ROBOT-ASSISTED SURGERY: AN ANALYSIS OF THE LEGAL AND ECONOMIC IMPLICATIONS

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Abstract:

The legal and economic issues that arise as a result of including artificial surgery in the medical field will be analyzed. The questions of liability will be addressed by exploring how to define surgical robots in legal terms, including artificial agents and electronic personhood. The incorporation of additional parties in surgical procedures complicates attributing responsibility, and court cases involving such complications are discussed. In the past, failed surgeries were the fault of the surgeon and hospital and rarely any other parties. Now that surgeon-operated surgical robots are being used to assist in procedures, software engineers, manufacturers, and machine producers can also be held liable for any malpractice. Finally, the financial component of purchasing this technology is contrasted with the benefits and revenue achieved with robot-assisted surgery. A number of surgical robots, such as probes used in procedures like endoscopies and bronchoscopies, aren't used for incisions and are usually less expensive and entail less liability. Another selection of surgical robots are used as tools controlled by the surgeon for performing procedures; these machines can cost millions and face more legal liability. Robot-assisted surgery can cause higher efficiency, shorter recovery times, and minimal scarring, but it also raises legal and financial questions regarding the risk and feasibility of incorporating surgical robots into the medical field.

Keywords: **liability, economics, artificial intelligence, surgical robots**

Introduction

Technology has advanced greatly in the past twenty years and has gradually been integrated into medicine, making the process of testing, charting, and organizing surgery schedules and patient records smoother and more precise. As technology has grown in its ability, questions have arisen on incorporating artificial intelligence with surgery. The aspiration is that surgery can be made faster and less invasive which can lead to shorter hospital stays allowing medical care to be more accessible to all. The shortened hospital stays incur less expense on the patients, lowering a barrier to obtaining health care further. However, the perceived benefits of robot-assisted surgery are accompanied by several questions about the risks and liability of a robotic third-party in addition to the economic analysis of investing in the expensive machines.

Integrating robots with surgery complicates liability. Typically, in cases of malpractice, the only parties who face liability are the surgeon and the hospital. When artificial intelligence is involved many more parties can be held responsible in the case of surgical complications or fatality. Both the surgeon and hospital can be held liable in addition to the machine's manufacturer and software engineering company as well. The process of designing machines capable of surgery is extensive because it requires machines who depend on consistency and predictability to perform in an environment where predictability cannot be promised. If a complication occurs during surgery, it will require prompt action from the surgeon and may cause an increased risk of serious damage than if performed in a traditional manner.

The question of efficacy of robot-assisted surgery being feasible also depends on economic restraints. Due to the complex software, mechanical tools, and liability involved, the machinery utilized is very expensive and is not possible for many hospitals to afford. Furthermore, the ability to use these robots requires extensive training and therefore educational facilities will increasingly be expected to train upcoming surgeries in using the machines.

This puts a financial burden on hospitals and institutions to invest large sums of money towards procedures that will become more popularized and increase the number of facilities that perform robot-assisted surgery.

It is assumed that the ability to perform more surgeries in an amount of time will increase income, but it must also be assured that a completion of more procedures generates enough revenue to cover the cost of the machines.

There are still many developments to be made in the production of machinery and artificial intelligence for robot-assisted surgeries. These developments include making the machines more capable of handling complications that may arise during surgery to ease the worry of legal issues and lowering the cost for hospitals to adopt the new equipment. Through the continued pursuit of bettering surgical artificial intelligence and machinery, the risk of liability and financial burden can be lessened. Therefore, more hospitals are able to participate in this minimally invasive approach.

The Legal Implications of Robot-Assisted Surgery

The laws and regulations related to robot-assisted surgery are being discussed worldwide due to its complexity and novelty. An article written by Aída Ponce Del Castillo for the European Trade Union Institute (ETUI) details how the European Parliament has been approaching the subject. In the case of robot-assisted surgery, it becomes more complicated to apply laws and regulations due to machinery not having the same legal attributes as humans. To address this issue, it is important to clearly define robot-assisted surgery in legal terms as well as determine how to attribute personhood and liability. Through this process, the ETUI established a way to appropriately categorize the machines and hold them accountable in an increasingly technological surgical environment.

