Sri Lanka Journal of Forensic Medicine, Science & Law — 2024; 15(1):29-33
DOI: https://doi.org/10.4038/sljfmsl.v15i1.7947

POINT OF VIEW

LEGAL AND ETHICAL FACETS OF ROBOTIC SURGERY: A SUGGESTION FOR A GUIDELINE

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ABSTRACT

Surgical negligence being a branch of medical negligence is considered a widely extended topic in the territory of Sri Lanka. The central focus of this paper is the use of robotic systems in the performance of surgical procedures and its legal and ethical facets. 'Robotic Surgery' is a novel form of technology that is efficient and productive and mostly preferred in sophisticated health systems and used in different fields of medicine namely cardiology, urology, oncology etc. In this method, the robots assist the surgeon in the performance of the surgery. The assistance given by a surgical robot is useful due to the efficiency, fewer incisions, less bleeding, and the lower possibility of infections. However, there are risks as well. If the risk and the injury were a result of the surgeon's fault, this gives rise to medical malpractice litigation. If the injury is a consequence of the malfunctioning of the surgical robot, it will create a defective product liability on the side of the manufacturer of the robotic system. If the hospital has undertaken the specific surgical venture without sufficient resources, expertise, and institutional stability, that will lead to the hospital's liability. Even, the liability of an error caused by robotic surgery can be imposed in different ways; the ultimate accused will be the health sector. The author's attempt in this paper is to discuss the legal and ethical implications of a surgeon-patient relationship in the performance of robotic surgery and thereby recommend a guideline to address legal and ethical issues relevant to robotic surgical procedures.

Keywords: *Ethics; medical liability; surgeons; surgical robots.*

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ARTICLE HISTORY
Received: 29.07.2023
Received in revised form: 14.02.2024
Accepted: 21.04.2024
Available online: 25.06.2024

INTRODUCTION

'Robotic Surgery' or 'Robotic Assisted Surgery' is an innovation in the field of medicine that has its pros and cons. The significance of such a surgical procedure is the minimization of pain and the less time it takes for the recovery[1]. It includes two categories namely the *controlled systems* and *automatic systems*. The significance of controlled systems is that such a procedure is controlled by the surgeon or dependent on the actions of the surgeon whereas the automatic systems operate after being programmed by the surgeon or the relevant operators[1]. The efficiency of robotic-assisted surgery is a revolutionary transformational technology. If further elaborated, the interference of robots in

surgical ventures transformed the era of traditional surgery into a new era of technological advancement. Even though the procedure has earned the epithet of opening avenues; it is considered as one of the more complicated scientific innovations which deal with both legal and ethical aspects[2]. The relevance of this discussion is of utmost importance to Sri Lanka as the technology is now being used in hospitals under different disciplines; urology, gynaecology, cardiology, and oncology. The handling of surgical robots necessitates special training and experience and the professional liability of the surgeon who operates the robot remains unchanged. However, there is a simultaneous concern about the ethical aspects as Robotic Surgery collides with the patient's rights. The methodology of the paper is qualitative and it is a content analysis of primary and secondary sources of law with a literature review.

MEDICAL AND PRODUCT LIABILITY UNDER LAW

A surgical robot is considered a 'self-powered and computer-controlled' device[3]. This helps in positioning and manipulating surgical instruments and supports the surgeon in carrying out complicated tasks. However, surgical robots still have no independence to work out of the supervision of the surgeons or to replace them[3]. This implies the fact that handling robots is the sole responsibility on the part of the surgeon who embarks on the particular act of surgery. This signifies that misconduct in the process of performing the surgery will create a liability for medical negligence. In the present context, different categories of surgical robots exist, namely internal, external, and mixed robots. Internal robots have the potential to perform surgery inside the human body (e.g.: endoscopic capsules) whereas external robots such as Acrobot, and Cyberknife are used to perform surgery on the surface of the patient's body. Mixed robots operate both inside and outside of the patient's body (e.g.: neuromate, da Vinci)[4].

The intervention of robots in a surgical practice has both positive and negative aspects. The positivity is highlighted when deeply analyzing the potential benefits namely the standard of clinical care, faster performance of the surgery, lesser number of incisions on the human body, lesser amount of bleeding, and the comparatively less possibility of infections[5]. However, seeking the assistance of robots to perform surgery has its risks as well. The risk is extended to several parties and it is not singlehandedly borne by the surgeon in a negligence claim. The risk is borne by the surgeon, manufacturer of the surgical robot, supplier, clinicians, and hospital staff while the main victims will be the patients. The manufacturer's liability in the context of a malfunctioning surgical robot is well discussed in the case of *Mraceck V. Bryn Mawr Hospital* (2010)[6]. The plaintiff of the case instituted an action in the court and the litigation was based on a malfunctioning 'Robotic Assisted Surgery Device' (RASD). The basis of the complaint was that there was a defect in the device which was not visible or known to a surgeon in the course of the operation.

ROBOTS AND PATIENTS

The right to health entitled to by the people ensures the fact that all human beings receive the highest attainable standard of health to preserve fundamental dignities[7]. Patient rights are based on the fundamental right to health. Patient rights are considered as 'basic rules of conduct between the patients and medical caregivers and the purview of it includes access to care, informed consent, confidentiality, right to information, and protection of the patient's dignity[7]. Patient rights have a significant ethical dimension. It would be useful to study the ethical implications of robotic surgery and the patient's rights. The positive aspects of robotic surgery include the convenience and timeliness of the procedure. Robotic surgery is lauded as a novel technological form of surgery that operates on patients through miniature surgical instruments[8]. However, there are risks involved in the process. The risks include the fear of complications, technical malfunctions, costs,

training, inexperience, liability, and brand reliability[9].

