

# Robots in Orthopaedic Surgery

*Past, Present, and Future*

*William L. Bargar, MD*

**Robots are increasingly being developed for use in surgery to aid physicians in providing more precision, especially during procedures requiring fine movements that may be beyond the scope of the human hand. In addition, robots enable the surgeon to provide improved accuracy and reproducibility with the goal of better outcomes. To date, most robotic surgical systems are in the design and experimental stage. For robotic systems to gain widespread acceptance in surgery, they must first prove their value in clinical application and ease of use as well as provide a favorable cost-to-benefit ratio. I provide an overview of the history of robotics in orthopaedic surgery and a review of their current applications with some predictions of the future for this technology.**

The use of robots in surgery dates back to the mid-1980s with the development of a system for performing stereotactic neurosurgery.<sup>9</sup> Similar systems for this application were under development throughout the world at about the same time.

The first active robotic system for use in orthopaedic procedures was ROBODOC (Integrated Surgical Systems, Davis, CA), developed at the University of California–Davis from 1986 to 1992 (Fig 1). Researchers at Northwestern University<sup>8</sup> designed a robotic device for performing TKA, and a robotic arm was developed to provide a highly accurate, portable coordinate measurement device for knee surgery (FARO Technologies, Lake Mary, FL). These systems were never commercialized.

## History of ROBODOC

The idea for development of the ROBODOC system began to take shape after the introduction of cementless THA

implants in the 1980s. The early cementless femoral components were prone to failure owing to lack of ingrowth of bone, activity-limiting thigh pain, or both. These problems were attributed to poor fit and stability of the implants. Howard A. Paul, DVM and I conceived of ROBODOC in 1985. It is a computed tomography (CT)-based, computer-aided robotic milling device that allows accurate preparation of the femoral bone and anatomic placement of the femoral component in cementless THA. These applications have since been expanded to include revision THA and primary TKA.

A feasibility study of the concept was performed in 1986 to 1987 at the IBM Thomas Watson Research Center in Yorktown Heights, NY. In vitro development of the system took place at the University of California–Davis from 1987 to 1989. This was followed by a canine clinical study from 1989 to 1991. In 1991 to 1992, the system was adapted for human application, at which point ROBODOC was licensed by Integrated Surgical Systems, Inc. The first human feasibility study was conducted on 10 patients at Sutter General Hospital in Sacramento, CA. The study, which started on November 12, 1992, was conducted for 1 year. A randomized multicenter study was then conducted beginning in 1994 through 1998 to perform cementless primary hip arthroplasty on 136 consecutive hips in 119 patients at three centers: Sutter General Hospital in Sacramento, New England Baptist Hospital in Boston, and Shadyside Hospital in Pittsburgh.<sup>12</sup>

The results showed statistically improved fit, fill, and alignment when compared with manual THA,<sup>1</sup> and intra-operative fractures were eliminated in the ROBODOC group. We observed no differences in Harris hip scores between patients operated on using the ROBODOC system and the control group at 2-year followup.<sup>1</sup>

There were, however, some problems with these early ROBODOC surgeries. Surgery times were longer, which was attributed to the learning curve required when beginning use with the system as well as a slow error recovery system. If the robot monitoring system detects an error (such as movement of the bone), the robot will stop. The

From the Sutter Joint Replacement Center, University of California–Davis School of Medicine, Sacramento, CA.

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Correspondence to: William L. Bargar, MD, FAAOS, Joint Surgeons of Sacramento, 1020 29th Street, Suite 450, Sacramento, CA 95816. Phone: 916-733-5066; Fax: 916-733-8705; E-mail: wbargar@jointsurgeons.com.