The complex computer software used in artificial intelligence creates greater barriers to understanding the actions of the machinery, examples of which occur in cases of computers interpreting MRI scans. These programs, created to interpret findings from scans and images are "modeled after the human brain, ... when given additional data, the neural network can modify its decision-making process for a more accurate response, without any explanation of how it has done so" (Sullivan & Schweichart, 2019). This situation is known as a "black box", referring to the lack of clarity in how conclusions are drawn by artificial intelligence (Sullivan & Schweichart, 2019).

This poses another legal issue because of the way liability in the medical practice currently stands. Producers of medical devices can be held liable for the damages caused by the device, but the issue becomes less clear when the producers of a machine are unaware of how the artificial intelligence will behave in practice.

To combat the issue of adapting laws to apply to artificial intelligence, it is important to clearly define what is meant when referring to robotic surgery or robot-assisted surgery. For the sake of legality, robot-assisted surgery cannot be referred to in broad terms. A largely accepted definition of robots is "an artificial device that can sense its environment and purposefully act on or in that environment; an embodied artificial intelligence; or a machine that can autonomously carry out useful work" (Winfield, 2012). This does not apply to robotic surgery. Instead, it is the "operation by telemanipulation of dexterous robotic tools through small incisions'' where the "surgeons sit at a console near the operating table and utilize joysticks to perform complex procedures" (Yang et al., 2020). The machines used in robot-assisted surgeries do not fall under the definition of robots due to their lack of autonomy, but they cannot be considered mere machines.

Ponce Del Castillo, a lawyer with a focus on regulatory issues of human genetics, goes on to explain how to properly define these machines by addressing their unique characteristics. She states that "the term 'artificial agent,' understood as a spectrum concept, makes sense because it covers a wide diversity of...decision-making algorithms, auto-mated machines, digital agents, hybrid multi-agents, Internet bots, robots, nano-robots, drones, etc" (Ponce Del Castillo, 2017). Since the machines are fully designed and created by humans they fall under the category of "artificial," and their ability to act as directed by the surgeon categorizes them as 'agents.' For this reason, when discussing robot-assisted surgery, it is in reference to surgeons performing procedures with the assistance of these artificial agents.

Most artificial agents are not considered autonomous due to their inability to act with intention or awareness of consequence, trying them legally as an electronic person is impossible. The machine itself cannot be prosecuted. In most cases, the surgeon has complete control over the artificial agent and therefore any malfunction is the responsibility of the software developer and manufacturer, not the machine (Kaplan, 2016).

A software developer of a surgical robot faces many difficulties such as mapping a large variety of individual cases, complicated surgeries causing a limited ability to operate, and the possibility of stains on the camera lens obstructing the surgeon's ability to navigate the procedure (Hu et al., 2020). Refining these possible liabilities can be achieved by further testing and thorough research. It is proposed that "real-time automated surgical video analysis could facilitate the objective and efficient assessment of surgical skills and provide feedback on surgical performance" in an article written by Yang et al. In addition, generating "timelines displaying tool usage during a surgery" can help with the data collection to make the artificial agents more capable of handling complex procedures. Familiarity with the way the machines operate, and the incorporation of data collected from live surgeries will benefit the performance of the artificial intelligence and ease the risk of legal action brought against producers of the machines.

Many lawsuits have been brought against producers of these surgical robots. A lawsuit involving a robot-assisted surgery was brought in 2016 against Intuitive Surgical on the grounds of a failed surgery performed with their da Vinci Robot (Kaplan, 2016). The same article goes on to explain that the plaintiff claimed that the machine was the cause of her postoperative infection, but the performing surgeon claimed that the fault was on her for ignoring post-operation instructions. In this case, Intuitive Surgical settled with the plaintiff, but other lawsuits had been brought against Intuitive, claiming they withheld knowledge of the machine's malfunctions (Kaplan, 2016). One attorney claimed that "in less than 1 percent of cases, patients or doctors reported that the insulation covering the 'wrists' of the robotic arms cracked, allowing electricity to shoot out and burn the patient" (Kaplan, 2016). When producers of surgical machines are involved in robot-assisted surgeries, they assume liability and face consequences for under-developed and refined machinery, as demonstrated in these allegations.

