Summary

✓ Computer-linked surgical systems allow surgeons to perform procedures without coming into contact with the patient. Indications for these robotic surgery systems are expanding.

✓ This technology offers potential advantages through enabling more precise surgery, which may lead to shorter patient recovery times, fewer complications and improved patient outcomes.

✓ Limited studies indicate the promise of these systems, which appear to be safe, but their efficacy is not fully established. In some procedures, the advantages they offer may also be achieved by newer non-computer assisted techniques.

✓ Capital costs are high and cost-effectiveness has not been demonstrated.

✓ Diffusion of these systems can be expected to continue, but their place in surgical practice is not yet clear. They are most likely to be of value for centres undertaking specialized surgical services.

The Technology

In robotic surgery, programmable machines are operated by surgeons using computer-based technology. The systems developed to date are computer-enhanced surgical systems, rather than full robots.

Typically, the surgeon operates the system while seated at a console viewing a three dimensional image of the surgical field. The monitor displays an image from a camera located in the robotic arm, allowing the surgeon to see the entire surgical field.

The surgeon's hand movements are translated into real-time movements of the surgical instruments. Access of the instruments and camera to the surgical site is made through small incisions. The procedure is performed without the surgeon touching the patient, with the incisions sutured by an assistant at the site. The types of operations targeted by this technique are those where operating through multiple small incisions is an option.

Davies classifies surgical robots into four broad categories - Passive Tool Holders, Active Robots, Synergistic Systems and Master-Slave Telemanipulator Systems.1 This bulletin considers the latter category of systems. (For a more complete list of surgical robot systems see the UK National Horizon Scanning Centre briefing, Surgical Robots.2)

Regulatory Status

The da Vinci™ Surgical System (Intuitive Surgical Inc., Mountain View, CA) received initial approval from the U.S. Food and Drug Administration (FDA) in July 2000, for use in general laparoscopic procedures, such as for cholecystectomy or treatment of gastroesophageal reflux disease. In June 2001, approval was extended to include use of the system for laparoscopic radical prostatectomy and thoracoscopic surgery. Licensing authorization of the da Vinci system for laparoscopic and thoracoscopic use was received from Health Canada in March 2001 (Kathleen Savage, Health Canada: personal communication, 2001 Oct 25).

The ZEUS® Robotic Surgical System received (Computer Motion, Goleta, CA) FDA marketing approval in October 2001.3 The system may be used to perform robotically assisted laparoscopic and thoracic procedures. The ZEUS system does not have licensing authorization from Health Canada (Kathleen Savage, Health Canada: personal communication, 2001 Oct 25). However, it is...
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currently being used at the London Health Sciences Centre, in Ontario, in the new National Centre for Minimally Invasive Robotic Surgery. An earlier product from Computer Motion, the AESOP System, is a robotic arm used in a variety of surgical procedures. AESOP has been used in several centres in Ontario and Alberta, for surgical applications, such as, radical laparoscopic prostatectomy; laparoscopic Nissen fundoplication, laparoscopic cholecystectomy, etc.

EndoAssist (Armstrong Healthcare, Ltd, High Wycombe, UK) received FDA 510(k) approval in 1997. Application has not been made to Health Canada for licensing authorization in Canada (Samantha Hazeldine, Armstrong Healthcare, High Wycombe, UK: personal communication, 2001 Sep 24). These systems have received CE Mark approval for marketing in Europe.

Patient Group

Computer-assisted systems have the potential to replace other approaches to surgery for a range of surgical procedures. To date, most common applications appear to have been in laparoscopic techniques and microsurgery. Some computer-assisted systems have been used in cardiac surgery, however, this application is still considered investigational by the U.S. FDA. Surgeons at Ontario's London Health Sciences Centre have used robotic systems for cardiac procedures, such as mitral valve replacement and single artery bypass surgery.

Current Practice

Current practice includes a wide range of conventional and minimally invasive surgical techniques. The disadvantages of current methods include adverse effects associated with surgeon fatigue and limits to the precision of surgical technique (hand tremor, etc.). However, fatigue associated with viewing a console may be an issue in use of computer-enhanced surgical systems when lengthy procedures are performed. Standard surgical methods often require the presence of a surgical assistant and other surgical staff, which may not be required for some robotic surgery applications.

