SURGICAL ROBOTS RIDING ON HUMAN SURGEONS: A LEGAL ANALYSIS

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Abstract
'Robotic Surgery' is an advanced technology in modern medicine which has an impact on surgical procedures. If an elaborated definition is given, robotic surgery is a combination of computer technologies and robot systems for the performance of medical procedures. As an emerging field of medicine, the doubt arises whether the robotic surgeons are subject to the same ethical code of human surgeons. In a science fiction of Isaac Asimov, he identified three laws of robotics in the context of interacting with humans. The three laws so identified are respectively, 'a robot must not harm a human being', 'a robot must obey the orders given to it by the human beings except where such orders would conflict with the first law' and 'a robot must protect its own existence.' Robotic surgeons are praised due to the benefits they have for both fellow human surgeons and patients. Robots have the skill to provide human surgeons with better view, precision and flexibility. Patients are simultaneously benefited with the presence of them due to lower risks of infection, smaller incisions and lower blood loss. However, although the surgeries performed by the robots are considered sophisticated, there is a hidden risk of failure as well. Thus, a doubt arises on the imposition of liability for an error committed by a robot in the course of surgery. Is that the general professional liability which falls under the purview of medical law and ethics? Is it apt to recommend a separate legal framework in Sri Lanka to govern robotic surgery? The methodology adopted in the research is qualitative in nature and it is library-based desk review. The author has focused on the content analysis of secondary sources of law. In the concluding perspective, the author holds the view that the failures on the part of the robotic surgeons can be covered by both medical malpractice and defective product liability.

Keywords: Robotic surgeons, Medicine, Liability, Ethical code

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INTRODUCTION

Morrell et al (2021) presented the fact that the idea of creating an autonomous machine to perform the tasks performed by the humans is not new. It commenced from the military field where in contingencies the provision of necessary healthcare becomes doubtful. Most of the injured soldiers in the battlefield died of their injuries and the consequences of hemorrhage and trauma. To minimize this dilemma, there was a necessity of expert surgical care with the quickest intervention. This marked the commencement of robotic surgery.

Saceanu et al (2015) defined 'robotic surgery' as a surgical procedure that has the effect of placing computers and computer technology between the surgeon and patient in the course of surgery. The intervention of robotic systems between the surgeon and the patient in one way exercises dominance over the surgeon. The history of 'robotic assisted surgery' is traced back to the North Atlantic Treaty Organization (NATO). A department in NATO was involved in the development of robotic surgery as a supportive pillar to perform surgery on the soldiers in the battlefield (Camarillo et al 2004) the developments under this purview led to the organization of robots and categorized them under taxonomy. Camarillo et al (2004) further elaborated on the fact that the classification of robots is based on the technology, application and the role played. The technology-based taxonomy includes autonomous and teleoperated robots. The application basically considers the branch of medicine in which the surgical robots work. The role-based taxonomy is divided into categories, namely the passive role, restricted role and active role.

Brahme & Pathak (2022) explain the most highlighted benefit of robotic surgery. It is praised and highly acclaimed in the purview of surgical procedures due to the fact that it reflects the involvement of minute incisions. Such subtle procedures are welcomed with the advancement of technology on the ground benefiting both the surgeon and the patient. In addition to this, the surgical robots are preferred due to positive features namely the less incisions, fewer infections and lower blood loss. It is obvious that active surgical robots are a part of technology which forms a substantially different environment than the human surgeons. Brahme & Pathak (2022) identified three basic categories of robot systems namely the active, semi-active and master slave. Still, there is a possibility of occurring errors when the surgical robots are involved. The errors mentioned above are the typical surgical errors like wrong site surgeries which in the long-term cause negative impacts on the patient. This creates an anomaly as to the imposition of liability. What is the legal facet pertaining to robotic surgeons? The author in this paper attempts to analyze the legal and ethical dimensions of robotic surgery with four objectives, namely, to study the nature of surgical robots and their emergence, to discuss the importance of ethical aspects of robotic surgery, to discuss and analyze the legal aspects of robotic surgery and to make recommendations for a separate legal framework in Sri Lanka to address the legal and ethical issues of robotic surgery.

METHODOLOGY

The author in this paper adapted a qualitative methodology which prioritized the literature review. The paper is mainly focused on academic publications, research articles on medical law and ethics including the literature which clearly explains the evolution and the significance of robotic surgery. The paper is prominently built on the content analysis of secondary sources of law.