ETHICS AND RIGHTS

'Patient autonomy' is a basic right and a fundamental ethical aspect in the field of medical practice. The autonomy simply stands to an instance where a patient is entitled to make decisions concerning medical care without being influenced by the physician[10]. Thus, it is evident that there is a positive link between autonomy and informed consent. However, the question is on the 'informed consent' of a patient undergoing a surgical practice intervened by a robot which is an innovative procedure and in some circumstances, the patients may be unaware of the fact that they are subject to a new technology[1]. This necessitates the disclosure of standard consent information to the patient and that includes a clear explanation of the procedure, risks and benefits, and the alternative options which are available[11]. It is mandatory to disclose all the foreseeable risks of the surgery to the patient. The potential risks of robotic surgery may incur as a consequence of equipment failures, malfunctions, system errors, problems with video imaging, unintended instrument movements and electrical problems[9]. Further, the patient should be informed of the potential risks that would arise as a result of the physical condition of the patient.

The disclosure of risks to the patient is of importance due to the possible harms. Robotic surgery is an innovation that will affect the increasing mortality and morbidity of patients. Patients in some circumstances may confront the tragedies of infections and harms which are financial and psychological. Non-disclosure of such risks will result in a loss of trust in the profession of medicine[1]. Thus, it is important to ensure the patient's safety which is a basic patient right.

In the scope of robotic surgery, the informed consent obtained from a patient is currently turning to defensive consent. 'Informed consent' becomes complete under three arrangements. The first arrangement is the integration of information present in the informed consent (causes of the diseases, consequences which arise if the disease is not treated, possible technique and the consequences if treated and the risk of reintervention) with the surgeon's experience of robotic surgery, procedures and expertise[12]. This is supplemented by the second arrangement of imparting patients with information about the responsibilities of lawyers and preceptors and the third arrangement of stimulating surgical societies to create guidelines on robotic surgery[12].

The next important aspect is the evasion of conflict of interest. As this is an innovative technology, the surgeons who embark on the venture may be affected unconsciously by the benefits and the upgraded social status originating from being a 'surgical innovator'[1]. This can be further accelerated by the personal preference of a surgeon to use a device in the process without concerning the interests of the patient. The surgeon will prioritize a technique on which they have invested time, training, and expenses and particularly be influenced by 'brand loyalty'[1]. When the subjective preferences of surgeons are not based on well-grounded reasons and override the interests of patients, a conflict of interests emerges.

Hospital liability for surgical misconduct is a well-known legal principle. Before undertaking ventures on robotic surgery, the hospital authorities have a foremost obligation to consider the appropriateness of the institution to handle an innovative technique. From the perspective of Moore, three criteria should be fulfilled to make a surgical innovation acceptable. Thus, the criteria specify that a hospital/ institution inclined to robotic surgery must ensure the fact that, there is sufficient laboratory experience before conducting innovative procedures, the availability of technical and intellectual expertise in the institution, and the existence of a good 'institutional stability' filled with resources, human resources including staff and supporting systems[1]. The staff and supporting systems

include well-trained surgeons with relevant technical expertise and knowledge.

CONCLUSION

Robotic surgery is hailed as one of the emerging innovative surgical procedures that support patients with minimal pain and a minimal number of incisions in the body. Such surgeries take place with the support of controlled and automated systems. However, the surgical robots work under the supervision of human surgeons. This clearly shows the fact that; the operation of surgical robots is primarily the responsibility of the surgeon. The use of surgical robots gives rise to two facets of liability. Medical liability is concerned with the liability of the surgeons, who are entrusted with the duty of handling surgical robots. The intervention of a surgical robot in a specific medical procedure has pros and cons. The robot's presence makes the process speedier, and more efficient with a lower risk of infections. However, an error caused by a surgical robot will be serious. In this instance, the malfunctioning of the robotic system may not constitute an error on the part of the surgeon who operated it. Thus, the liability shall be extended to the manufacturer as well. The manufacturer's liability emerges when the defects exist and such defects are unknown or invisible to the surgeon.

Robotic surgery has both pros and cons. There is a substantial impact on patient rights and autonomy. The surgeon is bound to disclose possible harms and risks of the procedure to the patient. This enables the patient to give informed consent. However, the modern concept of informed consent within the scope of robotic surgery is defensive. Thus, when imparting information to the patient, the surgeon should disclose the possible risks and consequences of treatment and non-treatment. However, the basic information should further be supplemented by disclosure of the experiences of the surgeon, procedures and expertise. The consent given by the patient should be free and voluntary. However, in certain circumstances, a surgeon's personal preference over the technology and robotic device or brand loyalty may override the patient's well-being.

The liability relating to robotic surgery is not solely focused on the surgeon-patient relationship. The hospital liability is of imperative concern. In addition to the individual surgeon's liability for handling the surgical robot, the hospital is accountable for ensuring that, there is a conducive technological background within their premises to work with surgical robots.

As an emerging field of surgery in the context of Sri Lanka, it necessitates a guideline to address the legal and ethical concerns on the handling of surgical robots prioritizing the competency, proficiency and minimum requirements of robotic skills training of surgeons, and clear classification of the roles of surgeons, robotic companies and hospitals in performing and facilitating relevant surgical procedures.

ACKNOWLEDGEMENTS
None.

CONFLICTS OF INTEREST
The author declared no conflicts of interest.

ETHICAL ISSUES
Not applicable.

SOURCES OF SUPPORT
None.

AUTHOR CONTRIBUTIONS
APR: Conception or design of the work; acquisition, analysis, and interpretation of data for the work; drafting the work and revising it critically for important intellectual content; and final approval of the version to be published.

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