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**Fig 1.** Photograph of the Robodoc system (Integrated Surgical Systems, Davis, CA). Robodoc was the first active robotic system for use in orthopaedic procedures, and was developed at the University of California–Davis, from 1986 to 1992. (Reprinted with permission of Integrated Surgical Systems, Inc, Sacramento, CA.)

recovery process is a series of steps that must be completed to allow the procedure to safely continue. This process was slow in the first FDA study, thereby contributing to longer surgery times. There was also a small increase in blood loss when ROBODOC was used as compared with the controls, which was attributed to the increased surgical time required with the system. In addition, separate surgery was required in the ROBODOC group to place “locator pins” before the CT scan was conducted, which were used for registration of the CT image to the robot coordinate system. Although these problems did not result in any specific complications, they had the potential to do so.

To address these concerns, several improvements were made to the system. A new registration method was developed that eliminated the use of locator pins (termed the “pinless” technique). This method uses contour-matching software to register randomly collected points to the CT contour. In addition, cutting times were reduced and a more robust error recovery system was developed that allowed much quicker error recovery times.

In 2001, the FDA authorized a second, multicenter US trial of the ROBODOC system using the pinless system along with the previously mentioned improvements. The centers participating in this trial are Sutter General Hospital in Sacramento, the University of Arkansas Medical Center, the Jewish Hospital in Cincinnati, and Lutheran Hospital in Cleveland. The aim of this study is to decrease surgical time and blood loss and to prove the efficacy of pinless technology. To date, approximately 80 cases have been performed. Average blood loss is 471.54 cc and average surgical time is 121.92 minutes. These results are a clear improvement over the results achieved during the first multicenter trial,<sup>1</sup> in which average blood loss was 1189 cc and average surgical time was 258 minutes.

ROBODOC was approved for sale in the European Union in 1994. It was first used by Dr. Martin Borner in Frankfurt, Germany.<sup>2</sup> Over the next 4 years, there was rapid growth of the use of ROBODOC mainly in Germany with over 30 systems installed in that country.

Although it has not yet been approved by the FDA for use in the US, many ROBODOC systems have been installed throughout the world, including eight systems in Japan and three in Korea (Table 1). By my estimation, the system has been used in nearly 15,000 cases worldwide.

Honl and colleagues<sup>6</sup> recently published a comparison of manual and ROBODOC-assisted primary THA in which they asserted a higher rate of postoperative dislocation (18% versus 4% in the control group) and revision (13% versus 0% in the control group) in the 74 patients operated on using ROBODOC compared with the 80 control subjects. All of the revisions were for recurrent dislocations and pronounced limp. At revision, the authors found the abductor muscles were detached from the trochanter and implied that in those cases, the robot damaged the abductor muscles, causing rupture. When the revision cases were excluded, the authors found the Harris hip scores, prosthetic alignment, and limb length differentials were better for the ROBODOC group at 6 and 12 months.

It appears the complications encountered in the Honl et al<sup>6</sup> study may be the result of human error rather than robot error. Because of the redundancy built into modern

**TABLE 1. Internationally Placed ROBODOC Systems**

Country	Number of Systems
Germany	31
Austria	4
France	3
Switzerland	1
Japan	8
Korea	3
India	1

robotic systems such as ROBODOC, it is not possible for the tool to deviate from the prescribed cut path. If an error is detected, such as bone motion, the robot simply stops. As with any robotic device, the operator must give the robot a clear workspace. In this instance, the abductors must be protected and retracted from the workspace of the robot. Neither the initial US multicenter trial discussed previously nor the current ongoing US multicenter trial (unpublished data) have the incidence of complications reported by Honl et al.<sup>6</sup> We believe the ROBODOC system is safe, improves the accuracy and reproducibility of implant sizing and placement, and does not increase the risk of performing THA surgery. When using ROBODOC to assist in THA or TKA, it is imperative that the surgeon select the proper design of the implant, plan the appropriate fit and positioning of the implant, and exclude patients who are not good candidates for robotic surgery such as those in whom the greater trochanter overhangs the medullary canal to such an extent that it may be damaged by the robotic cutting tool, which is axially directed. This is clearly visible on the CT as viewed at the preoperative planning workstation. In addition, meticulous care must be taken to protect the soft tissues during the surgery.