Administration and Cost

The capital cost of the da Vinci Surgical System in the U.S. is approximately US $1 million. The ZEUS Robotic Surgical System costs between US $100,000 and $800,000, depending on the number of arms. Maintenance, operating and training costs for the systems also need to be considered. A UK report estimates that annual maintenance contracts are typically 5-10% of the cost of the system. There is a potential for cost savings through the use of such systems if they reduce procedure time, the cost of some disposables and the need for surgical assistants. The more precise surgical procedures offered by such equipment may lead to further cost savings associated with reduction in length of hospital stay, fewer complications and improved patient outcomes. However, data to confirm such cost savings are lacking. In a U.S. study, Chitwood et al refer to cost savings of 34% when robotics were used to perform mitral valve surgery in 31 patients, as opposed to conventional sternotomy. Cost savings were mainly due to a reduced length of hospital stay due to the less invasive surgery. There is little published literature evaluating the costs or cost-effectiveness of computer-assisted systems.

Rate of Technology Diffusion

According to the Intuitive Surgical web site, there are over 70 da Vinci Systems in surgical facilities throughout the U.S., Europe and Japan. Computer Motion reports that 25 ZEUS systems are in place at procedure development and clinical development sites in the U.S., and 24 systems are installed in centres outside of the U.S. The extent to which replacement of existing surgical approaches would be justified in terms of improvements to health outcomes and overall cost savings is not yet clear. The scope of procedures undertaken by computer-enhanced systems is likely to widen. Given the cost of this technology, there might be a tendency to use it in relatively intricate procedures, where high levels of surgical precision are required. Decisions on procurement of these surgical systems will be informed by their overall costs to health care, judgements on the scope of procedures allocated to them and the degree of comparative benefit in terms of patient outcomes. The continued evolution
of minimally invasive surgical techniques could impact the use of computer-assisted systems. Some procedures may be performed without computer-assisted technology at a lower cost and with similar outcomes.

**Concurrent Developments**

Both computer-assisted surgical systems and other forms of surgery are continuing to evolve. A number of studies on newer applications of currently available systems are in progress. Future developments include the potential for telesurgery. Computer Motion received FDA approval for its SOCRATES Robotic Telecollaboration System in December 2001. SOCRATES enables a surgeon at a remote location to connect to an operating room and perform an operation using a computer-assisted surgical system.

**The Evidence**

There is a lack of controlled clinical trials of this technology. In a study associated with the FDA approval of the da Vinci system, 113 cholecystectomies and fundoplications were compared with results for 132 patients who had conventional laparoscopic surgery. The computer-aided approach was comparable in safety and effectiveness to standard surgery, though it took 40-50 minutes longer to perform.

Other studies on feasibility of the technology have reported shorter procedure times than conventional procedures or an ability to be able to undertake surgery, in some cases, without the need for an assistant. The basis of the comparative data is not always made clear. In the report of 200 procedures (cholecystectomy, gastric, colon and hernia repair) by Baca et al, almost half of the operations could be done without an assistant, with an assistant being required for the more complex operations.

Several groups have described large clinical series. Overall findings were that computer-assisted procedures were successfully and safely completed. These series include: 52 cases of mitral valve repair, cholecystectomy and fundoplication reported by Chitwood et al; a report on 110 mitral valve repairs by the same group; 131 coronary artery bypass graft (CABG) procedures and 17 mitral valve repairs, reported by Mohr et al, and 61 CABG operations reported by Kappert et al. A smaller study, by Prasad et al, on 19 CABG cases reported favorable short-term outcomes and no adverse events at one-year follow up.

Recent small pilot studies have included use of computer-assisted approaches for laparoscopic tubal anastamosis (Falcone et al), prostatectomy (Binder et al), and pelvic lymph node dissection (Guill).

**Implementation Issues**

Computer-enhanced surgical systems show promise as a means of improving the quality of certain surgical procedures, but at this stage they also raise dilemmas for decision makers in health care. There are only limited data from clinical trials with these systems, though there is initial evidence of their safety and efficacy in some applications, when they are used in centres of excellence, for procedures on carefully selected patients. Neither their efficacy, in terms of comparative patient outcomes, nor their cost-effectiveness, has been established. Advantages from quicker recovery and shorter hospital stays have already been achieved through the introduction of less invasive, non-robotic procedures. The benefit of computer-assisted surgery over the non-robotic techniques is not clear.

Information on overall costs of these systems is scarce. Capital costs are high and operating and maintenance costs must also be considered. There could be offsets to these costs through savings in operating room staff time, reduced length of hospital stay and improved patient outcomes, but there are as yet no conclusive data. The cost-effectiveness of the systems is likely to be affected by case selection and the organization of the service at individual centres. For example, reduction in operating room staff time may not have an impact if salaried assistants are required for other types of surgery, and if it is not possible to predict pre-operatively for which procedures they will be needed.

Centres that introduce this technology should be aware of the need for appropriate training, and given the substantial cost, to consider use of these systems in procedures where their performance is.
offers the greatest advantage over non computer-assisted surgical approaches.

References


