Current Concepts in Robotics for the Treatment of Joint Disease

Guest Editors: Michael A. Conditt, William L. Bargar, Justin P. Cobb, Lawrence D. Dorr, and Jess H. Lonner
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Editorial

Current Concepts in Robotics for the Treatment of Joint Disease

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1. Introduction

Adoption of a new technology in surgery today is subject to assessment by many stakeholders. These include surgeons, patients, hospitals, regulators, and payers. The fundamental tool for assessment is the determination of “value.” But value has different meanings for each of the stakeholders. The usual definition of value is “outcome divided by cost.” Although cost is usually measured in dollars, the measures for “outcome” are not clearly defined nor agreed upon. What follows is an attempt to define the value of robotic surgery in joint replacement surgery for each of the stakeholders.

First, however, we need to understand that the primary value of robotics in joint replacement is the reduction of human error by improving accuracy and precision. This is the same value that has resulted in adoption of robotics in most manufacturing processes. A major part of quality control in manufacturing is optimizing accuracy and precision by reducing human error. Surgery, however, is a blend of intelligence, art, and skill. There are many human skills that are poorly performed by robots and vice versa. The appropriate use of robotics in joint replacement surgery is intended to improve the accuracy and precision of implant selection and placement as well as execution by bone preparation. The goal is not to replace the surgeon but to enhance the surgeon’s performance. Robotics offers a tool that enables the surgeon to reproduce his/her best performance on a consistent basis.

2. The Surgeon

Surgeons assess the value of new technology in terms of the outcome of their patients as well as the effect on their practice. The academic assessment of patient outcome has seen a shift over the last 10+ years from surgeon-assessed measures (like the Harris Hip Score or original Knee Society Score) to patient-assessed measures (like the WOMAC or SF-36). Recently, it has been recognized that more sensitive measures like visual analog pain scales and patient satisfaction surveys are needed to assess differences in higher levels of function. Although surgeons follow the publications of these academic outcome studies, the practical assessment of patient outcome by the surgeon is a much more subjective process that is both surgeon specific and practice specific.

Surgeons are concerned with performance. In this way they are like professional athletes. Golfers prepare by using “positive swing thoughts,” and quarterbacks focus on execution of a pass play not the last time they threw an interception. Similarly, surgeons focus on how to achieve the best performance for each surgery they attempt. As they mentally prepare for their performance, they necessarily focus on their past successful surgeries. And, just like the athletes, they tend not to focus on their prior mistakes or failures. This is necessary and effective prior to and during the performance of a surgery. After the surgery, however, the best surgeons and athletes analyze their performance critically.
They acknowledge their mistakes and determine ways to prevent them in the future. But most surgeons, like most athletes, tend to gloss over their mistakes and remember their successes. This makes it difficult for them to determine the value of a technology like robotics that is designed to reduce human error.

The economic impact of adopting robotics on the surgeon’s practice has potentially both a positive and a negative effect. By using a technology that improves the accuracy and precision of their surgeries, they may attract more patients. Some surgeries, however, at present require longer operating times (10–20 min). This can have a negative economic effect if the surgeon is doing many joint replacements in a single day. But, for most surgeons doing only a few joint replacements in one day, the extra time would not allow the addition of another case. There is also additional time required for preop planning for robotic surgery (10–15 min). But, again, for the usual surgeon doing only a few cases each week, this additional time may not be significant.

3. The Patient

Cost is usually not an issue for the patient when determining value, since most are covered by insurance and usually no additional charges are passed on to the patient. Patients, however, obviously want the best outcome. Outcome can mean different things to each patient. Indeed, a large part of obtaining an informed consent from a patient is explaining to them what to expect in terms of pain, function, and limitations as well as reviewing the usual risks. What about the risk of using robotics?

There is an inherent fear of robots on the part of patients. In part, this is due to Hollywood movies and their fascination with robots that go crazy and cause havoc. But patients are also concerned that robots, like computers, may have “bugs” in the programming or “crash” like their home computers. Will the robot go crazy? This is where it is helpful to explain to the patient how the development of robots in industry over the last 30+ years has virtually eliminated robot error by the use of redundancy and internal safety checks. The engineers designing robots take Isaac Asimov’s First Law of Robotics seriously: a robot is not allowed to harm a human. Only human error can result in robot error. In this case, the human is the surgeon. In robotic surgeries, the surgeon has some very important responsibilities: select the best size and type of implant for the patient, position it appropriately, and provide the robot with a workspace such that no soft tissues are damaged.

It is quite a big step for a patient to surrender his or her body to a surgeon for an invasive procedure. It is also a very subjective and emotional decision for the patient. Once they have decided to have the surgery, they want to have faith in their surgeon. They want to believe that their surgeon is the best. Again, this presents a problem when telling patients about using a technology that reduces human error. They really do not like to think about their surgeon making errors. Here, another reference to sports may help. If you ask the patient who the best golfer in the world is, and then ask if he always hits the ball in the middle of the fairway, they will realize that even the best human skills are subject to error. In this way, they will be much more receptive to the use of robotic technology.

4. The Hospital

In my experience, hospitals are only concerned about patient outcome in so far as it might relate to complications that arise within the first 90 days. For hip replacement, robotics can help in reducing early dislocations as well as intraoperative fractures, but otherwise the use of this technology offers little to reduce short-term complications.

Hospitals are most interested in cost and return on investment “ROI.” Robotic systems can cost the hospital more than $1 million. There are some small potential savings for the hospital in terms of reduction of inventory and less use of conventional instruments, but these “soft costs” are difficult to measure. The true beneficiaries of reductions in inventory and instruments are the implant manufacturers. In the future, the hospital may be able to negotiate a lower price for implants used in robotic surgeries.

The cost of the technology to the hospital is mainly offset, however, by attracting new patients and “filling beds,” preferably with non-Medicare and non-capitated patients. There is also the so-called “halo effect” where new technology can attract patients that have other health problems which can result in increased admissions and testing for other conditions. If a preop CT scan is done (which is required by some robotic systems for preoperative planning and mapping), this may either be an additional source of revenue or expense for the hospital depending on contracts with payors.

5. Regulators

The US FDA defines value in terms of safety and efficacy. These requirements were stipulated in the 1974 Medical Device Act which basically said that medical devices should be treated in the same way as pharmaceuticals. They established two different pathways to FDA clearance: the so-called 510K pathway and the “Premarket Approval” pathway. The 510K process is for devices that can be shown to be “substantially equivalent” to a device already approved by the FDA. The Premarket Approval process is for a new device with no substantial equivalence to a device already on the market. Most new orthopaedic devices are cleared by the 510K process, since the Premarket Approval process is very costly and usually takes many years. For robotic device manufacturers, the issue of showing substantial equivalence to an existing device has been problematic. In the past, the 510K process did not require new clinical data, whereas the Premarket Approval process requires randomized controlled clinical trials. Recently, however, there has been a trend to require clinical data for many 510K applications. This may be in response to significant problems with some 510K devices after they have been cleared and in general use (e.g., metal-on-metal hips).

Beginning in the late 1990s, a third requirement (in addition to showing safety and efficacy) has been added for clearance called “clinical utility.” This is not defined by the FDA.
In fact, they usually ask the applicant to define the clinical utility of the device. Usually this has something to do with cost-effectiveness. The criteria for meeting the clinical utility standard are not clearly understood.

When it comes to evaluating the safety, efficacy, and clinical utility of robotics, there has been some confusion. Is a robot just a new more sophisticated tool to be used in surgery, like a smart reamer or saw? Are clinical data necessary? If so, how long should the patients be followed after surgery? If a complication arises, is it the tool that causes it, or is it the inappropriate use of that tool by the surgeon? Is there any real difference in control between semiactive (haptic) robots where the surgeon guides the tool but the limits of movement are restricted by the robot and active robots where the cut paths of the tool are guided by the robot with the same intended limits? These are all the questions under consideration by the FDA.

6. Payers

Usually insurance companies do little new technology assessment. If Medicare decides to cover something, they will usually follow suit. So far, there is no CPT code for the use of robotic surgery in joint replacement. Computer navigation does have a code, but reimbursement by Medicare has been spotty.

Payers should be most interested in reducing complications and improving longevity of the joint replacement. Readmissions and revisions of failed implants are very costly. Robotic joint replacement surgery offers the distinct possibility to reduce human error in surgery. Data supporting the reduction of complications or increased longevity of implants put in with robotics have been difficult to obtain. Without some data, some payers are unlikely to pay more for the use of this technology.

7. Our Opinion

The intrinsic value of using robotics to improve accuracy and precision in joint surgery will ultimately be recognized as adding significant value. We expect to see a surge of interest from surgeons in the future as new generations of robots with robust applications will address many, if not all, of the outstanding issues including ROI, reliability, better outcome, and operative times. With increasing emphasis on outpatient partial knee replacements, the role of robotic surgery in ambulatory surgery centers is a growing consideration and becoming a greater reality, particularly as pricing of systems improves. Current clinical applications of robotics in joint replacement will improve and different applications to other aspects of joint reconstructive surgery will be added.

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Clinical Study
Cement Removal from the Femur Using the ROBODOC System in Revision Total Hip Arthroplasty

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Introduction. The perforation and fracture of the femur during the removal of bone cement in revision total hip arthroplasty (THA) are serious complications. The ROBODOC system has been designed to selectively remove bone cement from the femoral canal, but results have not been reported yet. The purpose of our study was to evaluate the clinical and radiographic results of revision THA using the ROBODOC system for cement removal. Materials and Methods. The subjects comprised 19 patients who underwent revision THA using the ROBODOC system. The minimum duration of follow-up was 76 months (median, 109 months; range, 76–150 months). The extent of remaining bone cement on postoperative radiography, timing of weight bearing, and the complications were evaluated. Results. The mean Merle d’Aubigne and Postel score increased from 10 points preoperatively to 14 points by final follow-up. Bone cement was completely removed in all cases. Full weight bearing was possible within 1 week after surgery in 9 of the 19 cases and within 2 months in all remaining cases. No instances of perforation or fracture of the femur were encountered. Conclusions. Bone cement could be safely removed using the ROBODOC system, and no serious complications occurred. Full weight bearing was achieved early in the postoperative course because of circumferential preservation of the femoral cortex.

1. Introduction

The perforation and fracture of the femur during the removal of bone cement in revision total hip arthroplasty (THA) are serious complications that considerably affect the postoperative protocols and clinical results [1]. With the increasing frequency of revision THA, the incidence of intraoperative femoral fracture has increased recently [2, 3]. To prevent the perforation and fracture of the femur, several instruments and procedures have been developed especially for bone cement removal. However, sufficient results have not been achieved yet in the clinical setting [4–7]. Extended trochanteric osteotomy was introduced for difficult situations in revision THA [8–11], but good results have not necessarily been obtained with the procedure in terms of intraoperative femoral fracture [8, 10, 12]. Since 1992, a computer-assisted surgical system called ROBODOC (Integrated Surgical Systems, Davis, CA) has been used in clinical settings and is highly regarded for the accuracy of the surgical process [13–15]. After making system improvements, the ROBODOC system received 510(k) clearance from the US Food and Drug Administration in 2008. Using ROBODOC, the rate of intraoperative femoral fissures was significantly lower than that of the hand rasping conventional THA [16]. This system can also selectively remove bone cement from the femoral canal in revision THA [13]. However, results have not been reported yet.

The purpose of our study was to evaluate the clinical and radiographic results of revision THA using the ROBODOC system. Our research questions were as follows: (1) Did the system contribute to a reduced rate of intraoperative complications such as femoral fracture? (2) Did the use of the system
affect the postoperative rehabilitation protocol with regard to weight bearing? (3) Was bone cement completely removed from the femur?