Outside the US, ROBODOC has also been used in revision THA to remove cement at the same time it is preparing the femur for the implant. Robotic milling of the fragile, osteolytic bone offers less chance of intraoperative fracture than attempting to remove cement manually with gouges or handheld burrs. In primary TKA, ROBODOC mills the femur and the tibia based on the preoperative CT plan. In these cases, no instruments are required, and the surgery can be performed through a very small incision. ROBODOC may also prove useful in performing THA by less invasive techniques. Recent improvements in the ROBODOC system allow for a substantial reduction in access (less than 2.5 cm) required for THA femoral component preparation.

### Current Status of Robotic Surgery

The field of computer-aided surgery is expanding with many new devices under development in multiple centers worldwide. In addition, societies and journals devoted to the use of computers and surgical robots are emerging everywhere. This burst of interest in cybertechnology for medical use has spawned a surplus of acronyms, including CAOS (computer-assisted orthopedic surgery), MRCAS (medical robotics and computer-assisted surgery), MICCAI (medical image computing and computer-assisted intervention), and CARS (computer-aided robotic surgery) among others.

In 1998, a workshop was held entitled "New Engineering Technology Transfer in Orthopaedics," sponsored jointly by the National Institutes of Health and the

American Academy of Orthopaedic Surgeons.<sup>3</sup> This workshop developed the following terms in an attempt provide some order in this growing field: "active systems" are those capable of performing individual tasks autonomously (eg, ROBODOC, CASPAR); "passive systems" are those that provide additional information during a procedure but do not perform an action.<sup>11</sup> For example, the surgeon controls the system but acts on information (eg, navigation) provided by the device. "Semiactive systems" are those in which surgical actions are constrained or adjusted by the system, but the final control still depends on the surgeon (eg, computer-aided saw guides).

A review article on the state of the art in surgical robotics identified 159 robotic systems or projects either developed or under development.<sup>10</sup> Of these, 23% are from North America and the remainder are from Europe and Asia. Sixty-eight percent of the systems are based on serial kinematics (rigid links connected by joints), with only one-third using articulated robots, which were originally designed for industrial deployment. Pott and colleagues<sup>10</sup> reported 70% of the total robot systems were specifically designed for medical use. They also suggested 67% of all robots under consideration for medical use are in the experimental stage and have not yet been tested on patients. As of their report, only 24% of the total systems had been used experimentally on human subjects and only 9% were commercially available in some countries.<sup>10</sup>

Current areas of concentration for robotics in orthopaedics include various applications in hip surgery such as femur preparation, acetabulum positioning, and pelvic and femoral osteotomies. In knee surgery, robotics can be used in TKA, anterior cruciate ligament reconstruction, and arthroscopy. In trauma surgery, robotics can be useful in repairing pelvic, hip, and long bone fractures.<sup>4</sup>

As of mid-2004, the review article by Pott et al<sup>10</sup> identified 30 robotic systems developed for orthopaedic applications. Fifteen systems were for joint replacement surgery (four THA, eight TKA, three both), seven for spine applications, three for trauma, and five had other applications (Table 2). Of those, only four systems have become commercially available. The ACROBOT system (Acrobot Co Ltd, London, UK) is a six degree of freedom robot that is surgeon-controlled but allows only certain predefined trajectories (Fig 2). Its first application is for unicompartmental knee replacement surgery. The ROBODOC system (Integrated Surgical Systems, Inc) has been described and is currently in its second US FDA clinical trial for cementless THA. It is used in many countries throughout the world for THA, TKA, and revision THA. The PI GALILEO NAV system (Precision Implants AG, Aarua, Switzerland) uses two perpendicular axes to navigate and automatically move a cutting guide for TKA. The CASPAR system (Ortho-Maquet/URS, Schwerin, Ger-

**TABLE 2. Robotic Systems in Orthopaedics**

Type of System	Number of Systems
Joint Replacement	
Hip	4
Knee	8
Both	3
Spine	7
Bone Repositioning	3
Other	5
Total	30

Data extracted with permission from Pott PP, Scharf H-P, Markus L, Schwarz R. Today's state of the art in surgical robots. *Computer Aided Surg.* 2005;10:101-132 (Taylor & Francis Ltd, <http://www.informaworld.com>).

many) was an image-guided active robot used for THA and TKA similar to ROBODOC. The company is no longer in business.