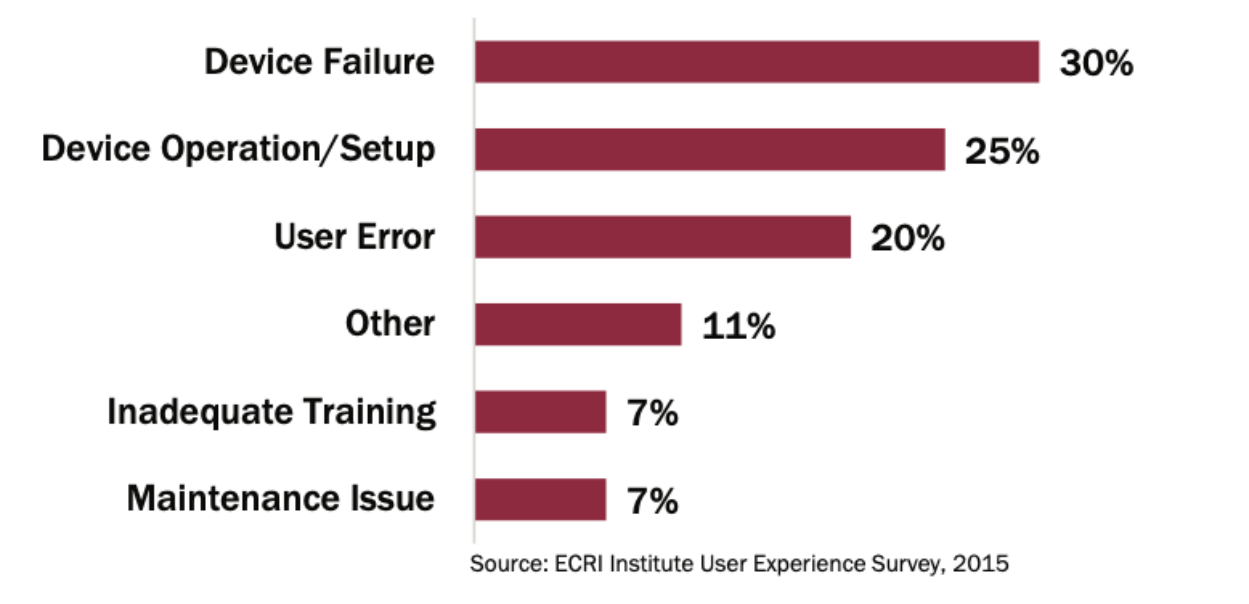

Fig. 1: ECRI Institute User Experience Survey, 2015

To determine who was most likely to blame for flawed performances by the da Vinci Robot, a survey was conducted by the ECRI Institute in 2015. Statistics gathered showed that over 50% of problems were due to the device's failure and flaws in operation and setup, while the remainder of issues were due to other causes including user error. This does indicate that when surgical robots are involved, device failure and liability is a considerable possibility. This nature of liability entails its own struggles as current law grapples with addressing artificial intelligence being incorporated with medicine.

The complex and diverse nature and usage of these surgical robots raise many questions about how liability ought to be applied. In the AMA Journal of Ethics, Hannah R. Sullivan and Scott J. Schweikart wrote that "it is challenging to find a responsible party, as so many different entities—software developers, hardware engineers, designers, and corporations—go into the creation of AI systems." (Sullivan & Schweichart, 2019) One solution proposed in this article is to "confer 'personhood' on the artificially intelligent machine itself, viewing the machine as an independent 'person' under the law." (Sullivan & Schweichart, 2019) This AI personhood wouldn't apply to machines like da Vinci where the surgeon has complete control over the device (Sullivan & Schweichart, 2019). For machines like da Vinci the responsibility if a mistake is made will either be attributed to the manufacturer of the machine or the surgeon/hospital in most cases. AI personhood would apply to programs made to interpret medical findings based on data collection. This example reveals the importance of distinguishing what type of machine is being referred to when speaking about surgical robots. There's a great variety of artificial intelligence, procedures, and parties involved, making liability a complex issue to tackle.

The Economic Implications of Robot-Assisted Surgery

Some artificial agents are already in use for surgeries and the data collected has indicated that despite the price tag, the number of surgeries performed with the help of artificial intelligence has increased dramatically. The most widely known machine used in robot-assisted surgery is the da Vinci Robot. The surgeon controls the arms of the da Vinci Robot while looking at a screen that projects a magnified view of the surgical field.

Laparoscopic surgery is well-known for its ability to decrease recovery time and scarring and da Vinci has become increasingly popular.

