Chapter 11
Robotic Surgery: Enabling Technology?

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Abstract Since its emergence, modern robotics has empowered mankind to reach goals ranging from the hazardous to unfeasible. In the medical field, robots have ushered in an era of minimized invasiveness, improved accuracy, lessened patient trauma and shortened recovery periods.

This chapter offers an overview of currently available medical robots and especially evaluates their technology-enabling capacities. Combination of significantly higher accuracy than conventional free-hand techniques with minimally invasive capability renders robotics an enabling technology. Obviously, dramatic dimensional changes in robots, to levels allowing for their introduction to the body for diagnostic and therapeutic purposes, also designates them to an enabling technology. The few currently available surgical robots are categorized in this chapter according to their enabling potential, along with a presentation of a future micro-robot for in-body treatment.

Keywords Active constraint · Enabling technology · Micro-robots · Minimally invasive · Pedicle screw · Snake robot · Spine surgery · Surgical robots

11.1 Introduction

Evolution of industrial robotics from its early inception in the early 1960s, has advanced this technology to autonomously perform common tasks in a more cost-effective and accurate manner. Its first applications were often toward activities which involved difficult or hazardous working environments. Later, as in the case of

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Unimate, robots were implemented in pick and place manufacturing applications to ease the tedious and boring labor characteristic of production lines. Introduction of remotely operated systems allowed for robot exploitation in execution of tasks otherwise impossible for humans to withstand, such as radioactive, subterraneal or undersea operations. Modern-day robotics integrates sensory and advanced navigational hardware into automative systems, rendering them more adaptable to dynamic environments. In industry, the advanced degrees of repeatability, accessibility and speed offered by robots, yield increased throughput and facilitate quality control.

The potential contribution of robotic precision and delicacy toward revolutionizing medical applications soon became appreciated. In practice, major surgical operations are performed under robotic guidance via less invasive methods, leading to lessened patient trauma and enhanced recovery rates. In addition, development of micro-robotics is currently underway to locate, diagnose and specifically treat diseases from within the body. Yet, although the seeds of introducing robotic talent to surgical practices were planted some 20 years ago, only a handful are in routine use.

Looking back at the 50-year robotic era, one may wonder whether modern robots accomplish missions unconquerable by unassisted humans. When considering extreme examples, such as the Mars Exploration Rover or NASA's Pathfinder and Sojourner operating in outer space, the muser will be convinced that robotics indeed possess enabling features. However, in most cases, robotics simply offers improved consistency and accuracy and performs tasks within shorter periods of time. Economically, accelerated operative capacities and notable operational accuracy are often sufficient enough justification for product marketing. Yet, the intent of the current article is to evaluate the enabling features of the growing medical applications of robotics. While numerous research and development projects aiming at incorporating robots in the medical arena are underway, only those which have matured and are in ongoing use are presented below.

Do surgical robots merely provide highly regulated clinical assistance, as in the case of Computer Motion's (now Intuitive Surgical) laparoscopic camera holder, or can they execute tasks otherwise impossible by free-hand performing surgeons? Are there insurmountable applications limited by human physical capacities that can be achieved by the robot?

11.2 OR-Implemented Surgical Robots

Integrated Surgical Systems Inc. (ISS) made the pioneering breakthrough in robotic-aided surgeries by developing the ROBODOC® designed to provide optimal fit and alignment of hip prosthesis placement procedures. The application's precision was manifested in its ability to accurately direct the robotically held mill along predefined trajectories and was applied in over 20,000 joint replacement cases. After several years of suspended operations, use of the ROBODOC® system was reinitiated by Curexo Technology Corporation with broadened applications for revision surgeries, and received FDA clearance in August 2008. The cumulative results of its clinical application demonstrate enhanced implant fit to the robotically-shaped cavity, with broader implant-to-bone contact areas and less susceptibility to bone severage. Yet, these reports and the long term results did not provide sufficient evidence demonstrating a substantial edge on free-hand techniques. While to date, the advantages of this pioneering robot did not provide ample justification for its standardized integration into operating rooms (OR), reevaluation of its accumulating clinical impact may modify this ruling.