RESULTS AND DISCUSSION

The birth of Surgical Robots and way forward

The concept of 'robots' became first popular in the world, due to a play named 'Rossum's Universal Robots' in the 1920s. Thus, the robot came into the picture with a definition: 'small, artificial and anthropomorphic creatures'. The significant feature of robots is their obeying the orders of their masters. Later in the year 1942, Isaac Asimov presented the world with three laws on robotics through his work 'Runaround'. Asimov's three laws are:

a. A robot may not harm a human being or through inaction allow a human being to come to harm.
b. Robots must obey orders given by the humans except those that would conflict with the higher order of laws.
c. Robots must protect their own existence as long as such protection does not conflict with the higher order of laws. (Brauner 2016)

Sahinpoor & Gheshmi (2015) reiterated the fact that, performing surgery on humans is subject to constant developments. The emergence of robotic surgery has created a paradigm shift in the scope of medical surgery. This has been developed as a supportive medical mechanism to expand all the surgical and microsurgical procedures. The positivity of robotic surgical systems is that it facilitated the laparoscopic procedures and the surgeon's ability to perform it by staying at a distant position with more concentration. However, there are negative aspects as well. Thus, the involvement of a surgical robot will cause the surgeon to lose the sensation and the feedback of the patient.

Sahinpoor & Gheshmi (2015) held that the highlighted advantage of a robotic surgery system is the ability to perform a surgery on a patient from a remote location. This has been developed to a stage where it becomes possible to perform a surgery on a patient in outer space. This signifies the convenience of the procedure. Thus, the surgeon who performs the surgery is no longer an entity who touches the organs, tissues and surgical instruments. In addition to this, laparoscopic techniques are of predominant consideration. Both the patients and surgeons benefit from minimally invasive procedures to facilitate access to damaged tissues. Robotic surgery is involved in making fewer openings from which the instruments and cameras are inserted. The technologically advanced nature of the surgery is conspicuous in modern robotic surgery systems. The technology involved with robotic surgery is always involved with the high magnification monitors which are supportive in the displaying of the surgical scene.

Surgical Robots and Human Surgeons: Is there a correlation between the two?

Sahinpoor & Gheshmi (2015) of the view that the robotic surgery provides a convenient posture to the surgeons. Thus, the surgeon is able to sit in a console and to be involved in the process with confidence and maneuverability. This provides convenience to the surgeon by eradicating the fatigue and the difficulty of a lengthy duration of performing the surgery. However, the success of the robotic surgery is dependent on the surgeon's training. This depicts the fact that there is a positive correlation between the training of the surgeon and the outcome of the robotic surgery. The training which is undertaken by the surgeon before the performance of the robotic surgery is predominantly a long process. Thus, it clearly shows that the training of a surgeon in relation to the performance of a robotic surgery is extensive and he/ she is expected to have a thorough training prior to performing it on a human being.

As the field of medicine deals with numerous disciplines, the application of robotics is guaranteed in the fields of neurosurgery, orthopedic applications, urology, cardiovascular surgery, gynecology and other procedures such as hair transplants. (Sharkey & Sharkey 2013) identified that there are two types of robotic surgical systems, namely *controlled systems* and *automatic systems*. The controlled systems are completely dependent on the actions of the surgeon and the automatic systems are involved in the process of performing surgery after being programmed by the surgeon.

Ethical issues in robotic surgery

Moore (2000) presented to the world three criteria important in the context of making a surgical innovation acceptable. The criteria consist of the necessity of sufficient laboratory experience before conducting innovative procedures, the existence of sufficient intellectual and technical expertise in the institution and 'good institutional stability' based on the resources and staff. When this criteria are made applicable to the context of robotic surgery, it can be stated that any institution which inclines to robotic surgery must comply with ethics and make sure that the surgeons who operate such systems undergo training. However, this is not sufficient due to the fact that the successfulness of the robotic surgery is not a singlehanded function of a surgeon, but it is directed to the institution full of technical expertise and to the staff which is knowledgeable on the subject.

Johnson & Rogers (2012) clearly identified the ethical challenges relevant to robotic surgery, namely the compromised informed consent, conflict of interests, harm to the patients and the unfair allocation of health resources. The scope of compromised informed consent describes that patient autonomy is risked with the inability to consent on the innovative procedures. This is a prominent issue to be addressed under the medically informed consent law. The impediments on the consent include the unawareness of the patient of the fact that he / she will be operated under a new technique, and the lack of a risk benefit analysis of the innovative procedure. The conflicts of interest commence on the side of the surgeon, who will more or less incline to adopt a new technique in the performance of the surgery than adhering to traditional modes. Selection of a new technique in the performance of the surgery can be based on different grounds namely the reputation and the time invested by the surgeon on the training. The common ethical ground relating to the robotic surgery is the harm which can be caused to the patient. A surgical innovation always involves risk to the patient and in some instances may lead to morbidity and mortality. The risk is not limited to the physical repercussions, but also the financial and psychological harm. This eventually leads to the loss of a patient's trust in the medical profession. Robotic surgery is comparatively expensive than other treatments in the field of medicine and has a danger or risk of attracting expenses from cheaper and safer options.

Legal aspects of robotic surgery: what happens when errors occur?