2. Materials and Methods

We reviewed the medical records and radiographs of the studied subjects after the approval of this study by the institutional review board committee. The subjects comprised 19 patients (17 women, 2 men) for whom bone cement of the femoral canal was removed using the ROBODOC system in revision THA, between 2000 and 2006. All patients provided informed consent for participation before surgery, and the procedure was approved by the institutional review board committee. The mean patient age at the time of surgery was 70 years (range, 51–85 years). Cemented femoral component had been implanted in all patients. The primary diagnosis was osteoarthritis in 14 hips, femoral neck fracture in 4 hips, and rheumatoid arthritis in 1 hip. The reason for revision was aseptic loosening in 17 hips, septic loosening in 1 hip (infection was completely cleared up at the time of surgery), and central migration of the bipolar head in 1 hip. The minimum duration of follow-up was 76 months (median, 109 months; range, 76–150 months).

Prior to the index surgery, 2 locator pins were implanted into the greater trochanter and lateral condyle of the affected femur under local anesthesia. Computed tomography (CT) (General Electric, Waukesha, WI) was then performed in accordance with the protocol specified by the manufacturer (slice thickness, 1 mm; scan interval, 1–6 mm; field of view, 200 mm; total slices, <200). CT data were imported into a preoperative planning workstation (ORTHODOC; Integrated Surgical Systems, Davis, CA) that displayed a 3-dimensional image of the femur (Figure 1(a)). The long axis of the femur was aligned. At least 8 cross sections were defined, and the surgeon demarcated a perimeter around the bone cement in the axial views of the femur. From these data, the ORTHODOC program automatically created a 3-dimensional cutting path for cement removal (Figure 1(b)). At this time, the surgeon could check and modify the cutting path. These preoperative planning data were recorded on a compact disc (CD). Before each surgical procedure, the surgeon loaded the data for that patient from this CD into the ROBODOC system and performed a startup self-diagnosis of the robot.

During the operation, the femur was exposed through a posterolateral approach in all cases, and the femoral component was removed using a conventional procedure. After the patient’s leg was fixed to ROBODOC and to the surgical table, registration was performed using the 2 locator pins. After the gluteus medius muscle was firmly retracted, ROBODOC milled the femoral canal to remove the bone cement. Finally, the surgeon performed manual reaming of the femoral canal and a long-straight-tapered cementless stem (Wagner, Zimmer, Warsaw, USA) was inserted (Figure 2).

Clinical and radiographic evaluations were performed on the day of operation and 6 weeks and 3, 6, and 12 months postoperatively, then annually thereafter. No patients were excluded or lost to followup. Clinical results were measured
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Table 1: The patients' demographic and operative data.

| Case | Age (years) | Sex | Primary diagnosis | Reason for revision | Operation time (min) | Blood loss (g) | FWB (weeks) | Stem subsidence |
|------|-------------|-----|-------------------|---------------------|----------------------|---------------|-------------|----------------|----------------|
| 1    | 76          | M   | FNF               | Aseptic loosening   | 210                  | 600           | 9           |                |                |
| 2    | 72          | F   | OA                | Aseptic loosening   | 225                  | 1600          | 1           |                |                |
| 3    | 69          | F   | OA                | Aseptic loosening   | 250                  | 450           | 5           |                |                |
| 4    | 63          | F   | RA                | Aseptic loosening   | 215                  | 1100          | 1           |                |                |
| 5    | 51          | F   | OA                | Aseptic loosening   | 180                  | 960           | 4 +         |                |                |
| 6    | 70          | F   | OA                | Aseptic loosening   | 225                  | 550           | 5           |                |                |
| 7    | 78          | F   | OA                | Aseptic loosening   | 258                  | 1000          | 1           |                |                |
| 8    | 73          | F   | OA                | Aseptic loosening   | 285                  | 1100          | 9           |                |                |
| 9    | 71          | M   | FNF               | Septic loosening    | 251                  | 3000          | 1 +         |                |                |
| 10   | 74          | F   | OA                | Aseptic loosening   | 420                  | 1350          | 9           |                |                |
| 11   | 77          | F   | FNF               | Septic loosening    | 300                  | 700           | 8           |                |                |
| 12   | 54          | F   | OA                | Aseptic loosening   | 285                  | 570           | 1           |                |                |
| 13   | 64          | F   | OA                | Aseptic loosening   | 405                  | 1450          | 9           |                |                |
| 14   | 75          | F   | OA                | Aseptic loosening   | 335                  | 1750          | 1           |                |                |
| 15   | 82          | F   | OA                | Aseptic loosening   | 205                  | 1100          | 1           |                |                |
| 16   | 59          | F   | OA                | Aseptic loosening   | 275                  | 2100          | 1           |                |                |
| 17   | 80          | F   | OA                | Aseptic loosening   | 212                  | 1500          | 1           |                |                |
| 18   | 75          | F   | OA                | Aseptic loosening   | 260                  | 1000          | 1           |                |                |
| 19   | 72          | F   | FNF               | Bipolar head migration | 290                  | 1600          | 1           |                |                |

Abbreviations: FWB: full weight bearing; FNF: femoral neck fracture; OA: osteoarthritis; RA: rheumatoid arthritis.

using Merle d’Aubigne and Postel score [17]. Each patient was questioned on each visit, regarding the presence of thigh pain, which was considered as a complication related to the femoral component. The time at which full weight bearing was resumed was recorded. The extent of remaining bone cement was assessed on postoperative anteroposterior and lateral radiographs of the femur, taken immediately after surgery. A stem was considered unstable when progressive subsidence > 3 mm, any change in position, or a continuous radiolucent line wider than 2 mm was seen [18].

3. Results

The patients' demographic and operative data are provided in Table 1. The mean operation time was 267 min (range, 180–420 min). The mean robotic milling time was 34 min (range, 17–51 min). The mean blood loss was 1236 g (range, 450–3000 g). The mean clinical score increased from 10 points (range, 6–12 points) preoperatively to 14 points (range, 9–17 points) at final follow-up. No instances of the perforation or fracture of the femur were seen during surgery or follow-up. No patients in this series displayed nerve palsy or infection, including locater pin cite. The only patient who complained of thigh pain displayed 3 mm of stem subsidence immediately after surgery. However, symptoms disappeared when subsidence stopped 6 months after surgery. Further revision was required in 2 cases for acetabular loosening.

Of the 19 cases, full weight bearing was possible within 1 week in 9 cases. In other 9 cases, because bone grafting was performed to correct an acetabular bone defect, the patients were forced to delay full weight bearing due to the unreliable stability of the acetabular cup. The remaining patient was the first case in this study, and we were overly careful not to allow full weight bearing too early. However, full weight-bearing was achieved by all 19 patients within 2 months postoperatively, and they all became able to walk with a single cane.

Radiographically, bone cement was completely removed in all cases. Stem subsidence was seen in 2 cases, including the one mentioned previously. In the other case, subsidence progressed to 2 cm because of an undersized stem. Dislocation was seen only in this patient and was successfully treated using an abduction brace for three months after close reduction. As of final follow-up, all stems were considered to be bone stable.

4. Discussion

The results of revision THA using the ROBODOC system have not previously been reported. The purpose of this study was to evaluate the clinical and radiographic results for the ROBODOC system. In particular, we focused on the presence of intraoperative femoral fracture, the timing of full weight bearing, and the extent of remaining bone cement.

Several limitations in this study warrant consideration. First, the study design was retrospective, and we had no control group. Second, the number of cases was small, so the efficacy of this system needs to be confirmed in a larger number of cases. In addition, this system is strictly designed for the removal of bone cement and cannot be used for
the removal of the stem itself. The primary disadvantages of this system are the need to implant locator pins before the revision surgery and the cost of the equipment.

The rate of the intraoperative fractures of the femur in revision THA ranges widely from 2.3% to 50% [19–23]. To remove the intramedullary bone cement safely, many new instruments and procedures, such as a ballistically driven chiseling system [7], a water jet [6], and high-energy shock waves [24], have been introduced, but clinical results have not yet been reported. Although an ultrasonic device presented some good clinical results [4, 5], Gardiner et al. reported complications related to the use of the device, such as superficial bone burns (9%) and bone perforation (3.3%) [5]. In addition, cases of radial nerve palsy and pathological humeral fracture reportedly developed after ultrasonic cement removal from the humerus [25]. Extended trochanteric osteotomies have been recommended to facilitate femoral component removal, femoral cement removal, and acetabular exposure in cases of difficult revision THA [8–11]. However, Noble et al. reported in an in vitro cadaveric study that extended trochanteric osteotomy reduced the torsional strength of the femur by 73%, even when the osteotomy fragment was repaired [26]. Moreover, Busch et al. postulated in a series of 219 revision procedures that the use of extended trochanteric osteotomy would represent a risk factor for stem fracture after revision surgery due to the poor proximal femoral bone support [19]. Cement-in-cement techniques have been introduced to reduce intraoperative complications in cases of well-fixed cemented stem revisions. Some good midterm results have been reported, but the perforation and fracture of the femur could not be completely avoided (1.5–20.4%) [27–29]. The ROBODOC system has been used without femoral fracture in a total of 900 cases of primary THA, clearly establishing the safety of this method [13]. Of note is the fact that no perforations or fractures of the femur occurred in our series. The ROBODOC system has an advantage over other new procedures, because the cutting area can be assessed 3-dimensionally before surgery and reproduced reliably during the operation.

The ROBODOC system allows early full weight bearing because of the circumferential preservation of the femoral cortex, which may help reduce the hospital stay and expenses. Among our 19 cases, full weight bearing was possible within 1 week after surgery in 9 cases and in all remaining patients within 2 months. The use of the extended trochanteric osteotomy reduces the rates of nonunion and migration of the osteotomy site (0–2%) [9–11]. However, to prevent these events, postoperative rehabilitation protocols must be restrictive. Brace wear and partial weight bearing may be continued for about 8–12 weeks before full weight bearing is allowed [9, 11].

Removing all cement from the femoral canal without using a cortical window or osteotomy is challenging. Schuman reported that in 12 of 15 cases, cement mantles were completely removed using the segmental cement extraction system. However, 2 cases showed retained cement along the medial wall of the femur, and the plug could not be extracted using this system in 1 case [30]. Jingushi et al. reported remaining parts of cement in the canal in postoperative radiography in 65% patients (13/20) using standard instruments for revision arthroplasty [31]. The clinical reports of the ultrasonic device did not refer to whether bone cement was completely removed [4, 5]. In our study, bone cement was completely removed without osteotomy in 19 cases, thanks to the 3-dimensional assessment of the cutting area and the reproducibility of the ROBODOC system.

Nogler et al. pointed out the risk of heat injury during the ROBODOC milling process of cement removal, if cooling facilities were insufficient [32]. Although heat generation may cause soft tissue damage and bone necrosis, no nerve palsy or pathological fracture was encountered in our series, and bone ongrowth fixation between stem and femur was achieved in all cases. This result indicates that the intramedullary irrigation system functioned well for cooling, and bone around the stem remained viable.

In revision THA using the ROBODOC system, bone cement could be safely removed without the perforation or fracture of the femur, and full weight bearing was achieved early in the postoperative course due to the circumferential preservation of the femoral cortex.

Conflict of Interests

The authors report no conflict of interests.

