AN INVESTIGATION OF THE SOCIAL IMPLICATIONS OF MEDICAL ROBOTS

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

The use of surgical robots for all general surgery procedures increased from 1.8% to 15.1% from 2012 to 2018 (Sheetz, Claflin, & Dimick, 2020). It has been proven to be a valuable tool for specializations such as urology, gynecology, cardiotomy, etc. In most cases, the usage of medical robots leads to better dexterity and precision for surgeons. A lower risk of infection and blood loss, smaller incisions, and reduced recovery time is observed in patients. However, there have been numerous instances where the technology has failed and led to dire consequences.

The da Vinci robotic system, for example, has previously erred in the following areas: set-up joint function, arm function, power, monocular monitoring, camera function, metal fatigue/break of surgeon's console hand piece, and software compatibility (Borden et al., 2007). Such failures indicate that "Although uncommon, malfunction of [these type of robotic systems] does occur and may lead to psychological, financial, and logistical burdens for patients, physicians, and hospitals" (Borden et al., 2007). As the usage of medical robots in the surgical workplace continues to rise, it is important to consider these types of scenarios and the implications it may have for the people surrounding these robot-assisted procedures.

In this paper, I explore the liability issues surrounding surgical robots, the potential impact such technologies may have on hospitals, insurance companies, and patients, and patients' level of comfort. I highlight the reasons why we should proceed with caution while using such surgical robotic systems and why patients should remain skeptical to a certain degree. The stakes are high, given that these technologies are used during surgery. While these surgical robots are far from being completely autonomous, I would argue that we will continue to get closer and closer to it with time, which makes it that much more important to have these discussions earlier on.

Theoretical Frameworks

The theoretical frameworks that will help us shape our answers to these questions include the Social Construction of Technology (SCOT) approach and Users vs. Non-Users. The SCOT theory revolves around this idea that users have the power to drive the types of technologies that emerge. According to the framework, they are the ones that determine which technologies are here to stay and which ones were just a fad. The patients that are willing to get these robot-assisted surgeries done are the ones that will have a direct impact on the medical robots we see in the future.

The SCOT theory comes with its own shortcomings nonetheless. It fails to account for the nonusers and the role(s) that they play when it comes to the design and usage of new technologies. Those who choose to go the conventional route with surgeries (without the medical robots) will indirectly shape the technology as well. It also does not address the social implications that technology has on its users and nonusers (Klein and Kleinman, 2002). Technology along with its users and nonusers is not a one-way street. Users and nonusers drive innovation in technology, but it does not stop there. The technology in turn has an impact on those same users and nonusers. It changes the way that they go about simple or complex tasks in their day-to-day lives. Surgical robots have already brought about significant changes for patients and surgeons alike, but there is also the potential for it to change the landscape of the healthcare system in a broader sense. Hospitals, insurance companies, etc. might see differences in their policies moving forward due to those liability issues mentioned earlier. No one wants to take on that responsibility in the event of a catastrophe, since it could become a big financial burden.

Liability Issues Surrounding Surgical Robots

In the event that a surgical robot was to malfunction or behave unexpectedly, who should be held responsible for the potential damages? There are a few options as to who to point to: the hospital, the creators of the technology, the physician/surgeon, or the patient. Of course, no one wants to take the blame though. The lack of clear guidelines for these types of accidents makes it difficult to deal with these situations as they occur. It is both frustrating for the patient and especially concerning from a legal standpoint. It should cause us to question how much faith we currently place and how much we should place in these technologies.

The best plan of attack would be to consider the socio-technical system that surrounds it and gain a better big picture. The system is comprised of separate entities that each play their own role. The surgeon uses the technology, but is only as good as good as its tools and schooling. The hospitals hire these surgeons based on their qualifications and are also the ones purchasing the equipment and surgical robots used by the surgeons. The creators of the technology could potentially be held responsible, but it's not possible to detect and resolve all faults present in any piece of software or technology. Just when a person thinks they have covered all their bases, something else pops up. Even if there were technologies free of any errors, the gap between the use intended by the creators and the actual usage by people would always exist. Bridging that gap is something that is a continual work in progress. There are many factors that need to be taken into account and no one group can take all the blame.