The da Vinci Robot is not a small investment. One machine alone costs upwards of two million dollars and each surgery costs anywhere from three to six thousand dollars for the patient (Scott, 2016). Over a thousand hospitals have adopted this device and the number of procedures done by the da Vinci Robot "rose from 1500 in the year 2000 to more than 20,000 in 2004" (Kumar R., 2005). While this increase may seem substantial, experts claim that "hospitals must perform anywhere from 150 to 310 procedures within six years to offset upfront and ongoing costs" (Scott, 2016). Unless developments are made to improve the performance of the da Vinci Robots, it is impractical for most hospitals to make this investment because although it does reduce scarring and recovery time, it requires many surgeries to be performed in order to be profitable. This problem is not only caused by a possible lack of surgical candidates, but the feasibility of providing enough hospital beds and equipment to support a large number of procedures.

Most procedures using the da Vinci Robot are surgeries that are more invasive, hence benefitting from the minimally invasive nature of robot-assisted surgery. Gynecology makes up 52% of all procedures performed with da Vinci (ECRI Institute, 2015), a field where minimal scarring is highly preferable. In a field, however, where procedures are already minimally invasive, there is very little incentive to invest in machines like da Vinci where procedure outcomes are not improved by its use. An example of this can be observed in the field of ophthalmology. Dr. Richard Lindstrom, an ophthalmologist in Minnesota, states that "eye surgery is already minimally invasive with very small incisions and nearly no blood loss. Also, visualization is usually excellent," but the final reason he shares for why the da Vinci Robot is undesirable in the field of ophthalmology is due to its cost (Lindstrom, 2021). Adopting this machine is not justified when "robotic systems are expensive, have a steep surgeon learning curve and usually require more time per procedure" (Lindstrom, 2021). He continues to explain how this also becomes unreasonable for educational facilities to afford because to master the use of these machines a student must perform between 150 to 250 procedures (Lindstrom, 2021).

There are several surgical robots on the market that are economically feasible, and the Monarch by Auris is among those. The Monarch is a robotic bronchoscope that is controlled by the surgeon with a controller that closely resembles that of an Xbox or PlayStation. This machine, unlike the da Vinci, isn't meant for surgical procedures that require incisions or resections.

The Monarch is designed to perform Bronchoscopies, an exploratory procedure intended to identify cancerous nodules in the lungs. While this procedure doesn't remove the nodules, it does have the ability to "detect malignant tumors at an earlier stage, therefore significantly increasing lung cancer survival rates'' (C.F. Graetzel et al., 2019). This surgical robot costs about $500,000 (Densford, 2018), which is significantly less than the da Vinci Robot. Bronchoscopies usually cost about the same as laparoscopic surgeries but are performed over 500,000 times a year, making the cost of the Monarch much easier for hospitals to recover from (Guglik, 2018). Robotic scopes like the Monarch incur less liability due to their benign nature and are typically less expensive than machines like the da Vinci.

To some hospitals, though, the fact that the cost of a surgical robot may not be recovered isn't an issue. A study conducted shows that in California, the profit margin for hospitals averaged 8%, which from the years 2013 to 2017 resulted in over 5 billion dollars in revenue being earned each year (Belk, 2021). Not all hospitals have profit margins of this extent, but this does illustrate that for some hospitals the attention brought by integrating a surgical robot into their facility can be worth the cost of machines like da Vinci. Additionally, having surgical robots allows for opportunity to facilitate education: another form of revenue. Less invasive surgery and shorter hospital stays are attractive to patients because they can save money on hospital bills and reduce the necessary amount of time off from work. As robot-assisted surgery becomes increasingly popular, hospitals may become more willing to accept the high cost of expensive machinery with the hope that the attention and opportunity it offers make up for the disparity.

Conclusion

Technology, as it's grown in scope and capability, has proven greatly beneficial in the medical field. Surgical robots have been integrated into many surgical programs and have resulted in less invasive surgery and shorter recovery time. However, it has created new obstacles of liability as there are now several more parties involved in the case of malpractice. Software developers and manufacturers are now involved in a field that previously only had two primarily responsible parties: the surgeon and the hospital.

In cases of highly advanced artificial intelligence, tort laws have been prompted to add terminology to address electronic personhood and create precise definitions to address whether a machine used in surgery is a mere tool or an artificial agent. Furthermore, economics impact the ability for hospitals and institutions to integrate surgical robots in the operating room. Robot-assisted surgery includes much more expensive machinery as well as hundreds of practice procedures to reach mastery. While surgical robots do assist with recovery time and minimal scarring, hospitals must weigh whether the publicity and financial benefits are worth the millions of dollars required to purchase these machines. Robot-assisted surgery is growing in popularity, but as technology advances rapidly, legal and economic discussions are being had regarding the feasibility of integrating these machines.

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