The growing need and demand for robotics supporting less invasive surgeries, a critical feature currently lacking in the ROBODOC® platform, initiated the development of new approaches to surgery-assisting robot design. The emergence of image-guided robotic assistance enabled surgeons to visualize and navigate complex anatomical structures during planning and executing stages. These remarkable advances ushered in an era of heightened accuracy and greater prospects for minimally invasive surgical approaches. More specifically, the Mako Surgical orthopedic device company engineered the RIO® robotic arm in response to the need for tools offering both accuracy and minimally invasive (MIS) surgical approaches for uni-compartmental knee replacement. As in the case of Acrobot's Sculptor® active-constraint robot, this robot is programmed to prevent the surgeon from moving a bone cutting tool beyond a predefined milling area. In this manner, the device keeps the active milling to within specific limits of the pre-planned field and at the same time offers minimally invasive access to the region of interest.

Prosurgics' Pathfinder and Neuromate® robots offer image-guided stereotactic neurosurgery robotics directing surgeons along a predefined path to the specific point of interest within the brain. While these systems claim sub-millimetric accuracy, beyond that of a free-hand surgeon, can they be considered enabling devices?

Robotically-guided radiotherapy provides accurate non-invasive treatment as reported for the CyberKnife and Gamma Knife streotactic radiotherapy systems which direct focused beams to their target tissue while correcting for natural patient breathing motions. Similarly, BrainLAB's Novalis Tx radiosurgery shaped-beam technology directs treatment beams to tumors in an accurate and non-invasive manner. Insightech's Exablate® provides a highly controlled and targeted method for uterine fibroid removal through noninvasive MRI-guided focused ultrasound. These systems offer accurate, non-invasive treatment and can therefore be designated enabling technologies.

Intuitive Surgical's *da Vinci*, currently the most widespread surgical robot, replicates and scales down surgeon hand motion and eliminates tremor leading to heightened accuracy. It allows dexterous manipulation of surgical tools within the body cavity, through small ports, thereby allowing for combined accuracy and minimal invasiveness. In these respects, the *da Vinci* robot system enables new operational technology otherwise impossible by the free-hand surgeon. Moreover, as the design of the teleoperating *da Vinci* also allows the surgeon to operate from a remote console physically separated from the robotic arms performing the surgery, future uses can be made in such remote locations as space, undersea or battlefields and will also globally extend expert abilities.

When looking back at the short history of surgical robotics, it seems that accuracy enhancement alone might not suffice marketing justification. Rather, the accelerating commercial competition and technological expertise demand advanced qualifications of such robotic systems, including significant minimizing invasiveness features, or decreased radiation exposure. Yet, marketing success will still not always reflect the degree to which a robotic device is enabling.

11.3 The SpineAssist Robot

Consider Mazor's SpineAssist robot (Figs. 11.1 and 11.2) developed by a team including the author of this chapter, designed to direct surgeons to accurate locations along the vertebra in efforts to enhance procedural accuracy of pedicle screw insertion, tumor resection or biopsy. This robot presents marketing advantages through its high accuracy, minimal invasiveness, and reduced radiation exposure [1–7]. It has performed in over 1,000 clinical cases, with more than 4,000 implants and reported no permanent neurological deficits, as compared to 2–5% reported in the literature for pedicle screw insertions [8–10]. Moreover, in 49% of the cases, surgeons acting with SpineAssist positioning preferred percutaneous over open approaches for screw insertions, in contrast to the 5% of non-robotically guided surgeries rate reported throughout Europe [11]. While these contributive elements do not mandate designation of SpineAssist an enabling technological advance, specific clinically complex cases where anatomical landmarks are missing and when free-hand surgeries are viewed as high-risk, as in severe cases of scoliosis and repeated revision surgeries, transform this positional platform into an enabling device.

