

Robotic Surgery – A Personal View of the Past, Present and Future

Invited Review Article

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Abstract

Research into robotic surgery has been undertaken for over 25 years. In that period a small number of companies have been formed to exploit this research and have undertaken clinical trials on patients. However, far fewer clinical applications have been undertaken than would have been expected from the level of research activity. This paper puts forward a number of reasons for this, many of which are not to do with the technology but are a consequence of the clinical and business environments. Recommendations are provided that will hopefully increase the number of clinical systems being applied. Some predictions are made for the future which should increase the number of commercial systems and thus achieve patient benefits.

Keywords Robotic surgery, Computer Assisted Surgery, cost-effectiveness, efficacy of robotic surgery, patent litigation, pre-operative plan, post-operative measures, small medical devices, interventional devices, robot sensors

1. Introduction

In April 1991, the author applied a robot called Probot, for prostate resection. This was the first time in the world that

a special-purpose robot had been devised and clinically applied to independently remove tissue from a human patient [1]. Since that time there have been many robotic surgery research projects and a small number which resulted in companies who have produced systems that have been applied clinically. However it is surprising that relatively few robotic procedures have been undertaken clinically. It is this aspect that will be the focus of this paper and an attempt made to suggest reasons and how we might best proceed in the future. To this end, it would be inappropriate to try to give here a resume of research projects and clinical procedures. These aspects have recently been the subject of a number of excellent books such as those of Paula Gomes [2] and Rosen, Hannaford & Satava [3]. Review papers tend to be more restricted and specific in area [4, 5, 6].

2. Perceived benefits of surgical robots

The most frequently quoted benefits for robot surgery is that it can produce accurate minimally invasive surgery which can actively constrain the surgeon to a safe region. Complex trajectories can be undertaken particularly using snakelike flexible arms to reach areas which are otherwise impossible to access. Multiple and repetitive motions can be made without tiring and can compensate for organ motion due to heartbeat or breathing. Special purpose robots can allow surgery within the narrow bore of an xray or MR scanner. In the latter case the materials used must conform to MRI requirements. The ability to hold and move tools within a radiation field, such as an X-ray c-arm, is of great benefit in minimizing surgeon exposure to radiation. Given the large number of benefits potentially achieved with surgical robots, perhaps it is surprising that they have not been more widely applied clinically. As will be discussed in the next section this is primarily due to questions concerning the cost-effectiveness of the systems.

3. Potential challenges for surgical robots

3.1 Costs

Traditionally robotic systems, particularly if they are large and used in a number of different applications, tend to be expensive, and this cost must be justified against the effectiveness of the robotic procedure. Robot capital costs, like navigation systems, are not just hardware dependent but have also to account for such aspects as marketing, training and technical support, insurance, patents and litigation. Typical prices of systems, not to be confused with costs, vary and are highly dependent on special deals. As an example, the author's ACROBOT orthopaedic surgery system was provided free for customers who used it to implant more than 35 of the company's patient-specific unicondylar knee implants per year. The MAKO orthopaedic robot similarly benefited from the sales of their high-cost prosthesis. The typical capital cost of a MAKO Rio robot was around \$700, 000. The much simpler NAVIO orthopaedic system costs around \$400, 000. The highly complex da Vinci system is quoted as having a capital cost of around \$1.5 million, and a cost per procedure for drapes and replacement tools of around \$2,000.

There are a number of aspects to cost and what is meant by effectiveness. Cost does not just apply to the capital cost of the equipment and costs per procedure but also the annual cost of maintenance. Nor are monetary aspects the only cost. There are also concerns about the difficulty and complexity of the robotic procedure, compared to conventional surgery. This can lead to the necessity for considerable training in the use of new devices, an aspect where the lack of training has led to a number of costly litigations in recent years. Retaining skilled support staff who are familiar with new procedures has also been a problem in a number of hospitals.