References


Research Article

Protocol for Evaluation of Robotic Technology in Orthopedic Surgery

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1. Introduction

In recent years, robots have become commonplace in surgical procedures due to their high accuracy and repeatability. The Acrobot Sculptor is an example of such a robot that can assist with unicompartmental knee replacement. In this study, we aim to evaluate the accuracy of the robot (software and hardware) in a clinical setting. We looked at (1) segmentation by comparing the segmented data from Sculptor software to other commercial software, (2) registration by checking the inter- and intraobserver repeatability of selecting set points, and finally (3) sculpting \((n = 9\) cases) by evaluating the achieved implant position and orientation relative to that planned. The results from segmentation and registration were found to be accurate. The highest error was observed in flexion extension orientation of femoral implant \((0.4 ± 3.7^\circ)\). Mean compound rotational and translational errors for both components were \(2.1 ± 0.6\) mm and \(3 ± 0.8^\circ\) for tibia and \(2.4 ± 1.2\) mm and \(4.3 ± 1.4^\circ\) for the femur. The results from all processes used in Acrobot were small. Validation of robot in clinical settings is highly vital to ensure a good outcome for patients. It is therefore recommended to follow the protocol used here on other available similar products.
as computed tomography (CT) to identify the pathology and plan the surgery virtually. During the surgery, a registration process takes place that matches the preoperative plan and imaging data to the patient [15]. This means the transformation between the virtual environment and the patient is known and any points in the plan can be located during the surgery. Results can be affected by both the software and hardware used by the robot [16].

The patient’s CT scan is often segmented using available commercial software (e.g., Acrobot Modeller for Acrobot Sculptor). This software can generate the surface structure of the specified bones. It is possible to use these three-dimensional (3D) images to diagnose the pathology even though the surface geometry is not accurate or in scale. However, in robotic procedures, the accuracy of these surfaces has a direct influence on the outcome of surgery. This surface model is then loaded onto Acrobot Planner software to carry out preoperative planning. The Sculptor has a cutting burr attached to its three degrees of freedom (DoF) arm which can sculpt the bone based on a predefined plan. A tracking arm is pinned to the bone so that the system is aware of the 3D position of that bone relative to the robot at all times. Following attachment of the bone to the tracking arm, the intraoperative procedure also requires registration of points on the bone surfaces [15].

Other than the validity of the software, potential sources of error which can influence the outcome of the surgery include (1) the inaccuracy in position of sculpting arm or tracking arm (poor calibration), (2) inaccuracy in the registration algorithms to match the CT data to the bone, and finally (3) the robotic control system that constrains the surgeon to resect only on the safe zone area. Additionally, there may be other errors arising from surgeons in charge such as poor fixation of bones to tracking arm or inaccuracies in the use of tools [16].

The accuracy of registration, specifically, is an aspect that remains to be determined. There are a number of methods through which registration can take place, such as use of X-ray or ultrasound [17]. Some systems use fiducial markers in order to register the bone and some use landmarks on the bone such as discrete identifiable points or the ridge line [17]. Each is subject to a certain type of error including fiducial localization and registration error and target registration error [18]. The Acrobot Sculptor uses a mechanical digitizer (a secondary use of the robotic arm) to register the surface, where the tip of the cutter (ball point) is used as a probe which has a 2 mm diameter. As a result of inaccuracy in calibration or radius of the ball point, the captured data can be displaced from the true surface.

Validation of robot is vital to ensure a good outcome and highlight their value in use with patients [19]. Although there are several technical papers that have talked in detail about the accuracy of registration algorithms and robotic manipulations [20], there is no real simple method to test the accuracy of the robot in a clinical environment, and the main reference point simply remains the manufacturer’s information. In this study, we aim to evaluate the above possible cause of errors in a clinical setting.

2. Materials and Methods

In order to evaluate the accuracy of the Acrobot Sculptor, the following steps were taken.

The initial step was determining the accuracy of the segmentation procedure. We compared the segmentation result of Modeller (Stanmore Implants, London, UK) from a single femur using various software used to convert CD data to 3D models. These are Mimics (Materialise, Leuven, Belgium) and Robin 3D (Cavendish Medical, London UK) [14]. These surfaces were then matched together using 3-matic (Materialise, Leuven, Belgium) software and the differences in size were analysed.

The second step in determining the reliability and reproducibility of the Sculptor was by placing a set of points (using a marker pen) on the dry bone femur that was CT scanned. A total of 45 points were selected randomly on the distal part of the femur, focussed on for medial UKA procedures and four observers used the Sculptor to register these points. The root mean squared (RMS) error of the registration process was recorded for each observer. In order to check the effect of different tracking and sculpting arm positions, the same procedure was repeated by changing the fixation of the femur. The positions mimicked those found in surgical operations for various patients’ size or surgeons’ preference.

The last step is to measure the accuracy of constraints set at the planning stage during bone resection. A senior surgeon (IPC) was recruited to plan the operation using the Planner Software. Uniglide implants (Corin, Cirencester, UK) were chosen (a size four tibial component and size three femoral component) to restore the natural joint line, incorporating a seven-degree posterior slope in the tibial component. Nine UKAs were implanted on identical dry bone knee models (Imperial knee, Medical Models Company, Bristol, UK) by three experienced users of the Sculptor (three each). The models used were CT-based replicas of a patient’s arthritic knee consisting of a capsule, replica ligaments, and muscle tissues. Following implantation, the knee joint was separated from femur and tibia and each bone was individually scanned using the NextEngine Desktop 3D scanner (NextEngine, Santa Monica, CA, USA). Prior to implantation, the implant was painted in white enamel paint to improve pick-up of the laser spot from the scanner on the metal surface.

These scans were exported as Stereolithography (STL) files to 3-matic software. The positions of the tibial and femoral components were then compared to those of the ideal plan by recording the coordinates of four points on the planned implants versus the achieved implants (Figure 1). Using MATLAB, a local frame of reference was created using these four points for the achieved implant and was compared to that of the planned in all six DoF. These coordinates were created so that they follow the anatomical frame of reference such that the x-, y- and z-axes correspond to mediolateral, anteroposterior, and superoinferior directions accordingly. The magnitude of translational (a combination of the mediolateral, anterior-posterior, and superior-inferior directions errors) and rotational (a combination of the axial, flexion-extension, and coronal alignment errors) errors were calculated for each case for both tibial and femoral components.
Figure 1: Four points selected on the (a) femoral and (b) tibial implants to construct the local frame of reference. Comparison of the planned versus achieved rotational and translational errors based on the local frame of reference for (c) femoral and (d) tibial implants.

Table 1: Translational and rotational error values in UKA implant placement ($n = 9$).

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3. Results

The results from segmentation using different software were almost identical. The measurements were performed in 3-matic software, and the difference was far less than 0.5 mm at all points.

The results for the registration repeatability (second step) showed a consistent mean RMS error were of 0.5 mm while the maximum error among all subjects was found to be 1.8 mm with mean maximum being 1.53 ± 0.2 mm.

The results for implantation are shown in Table 1. Placement of the femoral component in general was more prone to error with a maximum error of $5.3°$ around the $x$- and $z$-axes. Mean compound rotational and translational errors for tibia component were $2.1 ± 0.6$ mm and $3 ± 0.8°$ and for femoral component were $2.4 ± 1.2$ mm and $4.3 ± 1.4°$. 
for conventional surgeries [14, 22], and similar to other errors were accepted, far superior to what has been reported which may increase the error seen here. Nevertheless, these bone, as it is possible to deform this under higher loads plastic bone. This is especially important with use of plastic by robot but also, when the implant is hammered into the we believe is actually not only depends on the cut made source of error in both femoral and tibial components. This values given by software for the implant position.

It is therefore important for surgeons to rely on their own we found that placement of landmarks can be inaccurate. using different software. For the second part we evaluated the robot’s accuracy in house, which include testing both software and hardware and are applicable to a variety of similar products on the market. Robotics technology can improve surgical outcomes by providing the surgeon with the greatest amount of accuracy and precision regardless of long surgical training [21]. The robot gives the surgeon more control in terms of the position and alignment of the tools. The accompanied software can also assist in the planning of the surgery and also during the operation by supplying information on direction and amount of cut by enabling the surgeon to visualise these on the screen. These robots are prone to errors both systematic and those due to the operator. Validating the accuracy of image guided surgery is therefore an important issue that needs to be addressed.

The initial step was determining the accuracy of the segmentation procedure. There are numerous techniques available to create the bone surface from CT images. In lack of any available straight forward method, in this study we used comparative validation and found almost identical data using different software. For the second part we evaluated the landmarks that create the frame of reference. In this study, we found that placement of landmarks can be inaccurate. It is therefore important for surgeons to rely on their own experience for planning the procedure as well as the suggested values given by software for the implant position.

In this study, rotational error was found to be the highest source of error in both femoral and tibial components. This we believe is actually not only depends on the cut made by robot but also, when the implant is hammered into the plastic bone. This is on especially important with use of plastic bone, as it is possible to deform this under higher loads which may increase the error seen here. Nevertheless, these errors were accepted, far superior to what has been reported for conventional surgeries [14, 22], and similar to other robots available. For example, Dunbar et al. [22] found that the MAKO robot’s mean RMS errors for the tibia were 1.4 mm and 2.6° and for the femur 1.2 mm and 2.1°. Furthermore, the ranges found are within the safe range reported by Biomet [23].

We recognise the inherent limitations of our study, one of which is the use of dry replica bones rather than patients. To compensate, the dry bones were replicas of a patient’s arthritic tibia and femur, with replica ligaments as well as a surrounding capsule attached and hence were as realistic to a real patient as possible. Fixation of the tracking arm to the bone may also cause inaccuracy if fixation pins bend or loosen due to stress on the fixation point. It is therefore important to design fixtures that are robust and rigid and not loosened (i.e., no movement between the tracking device and the anatomy should be allowed). Furthermore, if after screwing the fixtures, the anatomy of the subject deforms due to overloading of the segment, the possible error as a result of this needs to be evaluated for each robot. In the Sculptor, the tracking arm is quite light, and therefore we assumed stress on the fixation point because the weight of the arm would be minimal.

We acknowledge that during the planning phase, landmarks used to define reference frames are located manually by the surgeon. Srivastava et al. [24] describe the effects of landmark placement variability on kinematic descriptions of the knee. The positions of these landmarks may be open to placement inaccuracy and variability between surgeons. In addition to the accuracy measurements described above, a sensitivity analysis should be performed to determine the likely variability in frame of reference orientations and implant position relative to these introduced by the human operator during planning.

Often in the literature, errors are based on the translational or angular location of the implant and cuts; however, Simon et al. [17] argued that there are ambiguities associated with these data due to a dependence upon the selected coordinate system. It is therefore anticipated in the future for the implant manufacturer to provide a standard protocol for evaluation of location of the implant. The use of dry bones meant that soft tissue balancing could not be recreated and the tibio-femoral angle could not be measured. Although this is an important measure of functional outcome following a UKA, it is widely accepted that component alignment is a major influence on the limb’s tibiofemoral angle [24]. In this study, we used a laser scanner instead of CT to find the position of the implant postoperatively since a metallic implant will create artefact in the CT scan and inaccuracy in segmentation. There could also be inaccuracies during segmentation and in CT data itself; however, this is not part of the system and would be operator error, not that of the software.

5. Conclusions

Overall our results of segmentation, registration, and cuts made by robot were satisfactory for both components using the Acrobat Sculptor. It is possible to apply the full or part of this protocol in this study in a variety of other

![Figure 2: Magnitude of resultant rotational and translation error for tibial and femoral components when compared to planned positions.](image-url)
products available on the market for better understanding and validation of robotic technology.

