a general practitioner, A.v.H) who was not involved in any stage of the treatment.

Data and statistical methods

Data sampling of this study was prospective from the time of admission. Before follow-up examination, the data were extracted to a database. Data from the follow-up were added. The descriptive statistics were performed using SPSS version 11.0 (SPSS Inc., Chicago, IL, USA). For statistical calculations, non-parametric methods were applied (median, quartile). Means were compared with non-parametric methods; for the median, the Wilcoxon rank sum test was used.

Results

Evaluation of intra-operative and early post-operative complications

There were no anaesthesiological complications in this series. The rate of technical complications was 9.3%, the rate of surgical complications 8.3% (for details, see Table 2). There was no statistical difference detectable regarding patients with a post-traumatic or non-traumatic condition ($p > 0.05$).

Surgical complications

During the pin implantation, one Kirschner wire broke, one case of temporary lateral femoral cutaneous nerve damage occurred and one post-operative knee effusion was seen (3.1% complication rate by the pin insertion process). In one case, the acetabular component was implanted at a suboptimal angle and had to be revised during the procedure, due to a dislocation tendency. In one case, the acetabular reaming was performed too deep and bone grafting was necessary as a consequence. Once, a femoral shaft fissure occurred during reposition and a wire cerclage was necessary. Twice, intra-operative blood

Table 2. Evaluation of intra-operative complications

Intra-operative complications	Non-traumatic <i>n</i> (%)	Traumatic <i>n</i> (%)	All <i>n</i> (%)
None	60 (84.5)	20 (77)	79 (81.4)
Surgical	5 (7)	3 (11.5)	8 (8.3)
Technical	6 (8.5)	3 (11.5)	9 (9.3)
Complication rate	11/71 (15.5)	6/26 (23)	17/97 (17.5)

loss required the supplementation of two and three units, respectively, of packed red cells.

Technical complications

Technical complications directly related to the robotic device occurred in nine cases (9.3%). Five times the milling process was halted by the bone motion monitor and re-registration was necessary. Two femoral shaft fissures that required wire cerclage occurred during milling. Once the rim of the acetabulum was damaged by the milling device and once a defect at the greater trochanter was milled.

Post-operative complications

Early post-operative complications (≤ 30 days post-operatively) were noted in nine patients (9.3%). Three times a significant haematoma developed; in two of these cases the wound was revised. There was one dislocation 12 days post-operatively (1%); after closed manipulation there was no recurrence. Twice a superficial infection was noted that healed under conservative measures; there was no deep infection in this series. There were three cases of deep venous thrombosis of the ipsilateral leg (twice below knee, once popliteal); one of those developed a mild pulmonary embolism.

Two late complications included a symptomatic Brooker type 3 heterotopic ossification that was removed at 25 months post-operatively, and a painful scar that had to be excised at 11 months.

Results at follow-up

Clinical

A positive Trendelenburg sign was found in 17 patients (18%). The sign was positive in 12 patients (19.3%) with non-traumatic arthrosis and five patients (14%) with a post-traumatic condition. The difference was statistically not significant ($p > 0.05$). Leg length discrepancy of up to 10 mm was found in 19 patients (22%). A shortening of 10–30 mm was noted in 4/85 patients (4.7%); in three of these the shortening was pre-existing, due to a post-traumatic condition, and in one case a pre-operative shortening of 1.5 cm had increased to a 3 cm deficiency. Although this case occurred in the subgroup with a non-traumatic arthrosis, the difference was not significant ($p > 0.05$). The maximal flexion at follow-up was mean 107° (range $95\text{--}140^\circ$); the mean extension was 0.8° extension deficit (10° deficit to 5° hyperextension). The abduction was determined at mean 27° (range $0\text{--}50^\circ$). There was no statistical difference between subgroups.

Merle d'Aubigne score

The pre-operative Merle d'Aubigne Postel score (22) was determined with a mean of 8.1 points compared to a post-operative mean score of 16.2 (see Table 3); the difference was statistically significant ($p < 0.001$). There was a statistically significant difference between the pre-operative score result of patients with a traumatic condition and those with a non-traumatic condition ($p < 0.05$), but the difference of the post-operative score result showed no statistical difference ($p > 0.05$).

Patient satisfaction

Asked about their satisfaction with the procedure, 71 patients (82 hips, 85%) stated that they were satisfied; 15 patients (15 hips, 15%) were dissatisfied. In the group with post-traumatic joint deformity, only 71% of patients were satisfied with the result, compared to 92% in the subgroup with a non-traumatic condition ($p < 0.05$).

Radiological examination

In 41 hip joints (42%), heterotopic ossifications were found (Table 4). One of these patients had previously had an operation for the removal of symptomatic ossification (Brooker grade 3). Although Brooker grade 2 ossifications were found in four patients with a post-traumatic condition and in one case with a non-traumatic condition, there was no statistical difference in the subgroups with traumatic or non-traumatic arthrosis ($p > 0.05$).

Evaluation of the femoral component showed an osteolysis in Gruen zones 1 and 4. There was no sign of prosthesis loosening in any femoral component; all femoral components were found to be adequately sized. No component migration or subsidence was observed.

