Robotic systems in total hip arthroplasty – is the time ripe for a new approach?

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Abstract
The technical aspects of manual total hip arthroplasty are briefly described. The development, technique and technical problems of previous robotic systems in total hip arthroplasty are described with special details of the Robodoc®- System (1). Recent advances regarding the minimally invasive technique of total-hip implantation and navigation are described. The current development of a robotic assisted system for total hip arthroplasty is presented. This project aims to combine the advantages of minimally invasive techniques and navigational systems with the accuracy that robotic assisted bone milling can provide. The project-name is RomEo® (Robotic minimally invasive Endoprosthetics), the main project partners are the Helmut-Schmidt-University/Hamburg and the Department of Trauma and Orthopaedics of the BG Trauma Hospital Hamburg.

Keywords: Medical Robotics, Hip Arthroplasty, Minimally Invasive Surgery, Bone milling

INTRODUCTION
Surgical robotic technology was initially anticipated to provide a precisely shaped and orientated cavity for hip surgery. For several reasons, many of these robotic systems have been withdrawn or have not become established in the market. This leads us to the question how a new approach such as RomEo could be beneficial for the orthopaedic world.

TOTAL HIP ARTHROPLASTY – THE STANDARD MANUAL TECHNIQUE
One of the main factors influencing the surgical success of cementless total hip Arthroplasty is the precision of the implantation. Although the idea of an artificial hip implant is much older (2, 3), the technique has been mainly developed in the 1950s and 60s (4–6). The surgical access routes have been modified over the time, optimizing soft tissue disruption (7–9). The tribology and design of hip implants have been modified and redefined since their initial development. Nevertheless the standard technique of this operation is rather imprecise with a somewhat “blunt” surgical technique. Preoperative planning uses acetate templates, showing the outlines of available implants, enlarged by the approximate factor of enlargement of conventional radiographs. These are then laid over the x-rays of the patient. The implant that seems to fit best into the cavity outlined in the x-rays is predetermined for use during the operation. In the operating
In the medical world, the operative, anatomical factors, the access route chosen and the preference as well as the experience of the surgeon. After exposure and dislocation of the hip, the neck of femur is cut in an angle and length that is predetermined by the type of femoral implant. This cut is performed “free-hand”, depending on hand-eye coordination and experience of the surgeon. After this there is free access to the acetabular fossa. With rotating reamers of ascending diameter the cavity for the socket of the prosthesis is formed. This is achieved between the operating table and an axis of the contralateral side. If the patient is positioned sideways, this is done in a way that an angle of about 90° is achieved between the operating table and an axis through the anterior superior iliac spines. An incision of on average between 12 to 25 cm length is made over the hip area, exact length and localisation depending on anatomical and physiological factors, the access route chosen and the preference as well as the experience of the surgeon. Same applies to the operating table because experience will allow to take this into account. Same applies to the acetabular orientation, even if there are 1, 2 or 3 theoretical definitions.

Nevertheless in 1992 Paul et al. reported on a research project of the Californian company ‘Integrated Surgical Systems’ together with the IBM-Watson Research Center and the IBM-Palo Alto Science Center regarding the development of a precise surgical robot for cementless hip arthroplasty. This robotic system later was named “Robodoc®”.

HIP ARTHROPLASTY – ROBOTIC SYSTEMS IN THE PAST

The motivation for development of such a system was described with two reasons: Firstly to optimise the implant size and orientation of the implantation, secondly to optimise the accuracy of the created cavity. In the past there have been two major surgical robotic milling systems in hip surgery, the Robodoc® and the Caspar®.

The Robodoc®-system was developed and marketed by Integrated Surgical Systems Inc. (ISS) in Sacramento, California. First clinical trials with the Robodoc®- system were on isolated femoral specimens and canines. In 1992 the ISS received the US Food and Drug Administration (FDA) authorization for clinical trials with human total hip replacements. The Robodoc® surgical system consisted of the Orthodoc® pre-surgical planner and the Robodoc® as the surgical tool. The Robodoc® composed of a five-axis Sankyo-Seiki industrial robot with an added six degree-of-freedom force-sensor. To assess the robot’s position redundant sensors were used. For a milling system a standard surgical high speed cutting tool was used.