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References


Robotic Assistance Enables Inexperienced Surgeons to Perform Unicompartmental Knee Arthroplasties on Dry Bone Models with Accuracy Superior to Conventional Methods

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Robotic systems have been shown to improve unicompartmental knee arthroplasty (UKA) component placement accuracy compared to conventional methods when used by experienced surgeons. We aimed to determine whether inexperienced UKA surgeons can position components accurately using robotic assistance when compared to conventional methods and to demonstrate the effect repetition has on accuracy. Sixteen surgeons were randomised to an active constraint robot or conventional group performing three UKAs over three weeks. Implanted component positions and orientations were compared to planned component positions in six degrees of freedom for both femoral and tibial components. Mean procedure time decreased for both robot (37.5 mins to 25.7 mins) \( (P = 0.002) \) and conventional (33.8 mins to 21.0 mins) \( (P = 0.002) \) groups by attempt three indicating the presence of a learning curve; however, neither group demonstrated changes in accuracy. Mean compound rotational and translational errors were lower in the robot group compared to the conventional group for both components at all attempts for which rotational error differences were significant at every attempt. The conventional group's positioning remained inaccurate even with repeated attempts although procedure time improved. In comparison, by limiting inaccuracies inherent in conventional equipment, robotic assistance enabled surgeons to achieve precision and accuracy when positioning UKA components irrespective of their experience.

1. Introduction

Although the benefits of robotic systems in terms of alignment and positioning compared to conventional methods are well established in experienced users [1], the effect of surgical experience and training on the ability to accurately position components with robotic systems is unknown. Conventional unicompartmental knee arthroplasties (UKAs) exhibit a learning curve whereby repetition and experience can lead to improvements in surgical technique, timing, and accuracy [2, 3]. Rees et al. in 2004 demonstrated that a surgeon's UKA performance is significantly worse in their first 10 cases compared to their subsequent 10 cases [3]. Other studies have shown a nonsignificant improvement in accuracy with experience indicating that conventional UKAs have a long learning curve and that even with experience and training obtaining accurate results is difficult [2]. In contrast early results of a preliminary study by Coon demonstrated that the MAKO robotic system may demonstrate a shorter learning curve and greater accuracy compared to conventional techniques [4]. By comparing their first 36 robot assisted UKA patients to their previous 45 conventional UKA patients, they showed that robotic surgery resulted in a posterior tibial slope accuracy that was 2.5 times better and a varus alignment that was 3.2° better than the conventional group.

Although there are reports of long-term survivorship following UKAs [5] as well as good kinematics [6] and function [7], others have reported a high early failure rate [8]. A variety of factors including patient selection [9] and implant design [10, 11] have been identified as predictors for revision or reoperation of the implant. Incorrect alignments of the tibial and femoral components when performing a UKA have led to poor functional results, high implant wear, and a high revision rate [10–13]. The UKA procedure
therefore appears to be more technically demanding, so despite being theoretically both cheaper and better than total knee replacement, its adoption may be limited by surgical skills. Robotic technology has facilitated more accurate and bone preserving methods of UKAs [1, 12, 13] compared to conventional methods which produce inconsistent alignment results [10, 14]. In 2006, Cobb et al. compared the accuracy of Acrobat—a surgical robotic system—to conventional methods of performing a UKA. They showed that all of the 13 robot treated patients had a tibiofemoral coronal alignment within ±2° of the plan, whereas only 9 out of 15 patients treated by conventional means had achieved this accuracy (P = 0.001) [1]. By providing computer assistance, the spatial locations of the tools and the patient can be tracked and depicted against a preoperatively created plan on a computer screen which is used by the surgeon as guidance. The plan consists of a three-dimensional (3D) computer model of the patient’s bone upon which the ideal position of the prosthesis can be determined and placed on the software. It defines regions within which the robot is constrained to avoid cutting critical areas and to facilitate accurate component placement [1]. This mechanism may enable surgeons to perform accurate UKAs in the early stages of their learning curve when inaccurate placement using conventional methods is most likely [3].

The aims of this novel research were twofold:

(1) To assess the accuracy with which surgeons inexperienced in UKAs implant the components using robotic assistance compared to conventional instrumentation.

(2) To assess the effect repetition has on component positioning accuracy in both groups.

We surmised that with robotic assistance surgeons inexperienced in UKA will position components consistently and accurately at every attempt, while with conventional instruments component positioning will be inaccurate and improve with more attempts.

2. Methods

2.1. Subjects. Sixteen surgeons consented to take part in the study, none of whom had experience in UKAs by neither conventional nor robotic means. Subjects underwent randomisation to one of two groups: conventional UKA or robotic UKA. Each subject performed a UKA once per week for three consecutive weeks by their allocated method on dry bone models. The models used were computer tomography (CT) based replicas of a patient’s arthritic knee consisting of a capsule, replica ligaments, and muscle (Medical Models Ltd., London).

Prior to randomization, a CT scan of the dry bone model used in the study was taken and was segmented using the previously validated Stanmore Implants Modeller Software (Stanmore Implants Worldwide (SIW), Elstree, UK) [15]. A plan of the ideal implant positions on the dry bones was created using the Stanmore Implants Planner (SIW, Elstree, UK) which recreated the joint line and was measured to size 3 and size 4 femoral and tibial Corin Uniglide implants, respectively. The plan was created by a consultant surgeon experienced in UKA and computer-assisted orthopaedic technologies and was designed to be anatomically optimal and achievable using the conventional cutting jig according to the published operative technique.

Subjects in the conventional group were instructed to recreate the plan using the Corin Uniglide UKA standard cutting jigs and instruments. A training video was made to show the group how to perform the procedure correctly prior to their first attempt. Additionally, a conventional UKA operating technique instructional booklet was produced based on the Corin Uniglide operative technique and the preoperative plan, which subjects read prior to the procedure and also referred to during the procedure. The guide detailed the steps the subjects needed to follow in order to achieve component placement that recreated the plan. Subjects in the robotic group were shown a demonstration of the UKA procedure using the Sculptor RGA (Stanmore Implants Worldwide, Elstree, UK) (formerly Acrobat) and were also presented with a robotic UKA guide detailing the methodology.

2.2. Data Collection and Analysis. Subjects in both groups were timed during the procedure starting with the initial tibial incision to the insertion of the mobile bearing device. All subjects were provided with feedback in between each repeat detailing the accuracy with which they had implanted the components in their previous attempt.

Once the UKA was complete, the bones were separated into the tibial and femoral parts with the Corin Uniglide implants attached and scanned using a 3D laser scanner which provided a computer generated image of the implanted bone. The completed UKAs were coregistered to their respective plan using the 3-matic software (Materialise, Belgium) [16]. This was initially done visually and then fine-tuned using the 3-matic surface matching function by a researcher blinded as to which group each bone model belonged to. The position of the components on the tibia and femur was then compared to that of the ideal plan by recording the coordinates of four points on the planned implant versus the achieved implant. Using Matlab software, local frames of reference of the planned implants were created and compared to those of the achieved implants in all six degrees of freedom (DoF).

The NextEngine 3D scanner (CA, USA) was used to scan the bones. It is reported to have an accuracy of 0.127 mm and a maximum of 15 samples (points) per millimetre [17]. To validate the accuracy of our methodology, a repeatability study was carried out. Intraobserver reliability involved five repeat measurements of the same bone from which the standard deviation (SD) of the mean translational and rotational errors was reported. Interobserver reliability involved two measurements of the error in six DoF of four randomly chosen bones by two observers from which a Bland-Altman plot was made. The average root mean squared (RMS) differences of three points between the CT-based and laser scanned original bones were also assessed.

The compound rotational errors (calculated as the square root of the sum of the magnitude of the axial, flexion-extension, and coronal alignment errors) and compound
translational errors (calculated as the square root of the sum of the magnitude of the medial-lateral, anterior-posterior, and superior-inferior errors) were calculated for each subject for both tibial and femoral components at attempts one, two, and three. A student's t-test was used to compare the difference in mean compound rotational and mean compound translational errors between groups at each attempt for each component. A repeated measures ANOVA was used to determine if there was any change in component error within each group between attempts one, two, and three. A post-hoc Bonferroni correction was used for any significant results. Analysis of procedure time was performed by the same statistical methods.

For each subject their RMS error in each of the six DoF was averaged over their three attempts. This was used to calculate the mean RMS error in each DoF for the robot and conventional group using the data from all three attempts combined. We could then compare this mean absolute error from the plan in each of these DoFs between the robot and conventional groups using a student's t-test.

All statistics were analysed with Statistical Package for Social Sciences 20 (SPSS 20, Chicago, IL, USA), with statistical significance designated as \( P < 0.05 \).

3. Results

Mean compound rotational error of the tibial component was lower in the robot group compared to the conventional group at all attempts. This difference reached significance at attempts one (3.0° versus 9.7°) \((P = 0.005)\), two (3.9° versus 9.5°) \((P = 0.001)\), and three (4.0° versus 9.0°) \((P = 0.001)\) (Figure 1(a)). The compound translational error was also lower with robotic assistance, reaching significance at attempts one (2.0 mm versus 5.2 mm) \((P = 0.046)\) and three (2.0 mm versus 4.2 mm) \((P = 0.005)\) (Figure 1(b)). Mean compound rotational error of the femoral component was lower in the robot group, reaching significance at attempts one (3.3° versus 10.8°) \((P = 0.002)\), two (3.6° versus 8.5°) \((P = 0.002)\), and three (3.6° versus 8.9°) \((P = 0.004)\) (Figure 2(a)) as was compound translational error, although this reached significance at attempt three only (2.0 mm versus 4.3 mm) \((P = 0.002)\) (Figure 2(b)).

For the tibial component the robotic group had a lower absolute error in each of the three rotational (axial, sagittal, and coronal) and translational (medial-lateral, anterior-posterior, and superior-inferior) DoF compared to the conventional group. This difference failed to reach significance in only the varus-valgus and superoinferior directions. The mean RMS tibial rotational error was 1.8° ± 1.6° for the robot group compared to 4.7° ± 3.2° \((P = 0.0002)\) for the conventional group, while the mean RMS tibial translation error was 1.0 mm ± 0.7 mm for the robot group and 2.1 mm ± 1.5 mm \((P = 0.021)\) for the conventional group.

For the femoral component the robotic group had a lower absolute error in each of the three rotational (axial, sagittal, and coronal) and translational (medial-lateral, anterior-posterior, and superior-inferior) DoF compared to the conventional group. This was significant in all DoF except for the superoinferior and anteroposterior directions. The mean RMS femoral rotational error was 1.7° ± 1.7° in the robot group compared to 4.7° ± 3.4° \((P < 0.0005)\) in the conventional group, while the mean RMS femoral translation error was 1.3 mm ± 1.0 mm for the robot group and 2.0 mm ± 1.3 mm \((P = 0.042)\) for the conventional group.

Mean procedure time decreased significantly for both robot (37.5 mins to 25.7 mins) \((P = 0.002)\) and conventional (33.8 mins to 21.0 mins) \((P = 0.002)\) groups with repeated attempts (Figure 3); however, neither group showed a corresponding significant change in rotational (conventional \(P = 0.943\), Sculptor RGA \(P = 0.724\)) or translational (conventional \(P = 0.373\), Sculptor RGA \(P = 0.184\)) component accuracy between attempts.

The results of the intraobserver repeatability study found the mean rotational error of the five repeat bones to be 0.45° ± 0.4° and mean translational error to be 0.23 mm ± 0.15 mm.

The results of the interobserver repeatability study found the mean difference in observation between the two observers to be 0.07 ± 1.39 for each DoF. All measured differences were within ±1.96 SD of the mean difference and hence were within the acceptable limits of agreement (Figure 4).

RMS errors between the three points on the planned CT bone and laser scanned bone were less than 1 mm for both the femur and tibia.