Fig. 11.1 SpineAssist surgical robot

Fig. 11.2 SpineAssist assembly in a less invasive pedicle screw insertion. A guiding tube attached to the robot arm guides the surgical tool along a predefined trajectory

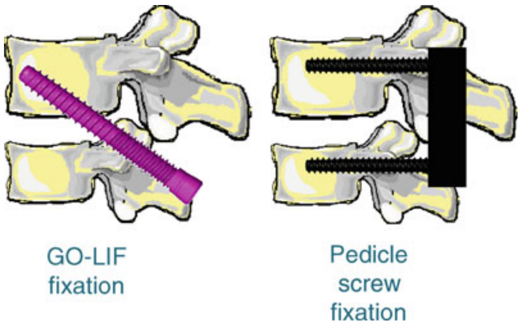

Fig. 11.3 Spinal fixation by pedicle screws and stabilizing rods vs. GO-LIF screw

A novel, developing application of SpineAssist may merit its characterization as an enabling technology. The Guided Oblique Lumbar Interbody Fusion (GO-LIF) procedure is a unique approach to vertebra fixation, such that two diagonally inserted screws connect and stabilize neighboring vertebrae. The required trajectory comprises delicate extension of implants both anteriorly and superiorly, crossing the inferior vertebra as well as the interbody disc space into the superior vertebra. This strategy requires instrumentation of two screws alone, in place of the four screws and two stabilizing rods otherwise necessary in spinal fusion procedures performed according to typical pedicle screws stabilization protocols (Figs. 11.3 and 11.4). However, the close proximity to the spinal cord and nerve roots render such a procedure neurologically risky. Thus, the GO-LIF approach would be inapplicable under unguided free-hand percutaneous surgical technique. SpineAssist's innate ability to accurately move along predefined trajectories along with its bone-attached structure, can be exploited in such cases to high degrees. In applications of this nature, the SpineAssist robot can be unequivocally classified as an

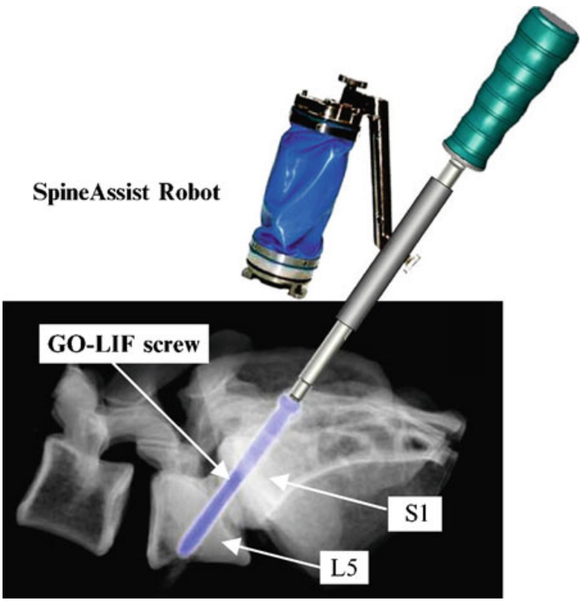

Fig. 11.4 GO-LIF screw trajectory guided by SpineAssist robot. Fixation of L5-S1 vertebrae

enabling technology by enabling percutaneous GO-LIF procedures with the added advantage of precision while considerably minimizing degree of invasiveness.

In collaborative efforts with Clevelend Clinic, fine-tuning of the SpineAssist platform to the GO-LIF implant technique has been effectuated. A preclinical cadaver fitting study has shown that GO-LIF fixation of 23/24 screws yielded a mean deviation of 1.3 $\pm$ 0.2 mm when compared to the preoperative plan, with no encroachment on nerve roots [12]. This early study, along with the results of 50 recent live cases, demonstrated that SpineAssist-guided GO-LIF is percutaneously attainable under robotic guidance.