The robot was mounted on a movable base and its arm could position the milling tool at any angle.
or location within the effective range. The robot arm movement was controlled by an industrial computer (IBM PC/AT). On commencement the robot was wheeled to the operating table and the base rigidly fixed in place. To secure the femur and to immobilise it in relation to the base a fixation device was used. Interaction between the robot and the surgeon during the course of operation was conducted with a gas sterilised hand-held terminal (pendant). This pendant supported motion, start/stop, manual guiding, emergency power on/off and similar functions. With help of the pendant the overall sequence of steps was controlled and it was possible to select error recovery routines.

Traditionally, as described above, the surgeon plans a total hip arthroplasty using acetate templates as overlays on plain radiographs to select an implant and plan its placement within the femur. The preoperative planning system (Orthodoc®) provided 1992 from Integrated Surgical systems/IBM (12) used digital data to describe the three-dimensional geometry of the femur from CT data and the geometry of the implant.

The Orthodoc® program was developed to run on an IBM RS/600 computer and the CT data of the femur was entered from a nine-track magnetic tape. The system created sagittal, coronal, and transverse images of the femur and the differing densities of the bone were represented by different colours, as determined from the Hounsfield units on the CT tapes.

During the preoperative planning the surgeon selected an implant from the library of implant shapes and sizes in the planning program. After selection, the image of the implant was placed on the desired location for implantation using a PC mouse. Simultaneously, the coronal, sagittal and transverse views of the femur and implant were displayed on the computer screen. This allowed the surgeon to rotate, move and change until the selected implant and its orientation were as required. The preoperative plan was stored on a tape cartridge.
that contained all of the data required by the robot. The robot then milled the planned cavity and orientation with respect to the three calibration pins in the femur. In the third generation of the product the patented THA Pinnless DigiMatch™ Single Surgery Application was embodied. This allowed robotic surgery to be performed without the need of a primary placement procedure (1). This advanced technology achieved accurate registration by matching the image of the surface of the bone to actual surface points gathered at the time of surgery.

The surgical procedure with the Robodoc®-system can be described as follows (12): Before the operation started, the robot had to be calibrated and placed in the standby mode. After that the surgeon started with the exposure of the femur in the standard manner. Then a femoral neck osteotomy had to be performed 2–3 mm proximal to the desired cut. The acetabulum had to be prepared manually for the installation of the acetabular cup.

The femur of the patient had to be secured by a femoral fixator. For setup of the system the surgeon installed a ball probe at the robot end effector. The
probe was then manually guided to the vicinity of each calibration pin by using the pendant to initiate a tactile search program. This program allowed the robot to locate the exact location on the centre point on the top of the calibration pin. To determine a discrepancy between the relative location of the three pins in the data plan, and their actual location in the femur, the system performed a transformation between the coordinate system of the patient, and the planning system. If there were discrepancies, an error recovery routine was activated and the calibration pins had to be relocated. The surgeon replaced the ball probe with the cutter after the calibration pins were located and the coordinate transformation was successful. Then the milling process was initiated. The operation process was directly visualised through an online display, which showed the position of the cutter on the CT images used in the preoperative plan. After completing the cavity of the femur, the robot system was moved away from the operating table. The surgeon then installed the implant and finished the operation in the usual manner.

The Caspar® surgical system was a similar product to the Robodoc®. The development of this robotic

Figure 6  MIS-Instruments, Acetabular reamer handle and head, cup inserter and femoral head application tool (pictures supplied by Biomet-Germany, R+D).

Figure 7  MIS retractor system, here the Omni Access™, Keggi™ minimally invasive retractor system (Picture Supplied by Omni-Tract, Stephan und Partner, Germany).