4. Discussion

This randomised study is the first to compare the ability of surgeons to perform accurate UKAs in their initial attempts using both robotic and conventional methods. We have shown that surgeons inexperienced in UKA are able to position components on dry bones when performing a UKA procedure significantly more accurately with the Sculptor RGA than by conventional methods alone and can do so repeatedly and without any prior experience. We have also used a novel method in assessing the accuracy of component positioning in dry bone models which seem robust when judged by our repeatability studies.

The goal of any instrumentation used in arthroplasty should be to allow its user to position the components in a position and orientation which is preoperatively or intraoperatively determined. While there is no precise agreement on the ideal position of implants during a UKA, correct alignment of the femoral and tibial components has been shown to be the most objectively quantifiable factor in determining the wear and longevity of UKAs [12, 18]. This is particularly relevant in the early stages of a surgeon's learning curve when improper component placement is more likely due to the difficulty of the procedure and the relatively little exposure surgeons have to UKAs [3].

In our study, the decrease in time exhibited by both groups between attempts signifies the presence of a learning curve; however, the conventional group did not demonstrate a corresponding increase in accuracy in either rotational or translational alignment between attempts, while robot assistance ensured that accurate placement was consistently
produced at each and every attempt. The lack of improvement in accuracy in the conventional group highlights the need for timely feedback for surgeons in training if they are to produce consistently accurate results. Although we were unable to show any increase in accuracy with repetition in this study, the variability of the component positioning was the highest in the conventional group’s first attempt for both tibial (Figure 1) and femoral (Figure 2) components compared to following attempts. This suggests that the precision of component positioning may improve with time, although the study was neither designed nor powered to detect this.

Accuracy of the compound rotational alignment of the tibial component was consistently more accurate than conventional methods over all three attempts. Compound rotational alignment consists of axial rotation, coronal rotation, and the posterior slope, of which the latter is the most reported alignment measure dictating outcomes of a UKA procedure, and as a result posterior slopes greater than $7^\circ$ should be avoided [12]. The $7^\circ$ slope built in the conventional jig did not prevent any of the subjects from producing a tibial component placement posterior slope of $>7^\circ$ with errors ranging from $+0.5^\circ$ to $+12.6^\circ$. Other robotic systems

![Figure 1: Bar graphs comparing tibial component positioning in robot and conventional groups at attempts 1, 2, and 3 by mean (a) compound rotational error, (b) compound translational error, (c) rotational alignment in each DoF, and (d) translational alignment in each DoF. $P$ values compare mean root mean squared errors between groups.](image-url)
with experienced users have also demonstrated improved sagittal tibial component placement, including the Acrobot [1] and the MAKO robot [4]. This concurs with our results, which showed a significant difference in the magnitude of posteriorslope error between the robot group ($1.2^\circ \pm 1.0^\circ$) and conventional groups ($4.6^\circ \pm 2.5^\circ$) ($P < 0.0005$).

Although compound translational errors were higher in the conventional group at every attempt, this was only significant at attempts one and three for the tibial component (Figure 1(b)) and attempt three for the femoral component (Figure 2(b)). Considering the individual femoral translational DoFs only the medial-lateral translation showed a significant difference, while superoinferior and anteroposterior errors were similar between the two groups (Figure 2(d)). This agrees with previous findings which also found similar results between the robot and conventional groups with experienced users in these DoF [1]. This may be due to the instrumentation used in a conventional UKA. The tibial stylus improves depth control when resecting the tibial plateau which dictates the inferosuperior component error explaining the similar mean robot ($2.0 \, \text{mm} \pm 0.9^\circ$) and conventional ($1.7^\circ \pm 0.9^\circ$) errors. During femoral preparation the small reamer can be set to an accuracy of 1mm, the result of which dictates the superoinferior positioning of the component. Comparatively, the rotational alignment and medial-lateral translational alignment of both components

**Figure 2**: Bar graphs comparing femoral component in robot and conventional groups at attempts 1, 2, and 3 by mean (a) compound rotational error, (b) compound translational error, (c) rotational alignment in each DoF, and (d) translational alignment in each DoF. $P$ values compare mean root mean squared errors between groups.
Overall our results of errors in the positioning and orientation of both components using the Sculptor RGA were comparable to results of experienced surgeons operating on real patients: Dunbar et al. [22] found that the MAKO robot’s mean RMS errors for the tibia were 1.4 mm and 2.6° and for the femur 1.2 mm and 2.1°, while Cobb et al. [1] reported mean RMS errors using the Acrobot to be 1.1 mm and 2.5° for the tibia and 1.0 mm and 2.6° for the femur. Our robot results using inexperienced UKA surgeons on dry bones are comparable: mean RMS errors of 1.0 mm and 1.8° for the tibial component and 1.3 mm and 1.7° for the femoral component indicate that novice robot users can reproduce experienced surgeons’ results. Our slightly lower values may be due to errors introduced during cementing in vivo, which has been reported to give errors of up to 2° in UKAs [23].

We recognise several inherent limitations of our study. It is a small study, using only 3 repetitions to demonstrate learning so may miss an improved performance later in the learning curve, although the largest improvement might be expected to be early in the experience. We did not demonstrate this. It is also a dry bone study. However, the dry bones were replicas of a patient’s arthritic tibia and femur with replica ligaments and a capsule attached and hence were as realistic to a real patient as possible. The fact that our accuracy results were comparable to published in vivo data supports the validity of the dry bone model. However, the use of dry bones prevents reproduction of soft tissue balancing and the selection of an appropriate thickness of bearing. Therefore, measurement of the tibiofemoral angle is meaningless. Although this is an important measure of functional outcome following a UKA, component alignment is a major influence of tibiofemoral angle [24, 25], thus justifying the conclusions.

Arthroplasty requires precision and accuracy to be delivered consistently for favourable outcomes. Robotic systems have repeatedly demonstrated superiority over conventional methods when used by experienced users. We have demonstrated that this level of exactitude can be replicated on a dry bone model by surgeons who are unfamiliar with the procedure. Robotic technology, in the form of the Sculptor RGA, enables surgeons to perform this demanding form of arthroplasty accurately without prior experience. It achieves this by removing the inaccuracies inherent in the use of conventional instrumentation.

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References


Review Article

A Perspective on Robotic Assistance for Knee Arthroplasty

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Knee arthroplasty is used to treat patients with degenerative joint disease of the knee to reduce pain and restore the function of the joint. Although patient outcomes are generally quite good, there are still a number of patients that are dissatisfied with their procedures. Aside from implant design which has largely become standard, surgical technique is one of the main factors that determine clinical results. Therefore, a lot of effort has gone into improving surgical technique including the use of computer-aided surgery. The latest generation of orthopedic surgical tools involves the use of robotics to enhance the surgeons’ abilities to install implants more precisely and consistently. This review presents an evolution of robot-assisted surgical systems for knee replacement with an emphasis on the clinical results available in the literature. Ever since various robotic-assistance systems were developed and used clinically worldwide, studies have demonstrated that these systems are as safe as and more accurate than conventional methods of manual implantation. Robotic surgical assistance will likely result in improved surgical technique and improved clinical results.

1. Introduction

Reconstructive knee surgery, whether unicompartmental (UKA), multicompartamental (MCKA), or total knee arthroplasty (TKA), is commonly performed on patients with end-stage osteoarthritis of the knee. Currently, there are approximately 600,000 primary TKA procedures and 45,000 primary UKA procedures performed annually in the USA [1]. The number of procedures is growing rapidly with TKA growing at a rate of 9.4% per annum and UKA growing at a rate of 32.5% per annum in the United States [2]. The goal of a knee arthroplasty is to restore the knee joint to a functional and pain-free state. In terms of clinical outcomes, TKA is a successful procedure when looking at pain relief and restoration of patient mobility with 10–15 years implant survival rates of greater than 90% [3–5]. Similarly, UKA has a ten-year survival rate of over 90% [6].

However, the surgeries still need to improve in terms of patient satisfaction, especially in the case of younger patients. Patient satisfaction remains at only 82% to 89% after TKA [7–9]. Patients who received UKA are satisfied only 80–83% of the time [10]. Additionally, for younger patients, increased implant longevity and the ability to continue an active lifestyle are strongly desired. Both the survival rate of knee arthroplasty and patient satisfaction are dependent on multiple factors including patient selection, implant design, the preoperative condition of the joint, surgical technique, and rehabilitation.

When looking to improve implant survival and patient satisfaction, surgeons may choose from a variety of implants and different surgical techniques. The first factor is implant design. It includes component geometry, materials, and manufacturing processes and have changed since total knee arthroplasty first came about. However, patient satisfaction does not seem to have improved with these contemporary implants [7]. Although the majority of implants used today are generic, there are now custom implants based on a patient’s individual anatomy (ConforMIS, Burlington, MA, USA). At this point, their use is too new to draw any conclusions regarding their effects on implant survival and
patient satisfaction. The other factor is surgical technique which includes access to the joint, implant sizing, implant alignment, and positioning relative to anatomic features, implant fixation to the bone, soft tissue balancing, and wound closure [3, 11]. It has been suggested that errors in surgical technique may be the most common reason for failure of TKAs [3, 12, 13]. Thus, many recent developments in knee reconstructive surgery have focused on improvements in surgical technique.

The traditional surgical technique involves bone cuts and soft tissue balancing. Bone cuts are typically performed with reference to anatomical landmarks and available implant geometry. Correct implant sizing is achieved when the native dimensions of the knee are reproduced as closely as possible by the implant. Conventional TKA instruments typically use intraoperative sizing guides to help the surgeon determine the appropriate implant size. In terms of implant to bone fixation, most knee replacement implants are attached to the host bone using bone cement (PMMA). In the alternative, cementless fixation, the implants generally have porous regions adjacent to the bone designed to allow for bony ingrowth. While bone cement provides good initial fixation even with poor quality bone, cementless fixation provides direct bone-to-metal attachment, which reduces migration after an initial period and thus may lead to a potentially longer implant life [14]. To achieve reliable cementless fixation, precision bone cuts must be made so that the implants achieve stable initial fixation with limited gaps. However, with conventional instruments, the bone cuts are made using bone-attached cutting guides and an oscillating saw. As demonstrated by Plaskos et al. [15], these cutting guides combined with an oscillating saw resulted in errors in cuts ranging from 0.6° to 1.1° in varus-valgus and 1.8° in flexion-extension. These cutting errors can result in gaps that delay bone ingrowth into the implant [16] or may require bone cement to ensure initial stability.

The postoperative alignment of the knee has a large effect on the load transferred through the implant. To spread the load evenly, manufacturers have traditionally recommended positioning the knee implants (totals or partials) such that the "ideal" mechanical axis of the leg is restored. This mechanical axis is defined as a straight line passing from the center of the femoral head to the center of the talus [17, 18]. In addition, the implants should be positioned such that the anatomic joint line is preserved or restored and minimal bone is removed. Although not all studies agree [19, 20], many studies have shown that restoring a neutral postoperative mechanical axis, defined by the center of the hip, center of the knee, and center of the ankle within ±3° of the mechanical axis, may result in improved postoperative pain, biomechanics, function, and an increased implant longevity [17, 21–23].

Traditional planning for implant positioning and alignment is done using acetate implant overlays on appropriately magnified radiographs of the knee [24]. During the actual surgery, mechanical alignment jigs are used to assist in making the bone cuts. These jigs reference the long axis of the bone either by estimating it externally or internally entering the intramedullary canal. Cutting guides are attached to the bones and a hand-held oscillating saw is used to perform the bony cuts.

