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ARTIFICIAL INTELLIGENCE AND AUTONOMOUS ROBOTIC SURGERY: INNOVATIONS, CHALLENGES, AND REGULATORY PATHWAYS

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ABSTRACT

Artificial intelligence (AI) in a surgical robotic system is currently revolutionizing the contemporary health sector because of its high performance, lower invasiveness, and better patient outcomes. In this review, we examine the historical process, current capabilities, and the future of AI-guided and autonomous robot surgery, including some of the major milestones between the prototypes, including PUMA and ROBODOC, and the latest, such as da Vinci and Mako systems. It explores the benefits of AI-powered surgery, such as in-time support to decision-making and decreasing fatigue in surgeons, and sheds light on the prominent drawbacks and obstacles, including financial barriers, bias in data, security exposure, and other ethical concerns. The paper uses the previously collected data retrieved from the MAUDE database at the FDA and recent histories of recalls to discuss device malfunctions, adverse events, and regulatory classification of the autonomy levels of the surgical process. It also discussed the regulatory, moral, and policy frameworks to be put in place to ensure that there are safe applications of autonomous systems in the civilian world and the military world. Finally, the review highlights the significance of technological progress with effective monitoring, guarantees safety, accountability, and patient reliance, in the age of intelligent surgical robotics.

INTRODUCTION

The following paper tries to give the pieces of frameworks of the development of standards in ethics, as well as in legal and regulatory compliance of artificial intelligence (AI) and autonomous robotic surgery. Under the circumstances of accepting such robots, two questions need to be debated ethics and trust. We consider such a discussion when it applies to both the open surgical intervention (eg, robotic laparotomy) and more minor variations of endoscopic variants of surgical interventions (eg, robotic bronchoscopy). We solve numerous provocative questions related to the socio-legal aspects of the concept of a robotic surgical aid, casually called a robotic-assisted surgery, and to the idea of an autonomous robotic surgery. Robotic surgery as a process can be traced back to the 1980s when the PUMA robot was introduced into the world (Theodore et al. 2018). In the last 20 years, the field of Artificial Intelligence (AI), machine learning, and robotic-assisted technologies has played a very important role in shaping the future of robotic surgery. The capability of modern robotic systems allows a surgeon to do more complicated procedures with greater dexterity, visualization, and control. AI and automation have been important in increasing the feel factor in robotic surgery and precision. Within the medical industry, AI is becoming an efficient tool that is being used in many ways, with medical image analysis and diagnosis being one of them, drug discovery and development (Paul et al. 2021), and robot-assisted surgery (Knudsen et al. 2024). Robotic techniques have been extensively used in treatment in different medical fields like gynecology, oncology, and even general surgery to enhance efficiency and the recovery time of patients (Čelebić et al. 2025). Da Vinci, designed by the California-based Intuitive Surgical and named after the artist and inventor of the same name who lived in the 15th century, is a state-of-the-art laparoscopic system to perform intricate minimally invasive procedures The da Vinci system consists of a master-slaves relationship that are one-to-one with 3D video imagery being used in the surgical process (MORRELL et al. 2021). According to which approved by the FDA in 2000, it has taken its place in procedures such as prostatectomies, hysterectomies, and cardiac valve repairs, in which it is used in approximately 200,000 Major surgical operations as of 2012 (Rivero-Moreno et al. 2023). The system improves surgical accuracy and recovery, specifically with cancer treatments, and about 75 percent of all prostatectomies in the US are completed with the use of the system (Ou et al. 2024). Although AI may not be ready to carry out such an invasion, the flow of model introduction is still open-mindedly accepted by people, despite the majority of the research conducted on data security, ethical issues, equipment safety, and lawyer topics remaining to be completed (Kumar et al. 2024). There has been a