3.2 Intuitive Surgical and cost effectiveness

Intuitive Surgical's da Vinci robot, primarily for soft tissue surgery, has made the company the most financially successful medical robot company in the world. The majority of procedures have been in Radical Prostatectomy. A meta-analysis of 400 studies over an 8 year period to 2010 of retropubic RP (ORP), laparoscopic RP (LRP), and robotassisted LRP (RALP) demonstrated that RALP is at least equivalent to ORP or LRP in terms of margin rates and suggested that RALP provides certain advantages, especially regarding decreased adverse events. However, the lack of randomized controlled trials, use of margin status as an indicator of oncologic control, and inability to perform cost comparisons were limitations of this study [7]. In a recent 120 patient trial, robot-assisted radical prostatectomy provided better functional results than laparoscopic radical prostatectomy, in terms of the recovery of continence and potency, without detrimental effects on the perioperative, pathologic, and oncologic results, however further studies are needed to confirm the results [8]. This is one of few studies to suggest that for Radical Prostatectomy, RALP may be better than LRP, although cost considerations were not included in the study. Intuitive Surgical's successful marketing campaign, targeted at the public, has persuaded hospitals to purchase the robot even though they have good laparoscopic surgeons. Recently even in Europe with a strong laparoscopic tradition, fewer laparoscopic radical prostatectomies are being performed, reducing the skill base. The result is that I now advise friends to have a robotic prostatectomy, provided the surgeon has performed more than 50 cases in the last year, which acknowledges the need for familiarity with procedures and constant update when using complex tools. A detailed technical study of the da Vinci robot has listed a number of changes to the design over the years that affect price and performance, whilst pointing to further features that could be improved [5]. The cost-effectiveness of robotics is a difficult area. If skilled laparoscopic surgery produces good results, it will be difficult to justify the purchase of costly robots when budgets are tight.

Many procedures are now approved for the da Vinci robot, however the advantages of a robotic rather than laparoscopic procedure are not always clear. For laparoscopic hysterectomy for example, 5 Meta-analyses seem to indicate robotic results are superior to open surgery and often similar to skilled laparoscopy. Stating: "These results confirm that robot-assisted laparoscopy has less deleterious effect on hospital, society, and patient stress and leads to better intervention quality" [9].

However, a more general gynecology review article [10] concluded: "Yet, in agreement with the ACOG Technology Assessment of "Robot-Assisted Surgery" in 2009 [11], further studies as well as additional cost-effective analyses need to be done to critically evaluate the role of robotic surgery in gynecology before it is adopted as common practice in managing gynecologic diseases". In spite of many studies, the cost-effectiveness of the da Vinci seems open to question in a number of areas.

3.3 Evidence-based medicine

A further concern about effectiveness is the increasing preoccupation with evidence-based medicine, in which the introduction of new procedures must be justified by clear clinical and patient benefits. However, this is difficult to

achieve in a climate in which the conventional surgeon claims "I always do it perfectly". Even in the area of orthopaedic joint replacement surgery, where one would assume that dealing with rigid bone is easier to demonstrate than soft tissue surgery, improved outcomes are difficult to show particularly over the long term [12]. The body tends to be very forgiving and if comparisons are made several years after the procedure, it is necessary to have objective data on such aspects as accuracy, alignment and range of motions rather than rely on subjective data such as "how well can you walk up stairs?" or " how much pain do you have?". In orthopaedics it is now generally accepted that the number of revisions in robotic hip and knee joint replacement surgery is fewer than conventional. Revisions generally occur within the first year of surgery, mainly due to misalignment of the prosthesis causing pain and loosening that requires a replacement operation. However it is only recently, with the introduction of newer more objective measures, that the improvement due to robotic orthopaedic procedures has been demonstrated. In the recent past such demonstrations have typically compared a large number of conventional knee surgery outcomes with a small number of robotic procedures. It is now generally accepted that there is a learning curve associated with new procedures and this is typically 25 to 30 robotic or navigation systems cases. E.g., If 50 robotic cases are compared with a large conventional study, the first 30 should be recorded but not included in the trial for the purposes of comparison.

A general understanding of this problem has more recently resulted in recognition of the considerable improvement from robotic procedures. A further problem with studies over a number of years is that the design of the robotic system is generally frozen for the period of the study. This is often at an early stage of development of the equipment which by the end of the study may have been improved considerably, rendering the results unhelpful. It should be pointed out that this is not a new phenomenon and is true of all advanced equipment trials. A further aspect seldom mentioned is that the thousands of cases in a conventional study will usually have been carried out over a number of years during which the protocols and simple tools will have evolved, particularly when data are gathered from a number of different centres.

An additional concern about the efficacy of robotic surgery is that the benefit should be compared to using alternatives such as much cheaper navigation systems, conventional surgery or using laparoscopic procedures. In some instances the robot can be seen as complex and requires extra training for surgeons and for specialist support staff. Although one would think that the quality of the result would justify a robotic procedure even if the robot takes longer than alternative means, the problem can be that the surgeon does not get through the list of procedures and so in the short term is in trouble with hospital authorities whereas the benefits due to increased accuracy will likely be only seen in the long term. This has led to the surprising pressure for robotic procedures to take a similar time to conventional.

