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Short Communication

Robotic surgery: Consent and medico-legal aspect

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ABSTRACT

Robotic surgery has rapidly evolving as a ground-breaking field in medicine, revolutionizing surgical practices across various specialties like oncology, urology, gynaecology, bariatric surgery.
Despite its benefits, the adoption of surgery faces significant medicolegal challenges. This article develops into the underexplored legal implications of robotic surgery and identifies distinct medicolegal problems. The article highlights the need for comprehensive guidelines, regulations, and training programs to navigate the medico legal aspects of robotic surgery effectively, thereby unlocking its full potential for the future development.

1. Introduction

Robotic surgery is a fast-growing field of medicine that is rapidly changing the surgical landscape. Though robotics has been used in other fields since the early 19th century, it made inroads in the field of medicine only about four decades ago.[1] Robota" (Czech for "servitude") refers to an "automated and programmed" help for humans. Neuromate (Integrated Surgical Systems, used to perform stereotactic brain biopsy, was oneof the earliest surgical robots.[2] Robotic surgical systems, currently existing as two main categories:

Teleoperated (master–slave) systems: a surgeon performs an operation via a robot and its robotic instruments through a televisual computerised platform (where the surgeon is the master, i.e. the operator, and the robot is the slave.

Active or semiactive systems: these are typically image-guided or pre-programmed. In active system, a surgical robot completes a pre-programmed surgical task. In semiactive systems, the robotic device may be in part pre-programmed and in part surgeon driven.

2. History

First documented clinical robotic procedure was a CT guided brain biopsy performed in 1985 utilising the PUMA (Programmable Universal Machine for Assembly) 560 system.[2] ROBODOC, a pre-programmed active robot that enabled precise preparation of the femoral implant cavity during hip replacement. In 1992 AESOP (Automated Endoscopic System for Optimal Positioning) system, which mounted the endoscopic camera on a single robotic arm, allowing the surgeon to control it remotely via voice command.ZEUS robot in 1996, a master–slave teleoperated system that provided three robotic arms, one for the voice-controlled endoscope and two further instrument arms.

REVO-I - four-arm robot is mounted on a single cart with 3D HD vision. Versius more closely mimic a human arm, improving freedom of port placement.

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2.1. Da Vinci surgical system

Number of advantages, including 3D surgical vision, EndoWrist precision instruments, tremor reduction, motion scaling and improved ergonomics. Upgraded to the da Vinci S (2006), the da Vinci Si (2009) and subsequently the da Vinci Xi in 2014. Single port system (da Vinci SP), which combines multijointed wristed instrumentation with wristed camera through a single port to further improve dexterity and minimise surgical trauma.

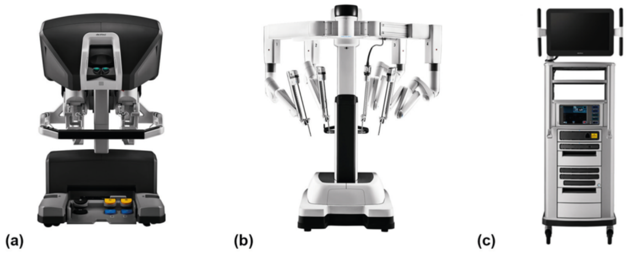

Figure 1: The da Vinci Xi system: (**a**) Surgeon console (**b**) Da Vinci Xi robot (**c**) Vision cart (courtesy of intutive surgical)

2.2. Advantages

1. Provide virtual information.
2. Stereoscopic vision with indepth perception
3. Superior precision in spatial resolution and geometric accuracy.
4. Improved dexterity.
5. Quicker manoeuvrability.
6. Ability to operate without fatigue, ensuring consistent, surgical isolation from external distractions and steady motion.
7. Less invasive.
8. Operate in space restrain areas.
9. Decrease blood loss and postoperative recovery periods.

2.3. Disadvantages

Lack of availability and training.

Mechanical failure or malfunction.

1. Main cause: Wear of the insulating membrane resulting from friction and also collision among instruments inside the abdomen, or during their insertion through trocars.
2. Instrument alteration.
3. Mechanical arm alterations.
4. Console defects.
5. Optical system problems.
6. Software issues.
7. Higher costs.

2.4. Training in robotic surgery

Since their is lack of adequate exposure training should be done during residency itself.

Dissatisfaction among residents and a perception among many that the introduction and dependence on robotic surgery in resident training hamper their learning and skill concerning open conventional surgery.

2.5. Surgical responsibility

1. Level 0 (no autonomy
2. Level 1 (robotic assistance
3. Level 2 (task autonomy
4. Level 3 (conditional autonomy
5. Level 4 (high autonomy
6. Level 5 (full autonomy

2.6. Informed consent

Mandatory that, if a patient is planning to undergo robotic surgery, their consent for the use of the robot be obtained beforehand.

Very common misconception — completely automated machine that will be operating without a surgeon or human interference.[3]

Robotic malfunction, though minimal, should be disclosed.

The exact steps in the surgery that would be robot-assisted also need to be communicated.

The advantages, risks, and alternative surgical options to robotic surgery also need to be informed. Some authors recommend disclosing the surgeon's experience and training in robotic surgery and the number of robotic procedures.