lot of hype in the past about surgical robot systems (SRS) that have reshaped the paradigm of surgical processes (Toader et al. 2023). The shift of the traditional open surgical procedure to minimally invasive surgery (MIS) in the late 1980s. Advantages of MIS: less risk of infections, accelerated healing, high accuracy, and better visualization. To know the effectiveness of the use of robotic devices in various minimally invasive operations, we retrieved useful information on the possible causes of robotic accidents. Our analysis covers the entire work that the FDA has gathered in ten years, between 2015 and 2025. The analysis of the patient outcomes and the reason behind adverse events recorded in various classes and types of surgery, and the recalls made by the manufacturing company were studied (Aboy et al. 2024). The following paper discusses how AI-based robotic surgery is currently used and the benefits and drawbacks of the technology, as well as how it could evolve in the future.

2. History

The use of hand controls in the control of robotic manipulation and camera robots was first created by Robert Heinlein in 1942 in his book Waldo, which even predicted brain surgery (Mohammad 2013). The earliest real surgical robot was the Arthrobot, which was developed in Vancouver and the first to be operated in 1983 during orthopaedic surgery, where a voice command directed the robot, which moved the leg of a patient. Another milestone was when PUMA 560 robotic arm powered the CT-guided brain biopsy in 1985(Kwoh et al. 1988). About the same period, the Imperial College London devised the PROBOT to perform minimally invasive prostate surgery, which stood out in precision and reduced surgeon fatigue complaints (Andellini et al. 2019). The ROBODOC system in orthopedics changed hip replacement surgery when it was released in 1992 and precisely milled the femur to facilitate the implants, and became the first surgical robot approved by the FDA in 2008. Robotics progressed very fast, as systems such as AESOP in 1994- the first system to be approved by the FDA to be used as a laparoscopic camera holder were later modified to have voice control. ZEUS, which was made available in 1998, led to telerobotics and facilitated, in 2001, the distant procedure, the Lindbergh cholecystectomy (Baek and Kim 2014). The da Vinci Surgical System, launched on the market in 2000, introduced the concept of wrist-like manipulator and tremor filtering into minimally invasive surgery, enabling complex surgeries like cardiac bypasses and kidney transplants (Lanfranco et al. 2004). Robotic advances also in the mid-2000s came to transoral robotic surgery, the first AI-performed unassisted heart surgery, microsurgical infertility procedures, and pediatric bladder reconstructions. Advances since then have been MRI-including the NeuroArm neurosurgery system in 2008, the variable DLR MiroSurge system, the force-feedback Sofie robot in the Netherlands, and the modular Versius launched in 2019 as a minimalist competitor to da Vinci. These milestones, combined, outline the great transformation of surgical robotics from a speculative fiction to becoming a necessity in operating rooms today.

3. Artificial Intelligence and Robotics

Artificial intelligence (AI) is a breakthrough in the field of improving the outcomes of surgeries and guiding rational decisions. Before an operation, AI algorithms may use any preoperative information, like CT scans and MRI, and 3D reconstruction of anatomy, to carry out a full anatomical evaluation. This enables surgeons to make plans and virtually train on procedures, anticipate challenges, and improve their surgical plans more accurately (Lee et al. 2024).

The AI uses real-time data of imaging systems and other surgical devices during surgery to help in complex anatomical structure navigation, placement of the instruments, and warn the surgeons of any risk or deviation. Robotic systems powered by AI will help automate traditional surgical procedures such as sutures and tissue handling, allowing for ease of thinking and enhancing performance in terms of efficiency (Bonaci et al. 2015).

Outside of the operating room, AI can analyze vast amounts of data from patient histories, surgical outcomes, and scientific literature to forecast patient-specific outcomes and plan treatment regimes on an individual basis. Machine learning also helps such systems to learn and improve constantly, and as every surgery is completed, it will improve the performance in the future.