With regards to soft tissue balancing, there are two main techniques employed by surgeons. The first is called the "gap balancing" technique. This method determines the rotational and AP position of the femoral component intraoperatively in an attempt to achieve a rectangular flexion gap equal to or close to the extension gap. This will theoretically achieve ligament balance, but may result in a nonanatomic alignment of the femoral component. The second method is called the "measured resection" technique. The measured resection technique relies on the intraoperatively determined location of the transepicondylar axis (TEA). The TEA has been shown [25, 26] to be the best indicator of a patient's true anatomic flexion axis. However, locating the TEA intraoperatively can be difficult due to osteophytes and problems that may arise with adequate exposure. Thus, several other alignment measures are often used instead of the TEA, such as Whiteside's line. Although Whiteside's line is likely easier to locate, it is also prone to error. As such, many surgeons will simply place the femoral component in a fixed position of external rotation (typically 3°) relative to the posterior condylar axis as an estimation of the TEA. Although this position is easy to find repeatedly, its relationship to the TEA is variable and can result in unequal ligament balance [27, 28].

Implant manufacturers have developed complex manual instrumentation to address each of the above factors and help the surgeon place the implants where they planned. Numerous peer-reviewed published papers have identified knee alignment as the most important factor in achieving good long-term clinical results [17, 21, 23, 29–42]. In addition to manual instruments, computer navigation and robotic systems have been developed to increase the accuracy of implant placement and knee alignment and reduce outliers with the overall goal of improved long-term clinical results.

2. Computer Assisted and Robotic-Assistance Surgery Systems

Computer assisted surgical systems include a variety of methods to address many of the challenges associated with knee arthroplasty. Surgical navigation systems typically provide the surgeon with information including bone orientations and limb alignments through a display. Additionally, patient-specific instrumentation and implants are now being used [53, 54]. These systems typically require computer-assisted planning and design of the instrumentation. They can assist the surgeon in creating a surgical plan or guiding surgical tools. These passive systems may be classified outside of the robotic realm.

Robotic assistive systems are robotic devices that perform specific tasks according to preoperative data. These systems can be classified into three main categories: passive systems, semiactive robotic systems, and active robotic systems [55]. Passive systems perform part of the surgical procedure under continuous and direct control of the surgeon. An example of a passive system is one in which a robot holds a guide or jig in a predetermined location and the surgeon uses manual tools to prepare the bony surfaces. A semiactive robotic system is a tactile feedback system that augments the surgeon's ability
to control the tool typically by restricting the cut volume by defining constraints of the cut motion in space; however, it still requires the surgeon to manipulate the cutter. Finally, an active robotic system performs a surgical task without direct intervention of the surgeon such as allowing the robotic arm to cut the bone without direct manipulation of the cutter by the surgeon.

Although navigation systems have been shown to reduce the number of mechanical axis alignment outliers [56], the actual cutting of bone relies on manual tools which limit the accuracy of the cuts [29]. For this reason, surgeons and engineers have worked to integrate robotically controlled surgical instruments into joint replacement surgery [40]. In addition to the computer-controlled cutting instrument, robotic systems use CT-based three-dimensional (3D) visualization and templating to plan the cuts. This allows easier preoperative identification of anatomical landmarks such as the TEA. Most robotic systems consist of very similar components. The steps to a robotically-assisted surgery typically involve (1) creating a patient specific model and interventional plan; (2) intraoperatively registering the model and plan to the patient's anatomy; and (3) using robotic-assistance to make bone cuts and carry out the preoperative plan on the patient.

Matsen et al. [57] were the first to describe a robotic system for knee arthroplasty. Their passive system was based on a robot positioning saw and drill guides with respect to the bony geometry. Kienzle et al. [58] developed another passive system that used a preoperative CT scan and a pin-based registration technique. The preoperative CT allowed the surgeon to plan and accurately execute implant placement based on 3D reconstructions of the bones. van Ham et al. [59] presented a semiactive system in which the robot constrains the motion of the cutting tool as it is guided by the surgeon. This system used an intraoperative registration method using an intramedullary rod. Martelli et al. [60] presented a passive robotic system for use in TKA based on preoperative CT. Intraoperative registration was performed using a surface-matching technique based on the surface models created from the CT scans. Glozman et al. [61], La Palombara et al. [62] and Fada et al. [63] used similar surface matching techniques to register bones without fiducial markers. These registration methods were then combined with active or semiactive robots that provided precision bone milling according to the preoperative plan.

In addition to these larger robots, there has been development of miniature bone-mounted robots. For example, PiGalileo (Plus Orthopedics AG, Smith & Nephew, Switzerland) is a passive system that uses a hybrid navigated robotic device that clamps on to the mediolateral aspects of the distal femoral shaft. The MBARS (Mini Bone-Attached Robotic System) was an active system developed for patellofemoral joint replacement procedures [64]. Plaskos et al. presented Praxiteles in 2005, as a passive system that is a miniature bone-mounted robot for total knee arthroplasty. Song et al. [65] have developed an active system consisting of a hybrid bone-attached robot for joint arthroplasty (HyBAR) that uses hinged prismatic joints to provide a structurally rigid robot for minimally invasive joint arthroplasty.

Although many of these systems have been developed and prototyped, only a handful have been used successfully in clinical settings throughout the world. These include the ROBODOC System (Curexo Technology Corporation, Fremont, CA), the CASPAR system (URS Ortho Rastatt, Germany), the Robotic Arm Interactive Orthopedic System (RIO; MAKO Surgical Corporation, Fort Lauderdale, FL, USA), and the Stanmore Sculptor Robotic Guidance Arm (RGA) System (Stanmore Implants, Elstree, UK), formerly known as the Acrobat System. MAKO's RIO and the Stanmore Sculptor RGA System are semiactive systems, whereas the CASPAR and ROBODOC systems are active robotic systems.

### 3. Clinical Results

A summary of published clinical studies in which robotic-assistance systems are used for TKA is presented in Table 1. The studies and their primary findings are described in the sections below for each individual system.

#### 3.1. CASPAR

A study using CASPAR for TKA was performed by Siebert et al. in [43]. Seventy CASPAR-assisted surgeries were compared to 52 control surgeries performed...
in Kassel, Germany. Postoperative standing long-leg radiographs showed that the robot group had a higher accuracy in achieving the planned femoral-tibial alignment with an average error of 0.8° (range 0–3°) compared to the control group’s average error of 2.6° (range 0–7°). Another study followed 25 TKA cases that were consecutively performed using the CASPAR system [44]. Postoperative followup ranged from 5.1 to 5.8 years. The results demonstrated that all angular measurements for the tibial and femoral components in this study were within 1° of the target as defined in the preoperative plan. Operating time for these first 70 cases averaged 135 minutes but towards the end of the study achieved a steady state of approximately 90 minutes, which is approximately equal to the control group. No major adverse events related to the CASPAR system were found, but one minor complication was recorded. One TKA in one patient was successfully converted to a manual technique after a femoral milling could not be completed due to a defective registration marker. Additionally, three patients had superficial skin irritations at the pin sites that were resolved using conservative treatment.

3.2. Stanmore Scultor RGA. The Stanmore Scultor RGA system, previously known as the Acrobat System, was utilized in a randomized study performing unicompartamental knee arthroplasty (UKA) [45, 66]. This study included 13 patients undergoing Acrobat-assisted surgery and 15 patients undergoing UKA using conventional techniques. Postoperative CT scans showed that the femoral-tibial alignment for all 13 patients undergoing Acrobot-assisted surgery and 15 patients undergoing UKA using conventional techniques for UKA. The surgeries were planned to maintain this alignment, and, after surgery, all of the knees succeeded in achieving the planned femoral-tibial alignment with an average error of 0.8° from what had been planned. There were no complications with the system and the wounds healed successfully.

A third feasibility study was reported by Sinha [48] involving their first 20 cases. All of the 20 cases were successfully completed as planned, and the results showed a good ability to recreate individual patient anatomy. Prior to surgery, 62.5% of the knees were in varus and 37.5% were in valgus. The surgeries were planned to maintain this alignment, and, after surgery, all of the knees succeeded in matching their preoperative alignment. There were no outliers in terms of flexion. With respect to the tibiae, they were all varus prior to surgery and this was maintained as preoperatively planned. The mean tibial slope prior to surgery was 5.00° ± 2.37° (mean ± SD) with 25% outliers (defined as <0° or >7°), and after surgery the mean slope was 4.29° ± 3.24° (mean ± SD) with 19% outliers. Sinha reported no failures using the system in the first 20 patients, but reported one failure of tibial registration in the next 17 patients. This patient was successful converted to a manual technique.

Coon et al. [49] compared 45 minimally invasive UKAs, performed using manual instrumentation, with 36 UKAs performed with RIO. They compared the Knee Society Scores (KSS) between the two groups postoperatively. There was no significant difference in terms of average KSS, change in KSS, or Marmor ratings between the two groups. This suggested that the RIO provides comparable clinical results to manual techniques for UKA.

Coon et al. [50] also compared a group of 44 UKAs performed using manual instrumentation with 33 UKAs using the RIO. The goal using both techniques was to match the natural tibial posterior slope, and the results showed that the RMS error using the manual technique was 3.5° and the error using the robotic system was 1.4°. Additionally, the variance using the manual instruments was 2.8 times greater than using the RIO. In the coronal plane, the manual instruments resulted in an average error of 3.3 ± 1.8° (SD) of varus compared to 0.1 ± 2.4° (SD) for the robotic system. Thus, the RIO resulted in improved accuracy in terms of implant placement during UKA when compared to manual instrumentation.

3.3. MAKO RIO. The MAKO Tactile Guidance System was used in a pilot study for UKA at Pennsylvania Hospital, Philadelphia, PA, USA using robot assistance from MAKO [46]. The study included 31 consecutive patients who underwent UKA using robotic arm assistance and 27 consecutive patients who underwent UKA performed with conventional manual instrumentation. Postoperative radiographs showed that the root mean square (RMS) error of the posterior tibial slope was 3.1° using manual techniques and 1.9° using robotic arm assistance. The average error of tibial alignment in the coronal plane was 2.7° ± 2.1° (mean ± standard deviation (SD)) using the conventional instruments compared with 0.2° ± 1.8° (mean ± SD) using robotic arm assistance. Varus-valgus RMS error was 3.4° manually compared with 1.8° robotically.

Another feasibility study was performed by Pearce et al. [67] in which 10 subjects needing a UKA were included. The results of this study showed that all of the patients had tibiofemoral angles in the coronal plane that were within 1° of what had been planned. There were no complications with the system and the wounds healed successfully.

3.4. ROBODOC. The ROBODOC System has been used clinically for TKA since 2000. The first 100 ROBODOC TKA procedures were performed by Professor Martin Börner at the Trauma Clinical of Trade Associations (BGU) in Frankfurt, Germany [30]. All of the patients received the Duracon Total Knee (DePuy Orthopedics Inc., Warsaw, IN, USA).