Burnett (2018) elaborated on a case which was an outcome of an unsuccessful robotic surgery. The victim was Mr. Pettitt who underwent heart surgery performed by a Da Vinci robot. The cause of the death of Mr. Pettitt was multiple organ failure. Mr. Pettitt's death was considered a direct consequence of the surgery performed and it was detected that the robot damaged a part of the heart. The incident related to the death of Mr. Pettitt raised issues of negligence, training policies and the use of technology. Thus, in a claim of negligence relating to a failed robotic surgery, there are certain facts to be considered namley whether the hospital has breached the duty of care and failed to ensure the fact that the surgeon has undergone appropriate training before the surgery. In addition to this, training policies are considered to be of high significance. Thus, the training policies adapted by the hospital to a great extent determine the liability of the hospital.

Robotic surgery is a play with the technology. Thus, when negligence is detected, the law focuses on the nature of the training that the surgeon underwent, the policy of the hospital on the training of surgeons to perform robotic surgery, the experience that the surgeon has on performing such ventures, the fact whether the surgery has been carried out by someone else, whether the company which invented the technology supervised the surgery and whether there were benefits from the robotic surgery than manual conventional surgery. Surgical negligence is measured in the same way as medical negligence. The proof of surgeon's negligence is based on the established duty of care to the patient, breach of duty by the surgeon, and the breach resulted in harm. Finally, the surgeon's liability comes out with the proof of the fact that the harm so caused has resulted in damage.

Guerra et al (2021) endorsed the view that in addition to the imposition of liability on the individual surgeon and the hospital, the manufacturer of the robot can also be held liable. However, Guerra's contention has not been asserted as a pragmatic approach to the question. Alexander et al (2021) emphasized the establishment of causal chain. Further, if the victim needs to make the manufacturer liable, the development of causation is imperative. Thus, the plaintiff must prove that the injury was caused as a result of a defective design, and the weak maintenance of the robotic device. In *Mraceck v. Bryn Mawr Hospital* (2010), the plaintiff filed a strict products liability case in relation to a robotic assisted surgery. The plaintiff's allegation was that the Robotic Assisted Surgery Device (RASD) was malfunctioning and there was a display error which the surgeon was unable to resolve. The surgeon subsequently performed the surgery by himself which resulted in symptoms. The defendant manufacturer presented a counter argument on the basis of expert testimony, but the plaintiff argued on the basis of '*res ipsa loquitur*' theory. The application of this theory asserted the fact that the defendant's liability can be established in the instances where the plaintiff proves the fact that the product was under the absolute control of the defendant, there is no contribution on the part of the plaintiff to the incident and the injury would not have occurred without the interference of the defendant who was in charge of the control of it. The intervention of the defective products liability amidst the surgeon and medical staff's negligence amounts to the unnecessary expansion of the purview of the medical liability. However, in one perspective, it exempts a flawless surgeon/ medical staff from the liability.

Sri Lanka's response to the technology of robotic surgery

The field of medicine in Sri Lanka is in the process of development and it is not confined to one discipline. The first '*Robotic Kidney Surgery'* was performed in the year 2020 at the Sri Jayawardenapura General Hospital. The type of surgery was a robotic assisted keyhole surgery, and the final outcome was the removal of the kidney. The robot that assisted in the surgical process was 'Soloassist II'. The nature of the robot is a specialized form of electronic arm which has the technology to display the internal images of the bodily organ. The entire kidney surgery was performed through minute holes created in the body of the patient contrary to the traditional open surgery. The commencement proved successful and currently, the robotics in the field of urology, gynecology, cardiovascular surgery has been recognized. As a country that still struggles to achieve the heights of medical development, it is doubtful to what extent Sri Lanka will incorporate defective products liability in framing a new legal/ ethical code. This is a question with the practicality of holding a manufacturer of surgical robots liable in a jurisdiction like Sri Lanka. Thus, the only possible option is to impose liability on a surgeon who handled the robot with his own skill and knowledge.

CONCLUSIONS/RECOMMENDATIONS

Surgical robots at present support the field of medical surgery to cure the patients with quick interventions. Robotic inventions such as Cyberknife, Acrobot, Endoscopic capsules have become active in the performance of surgery but there are problems as well. There is doubt relating to the imposition of liability in the cases where the surgical robots are in failure. This is common to both instances where the controlled and automatic systems of robotic surgeons are involved. In such instances, the hospital as a whole can be held liable on the basis of training policies and simultaneously, the defective product liability can be imposed on the manufacturers of robotic assisted devices for the malfunction.

In Sri Lanka, robotic surgery is emerging, and medical litigations are filed against surgeons for their negligence. This necessitates the establishment of a separate legal framework in relation to the operation of surgical robots. In the implementation of a legal framework, it is necessary to focus on the hospital liability, individual surgeon's liability and the manufacturer's defective products liability. Further, it necessitates a separate ethical code for the surgeons who take the support of robotic surgeons. In a country like Sri Lanka, the inclusion of defective productive liability is practically questionable. However, legal and ethical liability of the human surgeon who has a reasonable skill and knowledge in handling the robot can clearly be established. This can be formalized by introducing a separate ethical code to Sri Lanka governing the ethical aspects of robotic surgery, namely equipment and safety, reliability, adequate information and confidentiality.

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