4. DATA ANALYSIS

4.1. Frequency of Adverse Events and Their Patient Impact

The report also indicates that the number of incidents associated with robotic surgical systems has thousands of incident reports regarding the use of the device in the last ten years, based on data found in the Manufacturer and User Facility Device Experience (MAUDE) database run by the FDA. Nonetheless, due to the modern boom in the number of robotic surgery procedures, in particular urology and gynecology, the risks per case are minimal, with complication rates less than 5% in cases of critical issues. At that, every adverse event has serious connotations, including long recovery periods or lifetime disability.

Example: As a multicenter study determined, in the case of robotic prostatectomies, the general complication rates range at about 10%, most of them minor, but serious ones (e.g., organ damage or bleeding that necessitates transfusion) are reported to take place in about 12 or 2% of cases(Ferrarese et al. 2016).

4.2. Device Malfunctions

A large part of the reported events comprises device malfunctions. These are instrument arm failures, camera blackouts, unexplained shutdowns, and software freezes. As one example, surgeons report situations when robotic scissors were unable to cut correctly in the middle of a procedure and forced conversion to open surgery.

Example: In 2000-2013, scanning 14 years of FDA reports has revealed 1,391 malfunctions that devices of da Vinci involved, including instruments being left inside the broken, electrical arcing causing burns, or a sudden system shutdown (Jamjoom et al. 2022).

4.3. Injuries and Deaths

Relative to the total number of cases, there are documented instances of severe injuries and deaths, even though these are not large in number. They usually result from uncontrolled bleeding, bowel or ureteral injury at a time, which goes unnoticed and is not identified in time, or electrical faults in instruments that encourage burns.

Example: The identical review of data provided by the FDA reported a 14-years of 144 deaths in patients associated with robotic systems. These were often multi-factorial - device related, surgical complexity, and underlying risk to the patient (Sugoor et al. 2019).

4.4. Rate of Adverse Events

Taking adverse outcomes as being reported per 1,000 or 10,000 procedures gives sufficient comparisons between hospitals and between other surgical specialties. Robotic-assisted hysterectomies. Specifically, rates of major complications have been reported as approximately 1.5 per 100 cases performed using robotic assistance, which is similar to laparoscopic procedures, but may depend on the institution and experience of the surgeon(Lucas et al. 2012).

4.5. Impact of Device and Instrument Malfunctions

Failure might extend the time of surgery, extend the time of anesthesia, or require an extraneous conversion to open surgery, all of which expose the patient to increased risk. A glitch in software, taking 15-30 minutes to dock the instruments, may cause bleeding to aggravate in case of trauma patients.

Example: During a single series, approximately 20 percent of robotic malfunctions resulted in a delay of procedures, and 2 percent necessitated an open surgery conversion, which directly lengthened hospital stay and subjected one to infection (Friedman et al. 2013)

4.6. Reasons for Recalls and Recovery Actions

The instrument tip insulation deficiency (the risk of burns), camera failure, or records calibration faults have become common targets of FDA recalls of robotic systems. As an example, a massive recall in 2016 (affecting thousands of robotic cautery scissors) came about because of the cracking of the insulation that exposed the electrical current, with the possibility of a burn developing internally (Power 2024).

4.7. Adverse Events across Different Classes of Robotic Surgery

Not all robotic surgeries are of equal risk. Robotic cardiac surgeries are likely to have a high rate of conversion to open sternotomy because of complex anatomy and the importance of

the heart's physical activity, which is not the case in the robotic urologic surgeries, which are more predictable in terms of the anatomy (Marcus et al. 2024).

5. Levels of Autonomy

The surgical robot is categorized by the FDA under 5 grades from Level 1- Level 5. The majority of the FDA-cleared robots will be classified as Level 1- Level 3 because the Level 4, 5 robots are not FDA-cleared. In certain cases, the approval process of the RAS would be primarily 510(k), with the use of the de novo in certain situations. The issue of de novo process is employed in the absence of any evidence of relevance. There are five levels of autonomy as follows:

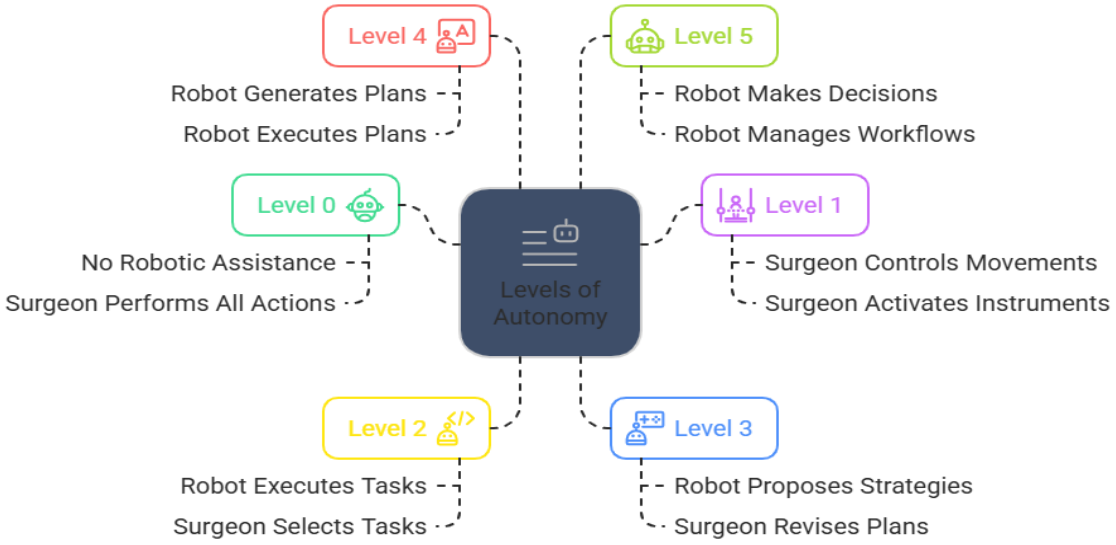

Figure 1: Level of Autonomy

In the business of surgical robots approved by the FDA in the period 2015-2025, the percentage of Level 1 (robot assistance) was almost 50 percent, but only a few of them reached Level 3 (conditional autonomy). Although the majority of them lie at Level 1, gradually, there has been an addition of more automation of tasks, and more systems appear at Level 2 (task autonomy). I have not been able to come across any systems Level 4 or Level 5 (complete autonomy) (Bonaci et al. 2015). Since 2015, the number of surgical robots that have passed through the FDA has increased with the introduction of new systems and improvements of the existing ones. The orthopaedic surgery, urology, general surgery, and neurosurgery have experienced the highest growth in the field. Fewer systems went through the De Novo pathway, but most cases were cleared under the 510(k) pathway.

6. ADVANTAGES AND LIMITATIONS OF AI INTEGRATION IN ROBOTIC SURGERIES

6.1 Advantages

Several obvious advantages that AI grants to robotic surgery. It assists the surgeon to carry out operations much more precisely and accurately, and this may result in an improved patient outcome (Collier 2017). Artificial intelligence also contributes to eliminating surgeon fatigue by freeing them to pay more attention to the most important aspects of the procedure by offloading repetitive duties to the machine (Takeuchi and Kitagawa 2024). Importantly, AI can boost patient safety by giving real-time alerts about possible problems, like bleeding or instruments getting too close to each other, helping prevent surgical errors (Choudhury and Asan 2020; Rasouli et al. 2021).

6.2 Limitations

However, there are some significant challenges. One is the high cost—AI-guided robotic surgery systems are expensive to develop, buy, and maintain. This means many smaller hospitals, especially in less wealthy areas, may not be able to afford them (Shen et al. 2020; Rus et al. 2023). Also, how well AI works depends heavily on the quality of the data used to train it. If the data is biased or incomplete, the AI might make poor decisions, which could worsen existing health inequalities (Peng et al. 2023). Finally, there are serious ethical concerns. As AI systems get more autonomous, questions arise about who is responsible if something goes wrong. Clear rules and regulations are needed to protect patients and guide how these technologies should be used.