3.4 Patents

A further problem confronting the introduction of new surgical robots is that of litigation due to claimed patent infringement, where large organisations have acquired a daunting portfolio of patents. This has led to concern, particularly in Europe, where funded research has resulted in small spin-off companies who find it difficult to obtain usually substantial funds for the first-in-man clinical application. This is due to the expectation that they may be sued for patent infringement. Often such claims are not justified but will require considerable funds, particularly in the USA, to demonstrate in court that there is no case to answer. Two examples are the MAKO case concerning the author's ACROBOT technology, where the threat of litigation resulted in MAKO acquiring the company for a small sum [13], and also the Stryker case against the new company Blue Belt with their "Navio" orthopaedic robot [14, 15].

3.5 Regulatory standards

The need for regulatory standards in robotic surgery is often raised, since unlike industrial robots, they cannot be fenced off away from people. Issues of "how safe is safe" are still open to question. The author's PROBOT robot was designed to have a mechanically oriented tool remotecentre-of-rotation in the belief that a software dependent motion of several axes was not sufficiently safe. This view has gradually been abandoned and a software controlled centre-of-rotation is now common in surgical robotics. However the question has never been answered and this has recently led to calls to generate international standards for robot surgery. A European funded project called SAFROS looked at patient safety in robotic surgery and made some useful preliminary recommendations [16]. Considerable efforts are being made by a joint working group, JW9, of the International Standardization Organization (ISO) and the International Electrotechnical Commission (IEC) to develop a new collateral standard for medical robot safety [17]. This is based upon the more general work for Medical electrical equipment and systems using robotic technology [18].

Caution is counselled however, since the larger robot companies will naturally ensure their delegates favour systems suited to their own products, while smaller companies find it difficult to support lengthy, often tedious, negotiations. It is however clear that, in the interim, risk mitigation can be provided by the surgeon being directly present at the scene, thus ensuring safety in the event of difficulties.

4. The importance of the integration of all the elements into a total system

Whilst it is the robots themselves which undertake the surgical intervention and deploy the surgical tools, it is the total system which is often found of most benefit in surgery, with the robot restricted to only a minor role in the cutting process. Integrated systems consist of patient-specific imaging, which may be preoperative MRI or CT or intraoperative X ray "C" arm or ultrasound. Patient images are used to form a plan of the procedure and also to simulate the process, partly for training purposes and partly to ensure the proposed procedure has no potential problems. Once the plan and simulation are approved, the patient is placed on the operating table and the robotic system is docked or "registered" to the patient. This process of registering the robot to the patient and to the preoperative plan is essential and is traditionally one of the greatest sources of error.

Many traditional laparoscopic surgeons, when questioned, stated that they did not need 3D vision since they were used to obtaining depth cues from the shadows and reflections of the surgical scene. Similarly they were used to judging forces from tissue deformation and so did not need haptics. A new and younger generation of surgeons who are used to computer games are much more positive. Lighter 3D endoscopes and more sensitive haptics are helping in this transformation.

Following the actual intervention it is becoming common to have an immediate post-operative assessment of how well the procedure was carried out. This can sometimes be undertaken using the robot to take measurements towards the end of the procedure, so that existing registration can be utilised, or alternatively requires some sort of postoperative image to be taken. Post-operative measurement is important for two reasons: first, together with the robot motion record, it can form a knowledge-base to assess how to improve the procedure and to answer questions which may arise from litigation. Secondly it ensures that objective measures, such as accuracy, can be captured in order to show the efficacy of a robotic procedure compared to alternatives such as laparoscopic surgery, conventional open surgery, or the much cheaper navigation systems. In orthopaedics, since we are dealing with solid bone, it is possible to say with considerable accuracy where the prostheses is located and hence be able to point to what criteria are important in the long term survival of a pain free joint. In addition the use of sensors is helping to define what are important features compared to the more simplistic measures previously adopted, such as mechanical axis alignment in knee replacement surgery.

Sensors and measurements are beginning to show that the process is much more complex than previously thought in knee surgery and requires consideration of a number of aspects such as the patella, the meniscus, soft tissue balancing and the state of the ligaments. Thus we see the gradual evolution of clinical procedures brought about by the use of Computer Assisted Surgery.

Neurosurgery can also benefit from the precision and repeatability of integrated robotic surgery. The EU project ACTIVE, for precise location of electrodes in epilepsy treatment, utilises 2 Kuka lightweight robots to hold tools whilst a custom parallel robot holds the head to compensate for motion monitored using cameras that track the surface of the brain [19]. The commercially available Canadian robotic system neuroArm utilises a specially developed neurosurgery MRI compatible tele-surgery pair of arms with "Phantom" haptic controllers [20]. The use of flexible steerable needles has also been advocated to travel a curved path in the brain, thus minimising damage to critical areas when travelling deep inside the brain [21].