Figure 8  Intraoperative implantation of the hip-loc© marker and acquiring of the Lewinnek reference points (28).
The system was a cooperation between Orto Maquet, Rastatt (Germany) and the Friedrich Alexander University, Erlangen (Germany). It was marketed in 1998 by Orto Maquet. The system consisted of the Caspar® robot and the preoperative planning station, the Proton®. The Caspar® was a Stäubli RX90 industrial robot and had six degrees-of-freedom. The Proton® planning station was in its

**Figure 9** After sterile draping, the reference point of the hip-loc® device is acquired again. The retro-reflective markers are clearly shown. Then the femoral data can be gathered.

**Figure 10** By determination of surface points and rotational axis, a 3D reconstruction of the anatomy is computed (Picture supplied by Praxim, La Tronche/France).
functions comparable to the Orthodoc® (ISS). It displayed a sagittal, coronal and transverse image of the femur.

The Robodoc®-system came under public pressure after a while. The reason for this was mainly the extensive soft tissue exposure needed during this operation (18). Some patients developed a limping gait and sued the operating surgeon and the manufacturer of the robotic system.

An extensive risk-benefit study (19) by the medical examiners service of the German health insurers (including a meta-analysis of all published studies) came to following conclusions with regards to the Robodoc®-System:

- The Orthodoc®-System is a reliable tool for the preoperative planning, the Robodoc® can follow this planning with a high accuracy;
- No evidence was found that these precisely implanted stems have a higher primary stability or osseous integration. The functional results where initially better than in manual implantations, at 2 years equal;
- The pain caused by the pin implantation was a robot-specific complication, a second operation for pin implantation required a further anaesthesia, operative time was longer than with manual implantation;
- Luxations, nerve damages, wound infections and revisions were found to occur significantly more often in robotic implantations compared to manual operation in a meta analysis of randomised trials.

Overall the presentation of research data in the Robodoc® project was criticised and it was recommended to all surgeons using this procedure to clearly identify the robotic implantation as a trial under scientific investigation rather than a standard procedure. Due to the extensive and largely negative media coverage, most surgeons stopped using robotic systems for hip surgery. The ISS Robodoc® has still no clearance of the US-FDA for general usage on humans. Courts in Germany have ruled for a surgeon in 2004, stating that the Robodoc®-operation was not medically negligent (20).

MINIMALLY INVASIVE HIP ARTHROPLASTY – RECENT DEVELOPMENTS

Over the past decade there has been a general trend towards smaller incisions and soft tissue protection. The general approach towards the hip joint remains the same. Possibly with the exception of the direct anterior approach and the two incision technique (21, 22), the approach to the hip joint is a variation of the standard access. Although the initial drive in the development was derived from a better cosmetic result in a more and more competitive orthopaedic world, recent clinical follow up studies seem to indicate that also quicker rehabilitation and hospital discharge is possible with these advanced techniques. In Minimally invasive surgery (MIS) - procedures, the amount of soft tissues (muscles and tendons, etc) that are disrupted during surgery is reduced.

With new implantation aids like the curved acetabular reamer driver, trial head placement clamp, curved acetabular cup impactors and broach handles it could be shown that incisions of about 8 cm are possible (23). These tools are now produced and clinically tested by all major implant manufacturers. Hand in Hand with this, newer retractor systems like the self retaining Omni Access-Keggi™ minimally invasive retractor system have reached the market. These allow good visibility with atraumatic soft tissue handling.

Although the advantages of the new lesser invasive approach are not as big as initially expected (24, 25), first mid-term follow up also suggest a reduced transfusion need, earlier ambulation and better functional result (22, 26).

Furthermore it could be shown that there is no increased risk of deep wound infection, dislocation and malpositioning after the minimally invasive approach (24, 26).

The most recent development is the combination of a minimally invasive hip approach with a surgical navigation-tool (27).