7. SEEKING APPROVAL FOR USING AUTONOMOUS SURGICAL ROBOTS

The process of seeking FDA approval of autonomous surgical robots is growing, multidimensional, and requires reconciliation on the dimensions of patient safety, technical validation, and ethical study. Historically, the majority of surgical robots available in the U.S., including and especially prominent ones such as the da Vinci, have been market cleared via the FDA 510(k) route, which is available to medical devices that have been significantly modified compared to known previously-approved devices (Cooper et al. 2015). This would function with the existing teleoperated systems, which are under full control of surgeons. Independent systems capable of making their intraoperative decisions, however, introduce new regulatory issues: these technologies may change medical standards of care, and the approval of these systems by the FDA is becoming increasingly stringent. Some AI-driven devices can continuously learn or develop their behavior, which is the center of attention of the Software as a Medical Device (SaMD) programs of the agency, such as its pre-certification pilots. The regulation system demands definite processes to evaluate safety, effectiveness, and reliability in various clinical conditions (Marcus et al. 2024).

Besides, ethical and legal regulations are increasingly discussed, including the idea that autonomous robots can be certified with the same professional requirements as their human surgeon counterparts or, even, higher due to the computational determinism. This also has consequences regarding liability, such as that in the case that an average robot surgery is better than a human one, then any future malpractice suits may question the decision to follow a human-performed procedure (Jamjoom et al. 2022). Research also cautions that vertical FDA approval should not become the end-all, as it does not confer sufficient critical post-market surveillance and explainable AI systems to establish trust and eliminate unforeseen risks (Power 2024).

Overall, gaining approval for autonomous surgical robots involves navigating not only the technical hurdles of safety and performance but also developing new frameworks for explainability, professional liability, and patient consent. As regulators like the FDA adapt, these processes will likely set global benchmarks for how AI autonomy is governed in the operating room.