Type of the procedure the patient is undergoing, the instruments involved, how the procedure is performed, alternative options, and what the protocol is in the event of an emergency.

2.7. Surgery

1. Risks, benefits, and side effects of the procedure;
2. Nature and intended purpose of the procedure;
3. Reasonable alternatives;
4. Risks and consequences of not obtaining the procedure or delaying the procedure;[4]
5. Likelihood of results.

2.8. Legal liability

Laws and guidelines about it are still evolving.

The surgeon, the hospital, and the manufacturer of the machine are all involved in the functioning or application of the machine and hence have some share of the legal responsibility.[3]

Law to date have predominantly seen the use of robots as tools of assistance to surgeons.

Use their discretion on the proposed actions of robots and provide a level of human check on any proposed actions of the robots.

Self-driven cars - monitored by a human being - mishap can be catastrophic and life-threatening.[5] If the crash involved fully autonomous vehicles, the human users were held less liable, and a majority of the responsibility was to be shouldered by the manufacturer and the government department that issued the manufacturing licenses. 'Blame attribution asymmetry bias', humans are prejudiced to judge these cases more harshly, more blame to the automation and its creators, and be inclined to award more compensation to the victims than in a similar case where no autonomous vehicle was involved.

This bias can impact future policies and deter the adoption of such technologies. Every country has to take into consideration its own legal principles, and social factors and frame its own law which is suitable and in keeping with the other laws of the country.

3. Litigation and Medical Malpractice Suits

The MAUDE database (2000–2013) reported 144 deaths (1.4% of the 10,624 reports), 1391 patient injuries (13.1%), and 8061 device malfunctions (75.9%).[6]

Regarding robotic system malfunctions 18 articles in the literature. In total, from 2005 to 2014, 386 malfunctions were described out of 14141 procedures, 20.9% of which was damage caused by malfunction of the Robotic surgery arms and instruments. The total percentage of conversion in reported cases was about 2%. From a Robotic surgery malfunction, 16 caused patient damage, of which 13 were mild and resolved without squeal, and 3 were complex, including an external iliac vein lesion, ileal perforation, and urethral lesion. The latter were treated intra-operatively with direct iliac vein and ileal suture and reimplantation of the urethral lesion.

Lucas et al. (2011) studied the last updates of the database and compared two periods, before and after 07.[7] Lucas estimated a total of 205 robotic procedures and reported 1914 cases of malfunction, with patient damage between 0.5% and 5.4%. The incidence of robotic procedure conversions diminished from 21.3% to 9.9%. By contrast, the mortality rate increased from 0.0013% to 0.0061%.[6]

3.1. Case example 1

The complexities involved in converting from RAS to laparoscopic or open surgery can increase patient risks.

Surgeons performed a robot-assisted hysterectomy on a patient who was morbidly obese. Complications during the surgery forced the doctors to convert to traditional laparoscopy and then to open surgery.

Following the surgery, the patient complained of arm pain, weakness, and numbness, and she was diagnosed with brachial plexus injuries. A review of the case determined that the lengthy duration of the procedure, the patient's obesity, and her positioning prior to the open surgery (in a steep head-down position) contributed to her injuries.[8]

3.2. Case example 2

Lack of defined training standards and limited awareness of the learning curve for RAS have played a role in malpractice lawsuits.

A surgeon performed an unsupervised prostate surgery on a patient after completing only two previous supervised robotic prostate surgeries. The surgery took more than 13 hours and resulted in multiple injuries and severe blood loss, as well as the need to convert to open surgery during the process. The complications from the surgery were alleged to have contributed to the patient's death several years later.[8]

3.3. Case example 3

Accurately portraying the benefits and risks of treatment is vital for patients to make informed decisions about their care. Failure to do so might result in patients feeling misled, which could potentially lead to a malpractice claim.

An OB/GYN case, a doctor proposed a robot-assisted hysterectomy as an alternative treatment option for a woman who knew little about the procedure. The patient agreed to the surgery based on the doctor's recommendation and online videos that extoled the precision of surgical robots.

Unfortunately, during the course of the procedure, the surgeon punctured the patient's bowel. The costly injury required nine operations to fix, and the patient had to be hospitalized multiple times. Following the incident, the patient stated that she felt deceived by the optimistic marketing of the robot from her doctor and the manufacturer.[8]

4. The Future of Robotic Surgery

Advancements in technology, refinements in technique, and increased acceptance globally are projected to propel its growth exponentially.[8] Level of precision and ability of robotic systems will increase further with breakthroughs like tremor filtering, enhanced three-dimensional (3D) views.

5. Conclusions

While robotic surgery has been growing in technology, technique, and popularity, one aspect that is still shrouded in ambiguity is its legal aspect.[3] There is still a lack of clear laws and legal guidelines on the legal liability of surgeons and manufacturers. There is also a glaring deficiency in organized training and credentialing.

This makes us believe that the moral, ethical, and legal aspects of robotic surgery may end up playing a bigger part in determining the future of robotic surgery than most people would suspect and desire.[8] A re-examination of ethical concepts and medicolegal proprieties from an Robotic surgery perspective could elevate standards of care and enhance outcomes, without an iota of ethical or medicolegal compromise.

6. Source of Funding

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7. Conflict of Interest

None.

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