5. Alternatives to robots in surgery

It is necessary to justify the benefits from using a robot against alternatives which may be much cheaper. Traditionally the main alternative has been the use of a navigation system, which may comprise a camera-based tracking system or a passive arm with encoded joints. Since this does not utilise motors it will inevitably always be cheaper than a robot. Robot procedures are in general more accurate than navigation but the difference may not lead to patient benefit. A more recent alternative to robots is that of smart medical devices and tools which contain some degree of sensing and localised decision-making. An example of this is a sensor-based cochleostomy drill, which uses a combination of torque and axial force sensing to determine imminent breakthrough of bone in ear surgery, even though the bone thickness is unknown [22]. Very small devices which are too small to incorporate a motor drive system can use an alternative external power source, such as magnetic systems in which devices can be precisely manipulated using external magnetic fields to control the orientation and position for interventional or diagnostic purposes [23, 24, 25].

One of the most successful clinically applied robots is used for proton beam therapy rather than for surgery. The CyberKnife system comprises a large robot that carries a linear accelerator. The proton beam can target a tumour from many different directions to ensure that healthy tissue receives considerably less radiation than the focus tumour. Later versions of the system can compensate for patient motion such as breathing [26].

The use of flexible snake-like robots has recently become popular. They can reach difficult to access areas of the body without causing damage, for example in cardiac surgery thin flexible and steerable probes are used. Sometimes these are biomimetic based [27, 28]. Others utilise the working channel of an endoscope to position the probe to give local flexibility once deployed at a particular location. While successful for natural orifices such as in colon or throat surgery, [29], it has been a particular challenge in neurosurgery to reduce diameters whilst retaining steerability, particularly in being able to follow the same path during extraction from the brain to prevent further damage.

Many of the above devices will be regarded as mechanisms rather than robotic systems but they are included as they show considerable promise as additions to robotic systems.

6. The intervention process

Another area of considerable change is in the interventional device. Early robot systems deployed scalpels, burrs or saws for cutting and the resulting forces needed to be resisted by the robot. More recently energy-based processes, e.g., lasers [30] or high intensity focused ultrasound (HIFU) [31], which do not produce reaction forces that need to be resisted, have been used for interventions thus resulting in smaller and simpler robots. The use of lasers is expanding and they are starting to be used in orthopaedic surgery for cutting bone precisely without thermal damage that could cause necrosis.

7. Conclusions and the Future

Recently there has been a need for existing complex and expensive robots to increase their sales by finding new clinical applications although the cost-benefit justification is often lacking. If the robot is no longer used for say, heart surgery, then perhaps capital cost is not an issue if it is deployed in a new area, but this will do little for the cashflow of the company. The development and implementation costs of complex and expensive robots, designed for a wide range of tasks, means research into such systems has lost popularity. This is exacerbated by fear of patent litigation from large companies. Instead the research focus is moving to simpler, low-cost, sensor rich devices designed for a few specific applications where patents are less of a problem. Over the years, since the author's first surgical robot, the regulatory requirements have increased considerably making the first-in-man application a major cost and time delay, and it is unlikely that this trend will be reversed in the future.

Robot structures can be made small if they do not have to withstand large cutting reaction forces thus leading to the further use of lasers or HIFU. Alternatively, if using cutting burrs in a small robot, inaccurate roughing cuts can be taken in which the robot is allowed to deflect, followed by fine precision cuts. The use of nanostructures, often in conjunction with 3D printing, is allowing smaller low-cost systems to be developed for specialist applications where the number of procedures is small.

Traditionally the robot sensors have primarily been spatial in nature, e.g., using spatial images that measure displacement and orientation. The use of low cost force transducers to measure different tissue states and also to minimise applied forces has been beneficial in robotic surgery and will become more widespread. However other sensors are still to be implemented. For example there is a need for low-cost temperature measurement e.g., to locate the focus of treatment in HIFU, and chemical sniffers that can locate infection or cancerous tumours, that have still to be developed. More recently the use of chemicals that preferentially uptake into tissues such as cancerous tumours has allowed cameras with narrow band imaging to identify regions that can be gradually ablated by laser rather than cut away. This will hopefully lead to less invasive treatments.

The surgical profession has been conservative and it is only now that computer literate surgeons expect computer assisted surgical systems to be available, removing a source of traditional reluctance. After the earlier success of larger complex systems, it is probable that progress in the next decade will be incremental rather than revolutionary, leading to many different smaller simple robotic systems across a wide range of applications. Robotic surgery is thus likely to see a change of direction but will become more clinically relevant.

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