NAVIGATION SYSTEMS IN TOTAL HIP ARTHROPLASTY

A further advance in recent years is the introduction of navigation systems for use in hip surgery. After successfully developing navigational systems in the field of knee and spinal surgery, it is now possible to computer assist the surgeon with inclination, ante-version and impactor/reamer position, in real-time.

There are several systems with different technologies entering the market. The OrthoPilot® by Aesculap (Tuttlingen, Germany) has been used in more than 40,000 patients, especially for knee surgery. The system works by implanted wires and sensors. These sensors allow the computer to track
the position with infra-red technology. A probe with another infra-red sensor marks out the bony anatomy.

Another system for image-free navigation is BrainLAB (Heimstetten, Germany), which uses preoperative CT scans or intraoperative Bone Morphing® software and infrared navigation during the operation to permit accurate reaming.

The system that the BG Trauma Hospital in Hamburg has experience is the Surgetics® Station by Praxim (La Tronche/France). After successfully using this system in spinal and knee applications, it has now been introduced into hip-arthroplasty navigation.

The Praxim–Surgetics® Station is an open platform supporting a number of computerised surgical protocols for different applications, which are specially adapted to specific surgical applications and techniques such as a knee implant or anterior cruciate ligament positioning.

This navigation system utilizes two infrared light emitting cameras which receive their signals back by disposable retro-reflective markers. It is a passive system without the need for wiring between these components. These markers are mounted in a specific way on different tools and anatomical landmarks and allow for a micro-millimetre exact positioning navigation aid. The visualization can be based on anatomic data obtained from imaging sources including X-rays, MRI, CT Scans, fluoroscopy, ISO-C 3D, or even Ultrasound.

Additionally, a system called Bone Morphing® has been developed that allows the computer to build 3D models of the patients bones directly during surgery, without any additional imaging tools. This is achieved by taking a large set of bone surface points with a pointing tool after surgical exposure (29, 30).

The software uses Bone Morphing® to reconstruct the anatomy of the hip, enabling the surgeon to measure the variation, the length and the lateralization of the lower limb. This device is universally usable for different implant types and manufacturers.

During manual reaming and cup implantation, the exact inclination and anteversion of the surgical tool is determined by retro-reflective markers on the tool in use (see Figure 11). Via the screen the surgeons then gets the feedback in which position the optimal angles are reached, then reaming or implantation can be started. During the process there is real-time feedback if the position is still correct. Due to the high level of accuracy the correct implantation of the acetabular cup component can be achieved.

ROBOTIC ASSISTED MINIMALLY INVASIVE ENDOPROSTHESIS – THE ROMEO PROJECT

The aim of the current ROMEO project is to combine the advances that have been made in hip surgery in the last years with a robotic milling system of highest accuracy. The goal is a system that will use a minimally invasive surgical approach and a 3D guiding navigation system in a soft tissue conserving manner.

The problems occurred with the Robodoc® and Caspar® system have been intensively studied. From the very beginning the focus was on identifying, addressing, solving or diverting the problems that had not been addressed in the above mentioned systems.

Experience with more than 150 Robodoc® implantations in the BG Trauma Hospital in Hamburg, proved the Orthodoc®/Robodoc® system to be highly accurate. This is also shown in the mid-term radiographic outcome and will be published later this year.

The soft tissue problems have been published, e.g. by Bach in a follow-up study (31), the patient satisfaction was not correlated to this issue in the follow-up study at the BG Trauma Hospital in Hamburg.

Analysing the technical and medical aspects of the Robodoc®-system, the ROMEO project team came to the conclusion that a technical advanced solution had been developed with some major problems regarding the medical usability. The Robodoc®-system was first used for hip replacements on canines. It was then optimised and adapted for the surgical use on humans (12).