This review of existing robotic systems in orthopaedic surgery and those under development is greatly limited by



**Fig 2.** Photograph of the ACROBOT system (Acrobot Co Ltd, London, UK). ACROBOT is a six degree of freedom robot that is surgeon-controlled but allows only certain predefined trajectories. Its first application was for unicompartamental knee replacement surgery. (Reprinted with permission of Acrobot Co Ltd, London, United Kingdom.)

the lack of information on these systems available in the public domain. This is a very new and emerging technology. Therefore published clinical studies are few. Only the ROBODOC and CASPAR systems have been used in large enough volume to permit clinical studies to be published.<sup>2,5,12</sup> Information on developing systems is even more difficult to obtain. Because of intellectual property concerns most devices in this stage of development are not publicized.

Navigation systems offer the advantages of generally being less expensive and easier to use than robotic systems. Also, many are “CT-free,” thereby avoiding the logistics and cost of obtaining these scans. They still require freehand cutting with power tools, which can introduce errors. Robots offer precision (accuracy and reproducibility), plus they execute the preoperative plan and offer the potential to eliminate human error.<sup>7</sup>

A blend of these technologies may provide the most versatile tool for orthopaedic applications. Those elements of orthopaedic surgery that do not require precise machining, such as acetabular cup preparation, may be better performed using a navigation system. This is not to say, however, that acetabular cup orientation, sizing and location are less important than for the femoral stem. Other elements of the procedure that require precise machining and preoperative planning such as femoral stem placement may be better suited for a robotic system.

## DISCUSSION

We are currently in what might be called the “preindustrial phase” of the evolution of surgical practice. We teach our residents and fellows by apprenticeship. Surgeons are basically “artisans” creating unique solutions to surgical problems based on their abilities and human variation of their techniques. This of course leads to variation in patient outcomes, some of which leads to undesirable complications. Just as the industrial revolution standardized production methods and controlled quality (CAD/CAM manufacturing), so can the use of robotics allow the surgeon to obtain accuracy and reproducibility to control quality and eliminate variation of outcomes.

In the future, robotics will enable true minimally invasive procedures. The ability to link surgical execution to the preoperative plan, without the need for visualization by the human eye, will allow the placement of implants into bones with the least amount of surgical trauma. For example, recent improvements in the ROBODOC system allow for a theoretical reduction of the required incision length for THA femoral canal preparation to less than 2.5 cm.

The use of robotics will lower instrument and inventory costs to manufacturers, helping to keep down implant

costs. Robotic devices do not need expensive saw guides, broaches, or reamers. The end effectors (burr or saw blade) are relatively cheap and disposable. Implant manufacturers spend millions of dollars each year on instruments. Lowering instrument costs to manufacturers means they can offer competitive pricing, ultimately leading to lower implant costs. The implant manufacturers also incur high costs to maintain inventories around the country and the world. Preoperative planning based on three-dimensional imaging linked with robotics offers the possibility of "just-in-time" inventories. We believe it likely robots will become commonplace in orthopaedic surgery. Based on advances that have already been made, precision in performing current procedures will improve. In addition, we can expect to see applications for robotics in operative procedures that are not presently feasible.

Robots offer some clear advantages. They are more accurate than the human hand in performing certain tasks. They can achieve reproducible results, which should lead to less variation in patient outcomes. They also have the ability to accurately execute the preoperative plan. The big question is, how long will this take? Future developments in robotics and surgery may be held back by three factors: (1) resistance by surgeons lacking confidence in these new technologies; (2) resistance by third party payers, either managed care or government; and (3) regulatory hurdles and political and economic forces may constrain the use of robotics in surgery.

The key to future acceptance of all new technologies lies in proving their "clinical utility." Although the FDA does not define the term, the agency requires proof of clinical utility before it grants approval. In part, clinical utility implies demonstration of a good cost-to-benefit ratio.