11.4 Micro-Robots

With the advance of robotically-guided surgeries, along with the advent of sensors and micro-manufacturing abilities, much research is being devoted to development of micro-robots, designed to enter, traverse and operate in areas too small or too dangerous for humans or large robots. Micro-robots are being engineered to provide enhanced visualization of the surgical environment and dexterous task assistance unconstrained by entry port incision limits.

The objectives of robot miniaturization encompass design of those which are inserted through small ports to operate from within the body under external supervisory control. Other micro-robots have been prepared to autonomously propel from within, without the need for actuation from the small entrance port.

Future supervisory-controlled robotic enabling technology will provide accessibility via minimally invasive procedures, to locations far beyond human hand reach. Development of such devices have been described in the planning of miniature snake-like robots such as Carnegie Mellon's CardioArm designed to dynamically negotiate complex three-dimensional configurations with possible implications in cardiac treatment [13]. Accurate catheter placement is advanced by Hansen's Sensei® Robotic Catheter System by translating hand motions at the workstation to full catheter control within the heart [14], while the Stereotaxis Magnetic Navigation System applies external magnetic fields to maneuver the working tips of catheters, guidewires and other magnetic devices in interventional procedures. Similar principles are being employed by Johns Hopkins/Columbia robotic engineers in preparation of miniature snake robots designed to perform in narrow throat regions or in the delicate areas of the eye [15, 16]. In addition, preliminary experience describing *da Vinci*-based support of 30 NOTES (Natural Orifice Translumenal Endoscopy) procedures in porcine has been recently published [17].

Much research in this fascinating field of autonomous micro-robots focuses on applications within the human body, e.g. [18–20]. However, to the best of the author's knowledge, no routine clinical use of micro-robots has been made to date. The ViRob, for example, engineered by Shvalb, Salomon and the author of this chapter (Fig. 11.5), is 1 mm in diameter and actuated by an external magnetic field, stimulating it to crawl through cavities. The vast, still theoretical, applications of the ViRob can encompass drug or catheter delivery, tissue sampling, blood vessel maintenance or imaging of internal organs. Other works have described a modular crawler which successfully explored the gastric cavity, collected liver biopsies and enhanced imaging resolution for surgical procedures performed in porcine models [21]. Similarly, autonomously propelled robots have been developed to explore hollow cavities such as the colon or esophagus with "inch-worm"-based locomotion technique [22].

Fig. 11.5 ViRob – a crawling micro-robot

Due to their size and dexterity, miniature robots bear great potential when applied toward delicate surgical applications. Moreover, cooperative robots can be simultaneously inserted and manipulated to allow for maximal visualization, precision and overall procedural efficacy. Many future surgical applications are expected to demand precision extending beyond human hand capacities, rendering accuracy an adequate promoting factor for novel surgical technologies. In this manner, upon materialization, micro-robotics will transform to an enabling technological discipline.

11.5 Summary

Surgical robotics offers enhanced dexterity, increased accuracy and minimal invasiveness directed toward reducing patient trauma and improving clinical results. Significant robotic advances have simplified complex surgical procedures and have broadened the range of conditions treatable in the modern operating room. However, labeling of surgical robots as technology enablers requires the combination of significantly enhanced accuracy in conjunction with the option of minimally invasive surgical approaches. In parallel, in cases of complex microsurgery, accuracy extending beyond human limits also encapsulates the enabling features of surgical robots. In the future, robots will be designed to work in vivo at the level of single cells, in arenas beyond the surgeon's reach. In this manner, technologically enabling surgical robots will be engineered to distinguish between tumor and healthy cells, clear blocked blood vessels, deliver drugs or perform biopsies.

Equipping the surgeon's armament with such enabling devices will allow for development of new surgical procedures solely based on the high precision, miniaturization and enhanced accessibility features provided by robots. While once categorized as science fiction, robotics is slowly advancing the medical field by enabling the otherwise unconquerable.

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