The ROMEO project aim is to design a specialised system in particular for the use on humans. Achieving this requires development of good working relationships between engineers and surgeons. Cadaver-studies are providing the opportunity to fashion the system to the human anatomy, not vice versa. In laboratory use, the Voxel-Man® (32) data provides the opportunity to simulate the anatomy and the interacting surgical system in Computer Aided Design (CAD). So, the operative process can be visualised and simulated to optimise the surgical robot system.
The ROMEO project is strategically split in several phases. Starting with the determination of technical and surgical aspects of a minimally invasive approach as well as technological parameters of the robotic process (e.g. bone milling). Currently the main focus is on the engineering process of the milling tool and intraoperative patient fixation.

As a next step the robot system will be implemented with a navigational tool and the sensor technology to survey process parameters while surgery.

After study of the literature regarding the technical aspects of bone milling, drilling and reaming (34), it was concluded that further information regarding the behaviour of human bone during robotic milling were required. Several experiments on the milling behaviour of bones and their structure have been conducted in the laboratories of the Helmut-Schmidt-University. Figure 12 demonstrates the test setup with bovine bone. These investigations have focused on the mechanical behaviour of bone while milling with different cutter forms and sizes in the layers of the bone. The temperature was measured by using a resistance thermometer (PT 100). These parameters are incorporated into the development of tools and equipment.

A further step was a study of the feasibility of the above described minimally invasive surgical access routes with a robotic device. The project team came to the conclusion that a successful device will either have to have the capability of one or two degrees of freedom (DoF) inside the milling area, or the capability to work around the corner. This corner
Figure 13  Cadaver feasibility studies with end-effector dummies, utilizing a minimally invasive surgical approach.

Figure 14  Volumetric determination of a minimally invasive approach in cadaveric studies is used for the development of the 3D robotic workspace. Here shown (a) acetabular and (b) femoral access volume in a dorsolateral approach.
was determined in cadaveric studies of different sex and weight to be an angle between 35–70°.

Therefore a prototype of a milling device has been developed that can mill at an angle as described previously. The angle of the end-effector is fixed, but can easily be changed into one with another angulation. Due to patent right issues this device can not been shown here.

To keep the time for the surgery as short as possible, two different specialised devices, to prepare the cavity of the femur and the acetabulum, are under development. The exchange of those two systems as an end-effector of the robot has to be easy and fast, therefore a special connector still needs to be developed.

A further problem which was encountered during interdisciplinary discussions was that of the work-space of the robotic arm, inside the patient. It soon became obvious, that the wound cavity that was produced by the surgeon during the operation and held open by devices applied by him was difficult to specify accurately. In addition the orientation of this cavity relative to the pelvis and the femur are not specified in the medical literature, or only in a descriptive manner. It was found to be helpful for the planning of robotic movements, to determine the exact volumetric data for the different access routes to the hip and proximal femur. These were therefore determined in a cadaveric study, using different standard routes for minimally invasive hip Arthroplasty (see figure 14).

Integration of a navigational system into the robotic milling process is the next planned stage; this would be a solution for the Robodoc®-problem of a near-total patient fixation. Only small locator-pins would be required. The leg of the patient could be placed more loosely into a leg holder. This is also in development at the moment.

OUTLOOK FOR THE FUTURE

As the next big step, the robotic end-effector for the milling process is build as a 1:1 fully working prototype. In addition a force-feedback control for the robotic system is also needed. An integrated patient fixation and self retaining wound access system have to be developed.

The end effector system needs the capability to mill at an angle and the ideal speed and driving system of this novel device will have to be determined.

To control the robot motion an adaption of a standard industrial robotic controller is planned for the specific needs of this project. A further characteristic required is an off-line planning system for the milling path generation, thus enabling the system to adapt to different types of industrial robot systems.

Figure 15  After digitalisation, the acquired data is used for computer simulation of robotic kinematics.
Therefore the aim of this project is to combine the accuracy of robotic milling including its primary fit of the prosthetic bed, with the minimally invasive surgical technique. As a result, dramatic reductions of hospitalisation and rehabilitation needs are anticipated. This will enable health care providers in the competitive health care market to benefit financially whilst increasing patient satisfaction at the same time.

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