In this study, the results showed that the ROBODOC system made cuts that were good enough to allow cementless implantation for both the tibia and femur in 76 of the first 100 patients. Sixteen of the remaining cases needed cement for the tibial component and 8 cases needed cement for both components due to poor bone quality. In 97% of the cases, the alignment of the knee was restored to the planned ideal mechanical axis (0° error). The remaining three cases resulted in knee alignment being restored to within 1° of the ideal mechanical axis. The operating time decreased from 130 minutes for the first case to a typical time between 90 and 100 minutes by the end of the study. Of the first 100 cases, five were successfully converted to a manual procedure due to technical issues with the ROBODOC system.
Another study was recently published by Song et al. [51] looking at a direct comparison between a ROBODOC-assisted TKA and a manual TKA in the same subject using a prospective randomized study. Thirty patients underwent simultaneous bilateral TKA with a ROBODOC-assisted procedure in one knee and a manual procedure in the contralateral knee. The alignment of the knee and the individual components were determined postoperatively along with clinical follow-up scores including the HSS and WOMAC scores. The results showed significantly fewer outliers in terms of alignment errors and nearly equivalent clinical outcome results for both HSS and WOMAC scores. The postoperative mechanical axis was improved to $0.2 \pm 1.6^\circ$ (mean $\pm$ SD) in the ROBODOC group and only $1.2 \pm 2.1^\circ$ (mean $\pm$ SD) in the manual group. Furthermore, the ROBODOC group had no outliers in mechanical axis, defined as an error $\geq \pm 3^\circ$, while the manual group had seven outliers. However, the ROBODOC-assisted surgeries took, on average, 25 minutes longer than the manual cases, but resulted in significantly less postoperative bleeding. There were no major adverse events related to the use of the robotic system reported.

Song et al. [52] also recently published another study comparing ROBODOC-assisted and manual TKAs. This study looked at 100 total subjects that were randomly divided into 50 receiving ROBODOC-assisted TKA and 50 receiving manual TKA. Once again, the main goal was to improve the mechanical axis alignment to neutral (0'). The results showed that the postoperative mechanical axis was improved to $0.5 \pm 1.4^\circ$ (mean $\pm$ SD) in the ROBODOC-assisted group and $1.2 \pm 2.9^\circ$ (mean $\pm$ SD) in the manual group. The ROBODOC group had significantly fewer outliers (0'), once again defined as error $\geq \pm 3^\circ$, compared to the manual group (12). The operative time was once again of an average of 25 minutes longer in the ROBODOC cases, but they once again resulted in significantly less blood loss. The clinical results (range of motion, HSS scores, and WOMAC scores) showed no differences between the two groups. Additionally, this study compared the ability to balance the flexion and extension gaps after the bony cuts and soft tissue balancing were completed. The ROBODOC group resulted in only three outliers (defined as a difference in flexion and extension gap outside of $2 \pm 2$ mm (mean $\pm$ SD)) which were significantly fewer than the ten outliers found in the manual group. Finally, the PCL tension was measured intraoperatively. The ROBODOC group resulted in 96% of the knees having excellent tension and 4% having poor tension, while the manual group only had 76% of the knees with excellent tension and the remaining 24% with poor tension. This difference between groups was statistically significant. The ROBODOC group experienced six local and five systemic complications compared to the manual group which experienced three local and eight systemic complications. These complication rates were not statistically different.

4. The Future

Knee arthroplasty is widely considered a successful procedure in terms of relieving pain and improving function [3]. Yet, recent studies [7, 68, 69] have demonstrated that patient satisfaction is still less than optimal. Although the primary aim of knee replacement is relief of pain, once this outcome measure is achieved, patients’ priorities may change and they may expect their procedure to enable them to return to original functional status, especially in younger patients [69]. Thus, the ability to accurately preoperatively plan to restore alignment or proper joint kinematics of the knee and then execute the plan is important in increasing patient’s functionality, increasing the longevity of the implant, and reducing pain [17, 22, 23, 29–41, 51, 52]. Computer-assisted navigation surgery is a valuable technological development in orthopedics; however, robot-assisted surgery can achieve an improved level of accuracy and precision that is not possible with navigation alone. The use of robotic technology takes implant placement accuracy with navigation one level further by using information-rich 3D data during preoperative planning in combination with robot-controlled mechanical precision during implementation. This combination allows the surgeon to begin with a better plan for implant positioning and reduces the inevitable margin of error associated with manual preparation [15, 29] of the bone surfaces by the surgeon with or without navigation. The clinical results presented above show that robot-assisted orthopedic surgeries can already safely and effectively enhance the accuracy and precision of knee replacement without any major adverse events reported in any of the studies.

The potential benefit of precise implantation may be clouded by a lack of sensitivity in outcome measurement techniques. Clinical outcomes after knee arthroplasty are typically measured using objective functional outcome scoring systems that depend on postoperative pain and function. The most widely used scales include The Hospital for Special Surgery score (HSS, [70]), the Knee Society score (KS, [71]), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC, [72]), the Oxford Knee Score [73], and the more generic Short Form-36 (SF-36, [74, 75]). These functional outcome scoring systems are completed either by the patients (WOMAC, SF-36, and Oxford Knee Score) or the clinicians (HSS, KS) and typically have a limited number of levels differentiating between the extremes of pain and functionality. Depending on the specific scoring system, there are only 4-5 gradations between these two extremes, and thus an individual with full functionality and another individual with approximately 90% functionality while walking will be counted in the same group. This may explain the differences found between patient and surgeon satisfaction when considering outcomes [7, 68, 69]. The criteria for a successful procedure may differ between patient and surgeon and thus outcomes may be exaggerated when reported by the surgeon based on outcome scores [76]. Taking this into account, Noble et al. [77] have recently introduced an updated Knee Society Scoring System that accurately addresses patient satisfaction, patient expectations, and patient symptoms while participating in a broad range of activities of daily living and activities important to each patient.

Furthermore, there is some debate as to what the ideal target for coronal plane alignment [19, 20]. Although navigation has been shown to reduce the number of outliers when
looking at alignment, it has not been shown to improve short-term results, suggesting that coronal plane alignment may not be related to postoperative outcome [47]. In any case, the clinical studies reviewed in this paper demonstrate that robotic systems allow surgeons to better achieve their goals. If and when these alignment goals change, robotic systems are poised to better help surgeons achieve them in the future.

Despite all the benefits, there is still room for improvement with these robotic systems. The CASPAR system is no longer manufactured or being used clinically, but the Sculptor RGA, MAKO RIO, and ROBODOC systems are being used worldwide. Perhaps the biggest disadvantage of using a robot-assisted system for total knee replacement is the increase in operative time. The ROBODOC system results in a longer operative time compared to manual cases [51, 52]. The MAKO RIO and Sculptor RGA also require an increased operative time due to navigation and burring [47, 67, 78].

It should be noted that not all of these robotic systems have been used clinically without technical problems. A study by Chun et al. [79] examined the potential causes that can lead to aborting a ROBODOC arthroplasty procedure. Of 100 consecutively planned ROBODOC-assisted arthroplasties, the surgeons aborted 22 cases for a variety of reasons including registration failure, robot workspace issues, and potential damage to the patellar tendon. Of the aborted cases, only one resulted in complications with partial damage to the patellar tendon. Similar to these issues exist for other robotic systems as evidenced by Sinha [48] who reported a failed tibial registration in the first 37 cases.

Additionally, the cost of these systems is substantial in some cases. While the Stanmore Sculptor RGA is currently being offered at no cost to the surgeon, the initial capital equipment cost for robotic systems can be up to $800,000 [1]. Furthermore, the per case disposable costs associated with these procedures are higher than those associated with conventional procedures. Some of these extra costs can be mitigated by the fact that a reduced inventory for implants is needed for each procedure since the exact implant size is known prior to beginning the surgery based on the preoperative plan. Yet, the overall cost of implementing these systems typically remains increased.

Robotic systems may affect implant design in the future. For example, patient-specific implants and instrumentation are currently available and are designed based on the patient’s individual anatomy. However, the bone-implant interface for these systems is still designed to be compatible with traditional manual tools, such as oscillating saws and reamers. On the other hand, robotic systems, especially active systems, are capable of providing a precise freeform surface or an undercut shape that is virtually impossible with manual tools. With this ability, the implants can be designed with different surgical approaches or different fixation methods that may provide better initial stability using cementless fixation.

The development of less invasive methods using robotic systems could result in faster recovery times and enhanced postoperative patient functionality. Robotic systems have the ability to work through smaller incisions than traditional instruments due to the ability to preplan the cutting path in an active system or restrict the movement of the cutter in a semiaactive system. This can protect the soft tissues around the joint which can help with postoperative recovery and patient satisfaction.

Robotic assistance can clearly improve the accuracy of implant placement and fit in knee arthroplasty. These benefits may lead to robotic assistance becoming the gold standard for not only knee arthroplasty, but all joint arthroplasty because the principle of resecting bones, based on a preoperative plan is the same regardless of the bony geometry. Robotic-assisted orthopedic surgery systems are currently capable of improving a surgeon’s ability to implement his/her preoperative plan. Although the clinical outcomes reported thus far for TKA using robotic systems are similar to those performed manually, the development of better more sensitive outcome measures such as the new Knee Society Scoring System [77] or gait analysis may be able to demonstrate benefits not apparent using current outcome measures. In the future, surgeons may be able to restore knee joints through even smaller incisions exactly as planned as robotic assistance becomes the standard in joint arthroplasty.

References


Research Article

Achieving Accurate Ligament Balancing Using Robotic-Assisted Unicompartmental Knee Arthroplasty

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1. Introduction

Unicompartmental knee arthroplasty (UKA) has seen resurgence in the past decade with approximately 51,300 cases performed in 2009 and an estimated growth of 32.5% annually [1–3]. Benefits of UKA compared to total knee arthroplasty include reduced blood loss, reduced perioperative morbidity, faster recovery, shorter rehabilitation, increased postoperative range of motion, and reduced surgical cost [4–9]. However, proper patient selection is vital and the procedure remains technically demanding as the minimally invasive procedure limits surgical exposure and impeded precise component alignment and fixation [3, 6, 10–14]. UKA failures have mainly been attributed to improper component alignment leading to altered knee biomechanics with accelerated polyethylene wear if deformity is undercorrected, disease progression in other compartments if overcorrected, and anterior knee pain [6, 8, 15–17]. UKA component position and alignment are intricately associated with soft-tissue balancing during this procedure.

UKA allows for minimal disruption of the patient’s native anatomy and is intended to restore the normal height of the affected compartment to produce normal ligament tension during the flexion-extension cycle. The success of UKA relies on proper soft-tissue tensioning to obtain a balanced flexion-extension gap and varus-valgus stability [14]. While advances in surgical instrumentation with improved alignment guides and cutting blocks for minimally invasive surgery and navigation systems have improved component positioning in UKA, soft-tissue tensioning is still dependent on surgeon ability and experience. Achieving proper ligament balance throughout the flexion-extension cycle and avoiding tightness or laxity
Figure 1: Ligament balancing was measured throughout various angles during the flexion-extension cycle relative to tibia and mechanical axis. (a) The colored dots represent measurements during femoral range of motion. (b) Intraoperative screenshot of the robotic system showing ligament balance at 0°, 30°, 60°, 90°, and 110° of flexion before resection, with the trial component in place, and after implantation.

are complex and partly rely on component size and position [14, 18]. Increased soft-tissue tightness may decrease the range of motion and increase wear while increased laxity may lead to joint instability and knee pain.

Robotic-assisted UKA allows for improved component positioning [2, 3, 19] with the ability of real-time, dynamic ligament balancing intraoperatively. The robotic system uses optical motion capture technology that dynamically tracks intracortical markers fixed to the tibia and femur. The purpose of the current study was to describe the technique of soft-tissue tensioning and assess the accuracy of robotic-assisted ligament balancing based on an intraoperative balance plan during 52 consecutive medial robotic-assisted medial UKAs. We hypothesized that robotic-assisted UKA accurately produces ligament tension according to an intraoperative balance plan devised before component implantation.