The case review of Therac-25 can shed some more light on this. Therac-25, a radiation machine used for the purposes of cancer treatment, had serious blunders that caused the deaths of several patients between 1985 and 1987. Software errors in the product led to the radiation overdosage seen in the patients and Therac-25 was subsequently recalled in 1987 (Besnard and

Baxter, 2003). The system's dependability relied on the work of the company, programmers, and regulation authorities to come together, but they collectively failed. Besnard and Baxter summarize where the pain points (as per the fault-error-failure model) for Therac-25 lied below.

> The programmer did not take all of the system's real-time requirements into account (fault). This led to the possibility of flaws in some software modules (error) which degraded the reliability of the software (failure). The company did not perform all the required tests on the software (fault). This resulted in bugs in some modules remaining undetected and hence unfixed (error), thereby triggering exceptions when the given modules were called (failure). The regulation authorities did not thoroughly inspect the system (fault). This led to some flaws remaining undetected (error). In turn, these flaws caused injuries and deaths when the system was used (failure) (Besnard and Baxter, 2003).

This chain of unfortunate, careless events is what ultimately led to the flawed Therac-25. It can be argued that some were more responsible than others, but no single individual or entity was responsible for the death of the patients. In this example, the programmers were at the start of the chain, so maybe they were more likely to receive the blame. However, the company and regulation authorities had what it took to stop these failures from making it to the final product. The situation with surgical robots is very similar. There are a handful groups that the success of the robot relies on and pinpointing one of them when failure occurs is nearly impossible.

The Potential Impact on Hospitals, Insurance Companies, & Patients

The surge in surgical robots is bound to have some everlasting implications for hospitals, insurance companies, and patients. Most minimally invasive procedures are currently covered by insurance companies, but will this continue to be the case? “The most recurrent issues concerning surgical robots and insurance are about the coverage of specific surgical interventions by the national health insurance service and about the reduced health insurance costs resulting from robotic assisted surgery” (Bertolini et al., 2016). Surgical robots are supposed to make procedures safer and if that’s the path they continue along, we would see a decrease in the health insurance costs. While this is great news for surgeons, hospitals, and patients, it would put insurance companies at a disadvantage.

The cost of such robotic surgical systems alone can range from $1.5 million to $2.5 million, not to mention the additional annual service fees ranging from $100,000 to $170,000 (Shih, Shen, & Hu, 2017). For hospitals with higher surgical volumes (more surgeries being done on a daily basis), the cost may be worth it. For smaller hospitals though, this technology will be far out of reach, unless additional federal funding is provided. “Business-wise, consumers may perceive the ownership of new technologies like robotic surgical systems as a signal of cutting-edge, high-quality hospitals; thus attracting more patients. Owning a robotic surgical system might also help to recruit surgeons, who then bring their patients to that hospital” (Shih, Shen, & Hu, 2017). It is no secret that most people would choose a hospital that has more cutting-edge technology than a smaller, less advanced practice hospital. It’s these choices that we make as patients, that cause some hospitals to swim and stay afloat, while others sink. The “recruiting” of surgeons only makes matters worse. Patients tend to place more trust in the physicians and surgeons that their family or relatives have received treatment from. This further contributes to the success of a select few hospitals and the failure or underperformance of others.

The disparity between different hospitals could lead to the introduction of groups of “resistors,” “rejectors,” “excluded,” and “expelled” (Wyatt, 2003). In the healthcare world, patients that are resistors would be people who will not undergo robotic surgery, because they simply do not want to. Rejectors are those that voluntarily choose not to opt for robotic surgical methods. Perhaps they trust the conventional procedures more or maybe they don't want to contribute to the disparity already present. Those that are excluded do not have access to such fancy equipment. Lastly, the people who fall into the category of expelled, involuntarily don't use such technologies. These four groups have the power to change the course of surgical robotics, because some believe that it is "appropriate to develop new services in order to attract the resisters and the rejecters" (Wyatt, 2003).