The ultimate acceptance of robotic surgery into common orthopaedic practice depends on its cost-effectiveness. The costs of new technology can be difficult to assess. The initial cost of devices that require extensive research and development can be quite expensive. In order to be commercially viable, these R & D costs must be offset by the price of the device. In the case of ROBODOC® the initial price in Europe in the 1990s was \$635,000. In some cases this cost was subsidized by orthopaedic implant manufacturers in order to increase sales of their implants. In other countries the actual price varies according to the costs of doing business in those countries. In some cases the end user has paid as much as \$1.5 million for the device. In the future, these prices are likely to come down. The price of a new ROBODOC device will depend strongly of the numbers of units produced. If ROBODOC gets FDA authorization for clearance to market in the US, and the volume of orders increases considerably, it is likely that the price of a new system in the US

will drop below \$350,000. To this initial price of acquiring the device, the cost of disposables must be added. In the case of ROBODOC these disposables amount to approximately \$150 per procedure. Finally, another added cost is the increased time in the operating room. For the ROBODOC system, preliminary data indicate that 30 minutes of additional time is required on average.

How can the costs of a robotic system be offset? The ROBODOC system eliminates the need for many trays of instruments. Today's total hip systems require between 3 and 7 trays just for the femoral portion of the procedure. Assuming an estimate of \$50 per tray of cost to the hospital for cleaning, sterilizing, and storage, this would amount to \$150 to \$350 in savings per case. Additionally, when parts are lost from the tray these parts need to be replaced at a cost to the hospital. Sometimes the entire tray needs to be replaced.

If this technology becomes widely accepted, there would be considerable savings by the implant companies in reduction of their instrument and inventory costs. As noted previously, this could result in savings for the implant companies of many millions of dollars. This may allow implant costs to decrease by several hundreds of dollars per case. This would help to offset the lease payments by the hospital, which can be arranged on a per use basis. Also to be considered by the hospital is the potential increase in volume of patients attracted to the facility by this new technology. Third-party payers may also increase the reimbursement to hospitals and surgeons that employ this technology if it can be shown to reduce complications and prevent some costly revisions.

One of the problems in determining the effectiveness of a new technology in our field of orthopaedic surgery is that ascertaining its success or failure typically requires decades of followup. New technologies may offer the potential for increased longevity of implants, but it is not possible to prove their effectiveness in the short run. We do not have the luxury of waiting decades to evaluate new technologies such as robotic surgery. What we need are "surrogate" variables we can measure in the short run and that accurately predict success or failure in the long run. A good example of a surrogate variable is the measuring of serum cholesterol and its association with the incidence of myocardial infarction. If a new drug is developed proven to lower serum cholesterol, it is not necessary to prove that it will reduce heart attacks. Unfortunately, in orthopaedic surgery, and specifically in joint replacement surgery, there are few proven surrogate variables for long term success or failure. We all believe and have been taught that appropriate sizing and fit of implants are important for long-term success, but our literature does not prove this association. More importantly, we do not have data on the tolerance for the magnitude of variations in technique that

correlate with success or failure. Future studies should look both retrospectively and prospectively to analyze the effect of variations in technique on long-term success or failure. One of the potential benefits of computer-aided surgery is that it can record these variations and perhaps yield these data in the future. Improved accuracy and precision, reduction in day-to-day variations in technique and the reduction of so-called “outliers” can be presumed to improve success rates and decrease complications.

Perhaps more importantly, however, new technologies (like robots in surgery) must address the following questions: Do they solve a real problem in clinical medicine? Do they improve the outcome of operative procedures? Do they result in savings without lowering quality? Are they worth the investment?

At the present stage of development, robotic surgery seems to offer some definite benefits. It remains to be seen whether these benefits will outweigh the associated costs over the long term. With advances in robotic technology, future surgical robots will be smaller, less expensive, and easier to operate, which may ultimately facilitate their acceptance in surgery and help to improve their clinical use.

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