Table 3. Statistical evaluation of post-operative Merle d' Aubigne score ($n = 97$ hips)

Merle d'Aubigne Score	Non-traumatic	Traumatic	All
Mean	16.2	14.5	15.6
25%Quartile	16.0	13.0	14
Median	17.0	16.0	17
75%Quartile	18.0	17.0	18
Standard deviation	1.96	3.72	2.8

Table 4. Number and percentage of heterotopic ossifications according to the Brooker (23) classification at follow-up ($n = 97$)

Brooker grade	Hips n (%)
None	70 (72.1)
Brooker 1	22 (22.7)
Brooker 2	5 (5.1)
Brooker 3	0
Brooker 4	0

Peri-acetabular radiolucencies around the acetabular component were noted in DeLee–Charnley zones at the following rates: none in zone I, two in zone II, and one in zone III. In addition, two implants demonstrated evidence of migration. There was no sign of excessive polyethylene wear in any of the prostheses.

Discussion

The Robodoc system for robot-assisted total hip replacement was initially designed to increase the accuracy of implantation by decreasing human errors (3). At the time of its development, it represented the most sophisticated piece of surgical equipment that the world of orthopaedics had experienced to that date. By its use, osteointegration was thought to be optimized and a longer-lasting prosthesis seat was hoped to result. Evident advantages of this procedure were the possibility of pre-operative planning and templating. Evident disadvantages were the increased theatre time, the direct cost increase and the necessity for a pre-operative CT scan. A further disadvantage of the system described here is the necessity for a further procedure to implant two pins before the scan. The early results of robot-assisted THA showed no significant short-term benefit regarding mobilization, rehabilitation or clinical result (9,14). Reports of a possible relationship between robotic THA and post-operative gait abnormalities led to great media coverage, especially in Germany (10), and a cessation of robot-assisted procedures in Western Europe (24).

The rate of general orthopaedic complications is in an area that is comparable to the described rates for manual implantation techniques (25–27). On the other hand, the rate of technical complications caused by the robotic system was worrying. In 9.3% of procedures, technical complications occurred. In 3.1%, these were caused by the pins required for registration; these were not required for the last available version of the Robodoc system. Although the application of these markers is often not mentioned as a cause of complications (2,3,28), Nogler reported about 10/18 patients having persistent severe pain at the site of pin implantation (7). Regarding the rate of transformations from robotic to manual technique due to robot soft- and hardware failure, a rate of 2.1% might seem high. Honl *et al.*, however, had to switch procedures in over 18% of cases; in four of their cases, the reaming process did not start at all (14). An unusual complication was the occurrence of fissures during milling in two cases (2%). So far this was thought not to occur in the robotic milling process, and has not yet been reported (2,14,28,29). This rate is about what can be expected in a manual technique (29–31).

The prosthesis model used in this study was shown in a computer simulation study to be favourable regarding the extent of muscle detachment produced by robotic milling (14). We found a Trendelenburg sign in 18% of patients after robotic THA at follow-up examination; in

studies reporting the results of manual THA via the same approach, the reported rate is 13–19% in medium- to long-term follow-up (32–36). We therefore can see no evidence that robotic THA, at least with an anatomically-shaped stem, increases gait abnormalities compared to conventional implantation. This is supported by a study analysing gait patterns in patients after Robodoc THA and comparing these to a control group with a conventional technique (15).

The discrepancy in leg length that often exists in post-traumatic arthrosis can often not be equalized during hip arthroplasty. The same restrictions occur in robot-assisted procedures and left three patients with a leg shortening of more than 1 cm; in one case the reason for this was faulty planning on the Orthodoc, a complication so far not described in the literature. The dislocation rate of 1% is a good result and in contrast to the 18% reported by Honl *et al.* (14). In this study, the conceptually quite different S-ROM prosthesis, which has a straight stem, was used, requiring an entirely different milling path and thereby possibly causing more soft tissue impairment (14).

The result as judged by the Merle d'Aubigne Postel (22) score was good, with an improvement from 8.1 points pre-operatively to 16.2 points at follow-up. This 8.1 point improvement is in the range of what has been described before and after robotic THA (12,14,16). More importantly, there is no evidence that, at least in short and medium outcomes, the results with the Robodoc system are superior to those with manual implantation techniques, with reported Merle d'Aubigne score improvements of 6.6–8.8 points (25,30,31).

The reported rates of loosening of the ABG II stem after manual implantation have so far been low (0–2%) on medium-term follow-up (25,30,31,37). It is thought that this is due to improved early osseointegration of this prosthesis model with its hydroxyapatite (HA) coating (38). Equal results can be reached after robotic implantation, but there is no sign that results are better with a robotic technique. The evaluation of osteolysis in the different Gruen zones (20) showed a low amount of osteolysis as compared to manual implantation (25,30,31,37,39). It has been shown, however, that the amount of periprosthetic osteolysis is largely dependent on the type and concept of prosthesis used (39,40); with our data we are not in a position to state that robotic milling decreases the amount of osteolysis. A rate of trochanteric ossification of 27.8% is in the range of what is also to be expected after manual implantation (41,42). We could see no evidence that the milling process, with its large amount of debris, increases the rate of ossifications.

In conclusion, we were able to show that the results of robotic-assisted total hip arthroplasty with the Orthodoc/Robodoc system achieves equal results regarding functional outcome, radiographic outcome and general complications as compared to a manual technique. At the follow-up period reported, there is no evidence that at medium-term follow-up a robotic technique is superior in any of the areas examined. On the other hand, there was a high frequency of technical

complications directly or indirectly related to the robot. The Robodoc had a very simple and plump milling device; it is likely that this could have been improved if the development of the system had not halted. Future systems should address the complications of former systems and the current trends in minimally invasive procedures.

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