2. Material and Methods

2.1. Robotic-Assisted Ligament Balancing Technique for UKA. While the surgical technique using a robotic-assisted UKA system has been described elsewhere in detail [6], this paper will focus on how to obtain accurate ligament balance for replacement of the medial compartment. Preoperative CT scans are used by the computer system to render a three-dimensional model of patient anatomy. Intraoperatively, anatomic landmarks are used to register the patient to the robot following intracortical placement of the femoral and tibial marker array. A minimally invasive medial joint incision is made, and medial osteophytes are resected. The knee is then ranged through a number of flexion-extension cycles. Valgus stress is then applied by the surgeon to open up the medial compartment and bring the knee into its “natural” alignment. The ligament balance is then analyzed and displayed by the computer system in real time as deviation from the optimal tracking pattern of the prosthesis calculated by the computer in millimeters (mm) during numerous flexion-extension cycles at 0°, 30°, 60°, 90°, and 110° of flexion (Figure 1). Negative deviation depicts ligamentous tightness and positive values indicate ligamentous laxity.

The values obtained during the range of motion with valgus stress serve as the intraoperative balance plan for ligamentous tensioning. Using the computer system, component position or size can be altered, and the resulting changes in predicted ligament balance can be observed in real-time. If there is predicted laxity, component size and position can be changed to increase tightness, thereby programming the robot to alter bone cuts based on the preoperative CT scans and intraoperative findings. After the bone resections have been made using the robotic arm, the trial components are inserted and ligamentous tension is compared to the intraoperative balance plan. If proper balance is achieved with the trial components in place, the final components are inserted and cemented, and final ligamentous balance is obtained during range of motion.

2.2. Assessment of Ligament Balancing Accuracy. The intraoperative data from 51 consecutive patients (52 knees) who underwent robotic-assisted UKA (MAKoplasty, MAKO Surgical Corp.) of the medial compartment by a single surgeon (RHJ) were prospectively collected over a 6-month period. All patients received a fixed-bearing UKA with an onlay cemented tibial component and cemented femoral component. Following registration of the robotic system and prior to incision, the intraoperative balance plan for ligament tensioning was obtained under valgus stress. After implantation of the final components, dynamic measurements were repeated without valgus stress. Data was stored on the computer system (Figure 1), and the actual ligament balancing was compared to the intraoperative balance plan by subtracting the planned measurements at 0°, 30°, 60°, and 90° of flexion.
from the actual postoperative measurements. Analysis of variance (ANOVA) was used to compare ligament balance at 0°, 30°, 60°, 90°, and 110° of flexion with Bonferroni post-hoc comparison with alpha 0.05. All data are presented as mean ± standard error of the mean (SEM).

### 3. Results

The mean age of patients in this study was 67 years (range, 50–90 years) with a mean body mass index of 31.4 kg/m² (range, 21.5–43.8 kg/m²). The surgical indication in all patients was isolated osteoarthritis of the medial compartment of the knee. Intraoperative measurements under valgus stress before component implantation revealed that ligamentous balance significantly changed during the flexion-extension cycle (Figure 2, *P* < 0.001). At 0° (0.34 ± 0.12 mm) and 30° (1.31 ± 0.13 mm) of flexion, the ligaments were relatively loose, at 60° (−0.28 ± 0.11 mm) and 90° (−0.49 ± 0.12 mm) of knee flexion ligaments were relatively tight, and at 110° of flexion close to neutral (0.07 ± 0.15). Comparison of the intraoperative balance plan to measurements after component implantation revealed similar ligament balance at 0° (0.11 ± 0.17 mm), 60° (0.78 ± 0.18 mm), 90° (−0.28 ± 0.13 mm), and 110° (−0.02 ± 0.19 mm) degrees of flexion (*P* > 0.05). Ligament balance at 30° of flexion was significantly reduced (0.88 ± 0.18 mm) after component implantation compared to the intraoperative balance plan indicating tighter ligament balance (*P* < 0.05).

Overall, the variation in ligament tensioning between the intraoperative balance plan and measurements after component implantation was less than 1 mm in 83% of the cases (Table 1 and Figure 3). At 0°, the mean change was −0.26 ± 0.17 mm (range, −4.40–2.20 mm), at 30° −0.53 ± 0.18 mm (range, −5.30–1.80 mm), at 60° −0.04 ± 0.15 mm (range, −3.10–2.30 mm), at 90° 0.16±0.13 mm (range, −2.70–2.00 mm), and at 110° −0.10 ± 0.14 mm (range, −2.2–2.0).

### 4. Discussion and Conclusion

Successful outcomes of UKA rely on the restoration of normal knee kinematics and muscle lever arms of the knee joint. Therefore, restoration of proper ligamentous length and tension is a vital component of the UKA surgical technique. Using a robotic-assisted UKA system, we showed that real-time, dynamic ligament balancing reproduced planned ligamentous balance and, when appropriate, was able to increase ligament tightness when there was relative preoperative laxity.

Whiteside pointed out that proper ligament balance in combination with component alignment and fixation is vital for the success of UKA [14]. In a normal knee, the ligaments and menisci control anterior-posterior and varus-valgus movement between the femur and tibia. Medial compartment osteoarthritis with loss of cartilage and bone substance leads to a varus deformity and contracture of the medial capsule and ligaments [20]. The goal of medial UKA for a correctable varus deformity is to restore the normal height of the compartment, thereby achieving ligamentous balance and natural alignment of the joint. This “gap filling” procedure is in contrast to total knee arthroplasty in which bone cuts are made first and then soft-tissues are released to obtain a rectangular flexion-extension gap. Component malpositioning by only 2° during UKA can lead to failure [6, 9, 10, 13, 21], because normal joint biomechanics are altered without achieving proper ligamentous balance possibly leading to increased polyethylene wear and accelerated progression of degenerative disease in the uninvolved compartment [15–17].

During conventional UKA, soft-tissue balance is assessed with the trial components in place and with subjective varus-valgus stress testing, commonly at 0° and 90° [22].

**Table 1: Comparison of the intra-operative balance plan and ligament balance measurements following component implantation. Data is expressed as mean ± standard error of the mean in millimeters.**

<table>
<thead>
<tr>
<th>Flexion angle</th>
<th>Balance plan</th>
<th>After implantation</th>
<th>Change in balance</th>
<th><em>P</em> value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0°</td>
<td>0.34 ± 0.12</td>
<td>0.08 ± 0.18</td>
<td>−0.26 ± 0.17</td>
<td><em>P</em> &gt; 0.05</td>
</tr>
<tr>
<td>30°</td>
<td>1.31 ± 0.13</td>
<td>0.78 ± 0.17</td>
<td>−0.53 ± 0.18</td>
<td><em>P</em> &lt; 0.05*</td>
</tr>
<tr>
<td>60°</td>
<td>−0.28 ± 0.11</td>
<td>0.33 ± 0.14</td>
<td>−0.04 ± 0.15</td>
<td><em>P</em> &gt; 0.05</td>
</tr>
<tr>
<td>90°</td>
<td>−0.49 ± 0.12</td>
<td>0.16 ± 0.13</td>
<td>0.32 ± 0.13</td>
<td><em>P</em> &gt; 0.05</td>
</tr>
<tr>
<td>110°</td>
<td>0.03 ± 0.16</td>
<td>−0.07 ± 0.19</td>
<td>−0.10 ± 0.14</td>
<td><em>P</em> &gt; 0.05</td>
</tr>
</tbody>
</table>

* A *P* value less than 0.05 was considered statistically significant.
The restoration of the normal height of the compartment is vital to achieve proper ligamentous balance. The appropriate ligament balance is left to surgeon’s feel and has been described as an art that requires ability and experience [23]. While intraoperative measuring devices are available for total knee arthroplasty [23], their use remains ambiguous and there is currently no such device available for UKA. Navigation systems for UKA have become available to improve component positioning and alignment; however, these systems are incapable of assessing ligament balance. Robotic-assisted systems assess ligamentous balance dynamically and in real-time at various flexion angles. Placing a valgus stress on the knee after medial osteophytes have been removed opens the medial compartment and brings the knee into its natural alignment. These measurements enable the fine tuning of the planned component position to achieve optimal component height and orientation, and thereby ligamentous balance. Following bone resection using the high speed burr with haptic feedback, the femoral and tibial trial components are inserted, and balance measurements are repeated. If necessary, bone cuts can be adjusted for optimal implant orientation. Using a robotic-assisted UKA system, the surgeon has the ability to measure ligament tightness or laxity objectively during dynamic, real-time analysis by the computer system. Natural knee kinematics can be restored based on objective measurements, in addition to surgical acumen.

Specifically, fixed-bearing tibial components, such as the implants used in this study, rely on proper soft-tissue tensioning. There is low conformity between the femoral and tibial components with low contact areas allowing for unconstrained movements between the femur and tibia controlled only by the ligamentous apparatus [24]. Conversely, mobile-bearing UKA systems have high conformity of the tibial and femoral components to increase their contact areas and reduce contact stress. Mobile-bearing systems came in favor to reduce contact stress of the articulating surface thereby preventing polyethylene fatigue and failure [24]. With highly-crosslinked polyethylene components available that are more resistant to wear, Burton et al. and Taddei et al. showed decreased wear during in vitro testing with a fixed-bearing UKA compared to a mobile-bearing UKA [24, 25]. In a recent meta-analysis of clinical, radiological, and kinematic outcomes comparing fixed- to mobile-bearing UKA, Smith et al. showed similar improvements and outcomes between 146 mobile-bearing UKAs and 147 fixed-bearing UKAs at a mean 5.8 ± 3.1 years [26]. Despite the design of the prosthesis, proper ligament balance is essential for long-term survival and functional improvements.

There have been numerous advances in UKA instrumentation and cement or cementless fixation techniques that have led to an increase in the survivorship of UKA in the past decade [27, 28]. Minimal invasive instrumentation has become available for more precise component positioning, and improvements in polyethylene components have led to decreased wear. However, robotic-assisted UKA systems have been shown to increase the precision of component placement [2, 19, 29], and the opportunity for real-time, dynamic ligament balancing offers an additional advantage. Dunbar et al. assessed the accuracy of component placement in 20 patients who received postoperative CT scans [29]. In comparison to the preoperative plan, accuracy (root-mean-square error) for femoral and tibial component placement was within 1.6 mm and 3.0° in all directions [29]. Lonner et al. compared tibial component alignments between manual UKA and robotic-assisted UKA and found a greater variance

Figure 3: A(a), 60° (c), 90° (d), and 110° (e), ligament balance between 1 mm and −1 mm was achieved in 81% to 93% of cases. A(t), 76% of cases were balanced between 1 mm and −1 mm due to a necessary increase in ligament tightness.
in component position, increased tibial slope, and increased varus alignment when the tibia was prepared manually [19].

A major limitation of this study is the lack of clinical or functional outcomes in this patient cohort; however, further investigations into the benefits of accuracy of component placement, robotic-assisted systems in component position, increased tibial slope, and increased patients; however, further investigations into the benefits of accuracy of component placement, robotic-assisted systems time, dynamic measurements. In combination with high intraoperatively planned ligamentous balance using real-

robotic-assisted UKA can accurately and precisely reproduce 
system for UKA. We conclude from our findings that 
robotic-assisted UKA can accurately and precisely reproduce intraoperatively planned ligamentous balance using real-
time, dynamic measurements. In combination with high accuracy of component placement, robotic-assisted systems may improve functional outcomes and survivorship of UKA patients; however, further investigations into the benefits of robotic systems for UKA are needed.

To our knowledge, this is the first study assessing real-
time dynamic ligament balancing with a robotic-assisted system for UKA. We conclude from our findings that robotic-assisted UKA can accurately and precisely reproduce intraoperatively planned ligamentous balance using real-time, dynamic measurements. In combination with high accuracy of component placement, robotic-assisted systems may improve functional outcomes and survivorship of UKA patients; however, further investigations into the benefits of robotic systems for UKA are needed.

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