Patients' Level of Comfort

As some individuals continue to favor the hospitals that have the latest technology and advanced practices, there are others that remain skeptical of going under the needle when robotic procedures are involved. Based on data publicly made available in the MAUDE database, 144 deaths (1.4% of the 10,624 reports), 1,391 patient injuries (13.1%), and 8,061 device malfunctions (75.9%) were reported from 2000 to 2013 (Alemzadeh et al., 2016). These numbers alone are enough to make someone reconsider following through with a robot assisted surgery. As of 2016, the numbers on deaths and injuries per procedure remained relatively constant (Alemzadeh et al., 2016). The potential for device malfunction remains one of the biggest concerns.

There is a lack of universal standard guidelines for the training and credentialing of surgeons as they use these surgical robotic systems (Kirkpatrick and LaGrange, 2016). Surgeons are more likely to misuse the robotic tools, if they don't receive formal training and hands-on learning experience. "To become adept at robot-assisted procedures, a surgeon must perform 150 to 250 surgeries" (Shih, Shen, & Hu, 2017). Regardless of which hospital the surgeon is working for or how early on he/she might be in their career, performing 150-250 surgeries within a reasonable timeframe could become quite a difficult task. Some hospitals will take the shortcut and consider the surgeon to be adept enough to perform these robot-assisted procedures after performing less than 10 surgeries. The reason why they do this is to compensate for the expensive machinery.

Some other things patients need to keep in mind are the push towards robotic surgery from their physician/surgeon when they may not be good fit and/or the absence of full disclosure. The intent behind the push is once again to compensate for the pricy robotic equipment. If robotic surgery is extended as an option to patients who do not make suitable candidates for these types of surgeries, the pressure may translate to inferior patient care (Shih, Shen, & Hu, 2017). It could lead to complications that may have not been present, had the patient gone with a conventional surgical procedure. Physicians might also only present patients with the partial truth. "Kaushik and colleagues found that less than 70% of patients were appropriately counseled preoperatively on the potential risks specific to robotic surgery, including possible robotic malfunction or potential conversion to an open procedure" (Kirkpatrick and LaGrange, 2016). The possible unfavorable outcomes and how they would be handled need to be clearly communicated from the surgeon to the patient prior to the procedure.

Finally, the impact of marketing language is a factor that should also be weighed. In a discrete choice experiment conducted by Dixon, Grant, and Urbach, "subjects were more likely to select robot-assisted surgery over conventional laparoscopic surgery when it was described as "innovative" and "state-of-the-art" as compared with when the description included disclosure of the limitations of available evidence" (Dixon, Grant, & Urbach, 2015). It is important to bear in mind that these are merely marketing tactics. The diction one is presented with does not take away from the fact that there is limited evidence for robot-assisted surgeries.

Conclusion

Throughout this paper, I argue that while robot-assisted procedures have made revolutionary changes to the surgical field, we should proceed with caution and consider the consequences. As robotic technologies continue to become prevalent in healthcare, it's important to identify the liability issues and how they should be resolved, the impact such technologies would have on hospitals, patients, and insurance companies, as well as how comfortable patients are undergoing surgery with a robot. The area of liability still seems to be a grey area, since several people are behind a failed piece of technology. Insurance companies might take the hit if surgical robots thrive in the years to come, but patients and large hospitals will be in the clear. It is up to us as patients, physicians, users, nonusers, and the like to determine which direction surgical robots head in. Whether or not patients are comfortable with such procedures can be attributed to factors such as previous statistics, surgeon interaction, marketing techniques, etc. Complications can be reduced to a certain degree in the future by generating universal, standard guidelines for surgeons and having clear, open communication between patients and their respective surgeons so they're not blindsided.

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