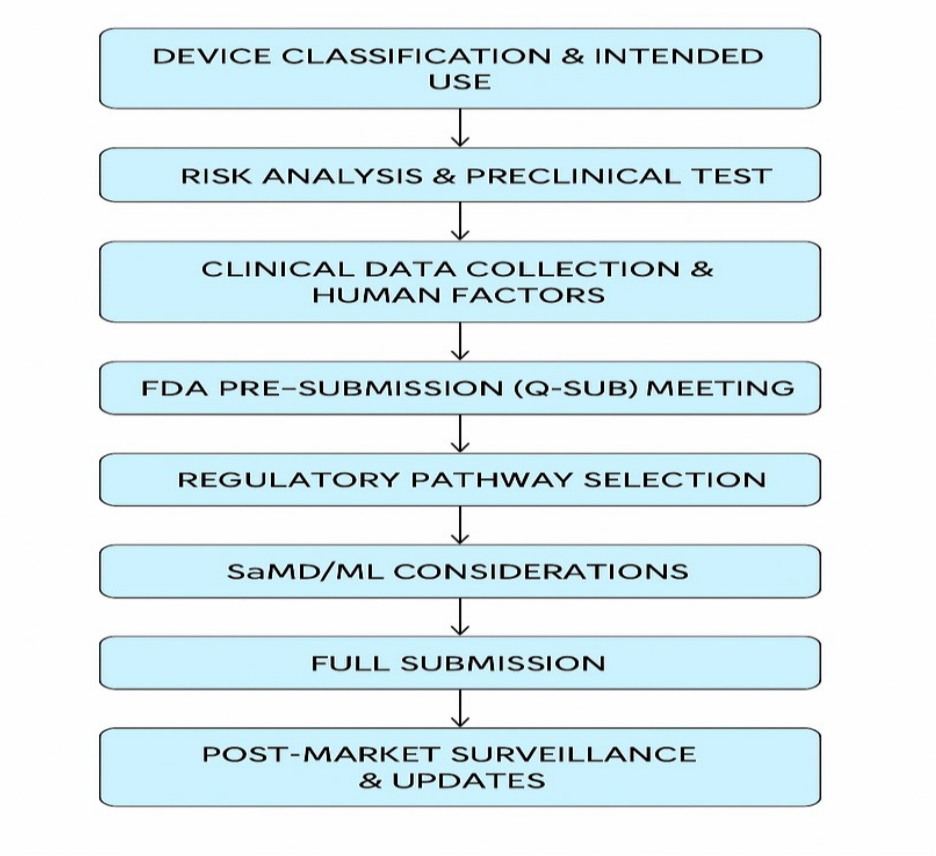

Figure 2: FDA process for autonomous surgical robots

Device	Year of Approval	Level of autonomy	Clinical Use
da Vinci Xi & SP(Intuitive Surgical)	2018	**Level 1-2**	Urology, colorectal, cardiac, head & neck
Mako SmartRobotics(Stryker)	2015–2025	**Level 2**	Knee & hip arthroplasty
Next-gen AI Visualization Systems(Various)	2018	**Level 1-2**	Tumor & anatomy guidance
ROBODOC replacement system(Ortho alignment)	2019	**Level 2-3**	Hip & knee orthopedic surgery
Moon Surgical Maestro	2024	Level 2–3	Laparoscopic general surgery
Quantum Surgical Epione	2023	Level 2	Percutaneous ablation of abdominal tumors (liver, kidney, pancreas).
Da Vinci 5	2024	Level 1	Multispecialty minimally invasive surgery

Table 1: List of FDA approved Robotic-assisted Medical devices (2015-2025)

8. SAFETY-CRITICAL SYSTEM AND CYBER SECURITY

Autonomous surgical robots are at the very edge of modern medicine, yet there exist some very pressing concerns as safety-critical systems, particularly in the context of cybersecurity (Ullman and Malle 2017). presented recent work showing how teleoperated surgical robots are vulnerable in that way, and gaining direct control of their actions is possible, and this harrowing thought again leads to even the semi-autonomous systems of today being susceptible. With these robots aimed at autonomy, new kinds of threats crop up: attackers will be able to trick the robot sensors or algorithms and make it reach dangerous conclusions on its own. However, in the meantime, the world is not short of real-life events, such as the ransomware onslaught on the UK's NHS, which affected most of the embedded medical systems (Takeuchi and Kitagawa 2024). This highlights the importance of careful tests, certification, strict patch management, as well as complete traceable logs when operating surgery-in addition to a policy where software upgrades do not occur during a surgical procedure. According to Amoroso (2012), critical systems are considered to be in need not only of technologically resistant defense, but common perception. Robotic surgery is a high-risk situation, and a cyber-attack is not merely inconvenient but completely unacceptable.

9. LEGAL AND REGULATORY FRAMEWORKS

The policy, regulatory, and legal landscape of autonomous surgery robots is growing more complicated, not to mention high-risk scenarios such as those occurring on the battlefield rather than in the hospital. There is a sound set of rules of engagement and

accountability systems with a common structure that exist in a hostile military context and that, logically, could be applied to operating surgical robots. These systems may be the only viable solution to carry out their operations in the areas that are too risky to be visited by human medical teams, such as active war zones or mine fields. Although their application may be acceptable even at such capabilities, there is a stiff demand to use the state of art safety-sensitive systems (Moustris et al. 2011). It is sometimes possible to defend any unintended occurrence by claiming that the use of the best available technology under the conditions has been applied to it, noting the fact that a mistake is more likely to occur in military undertakings. Nonetheless, such legal safeguards are highly problematic as soon as the autonomous surgical robots arrive in the civilian sector. A malfunction of a robot that leads to the death of civilians may lead to manslaughter charges amongst others, because in certain situations, a soldier may have a legal obligation to attend to the casualty of a civilian. A successful major surgery performed remotely (a tele-surgery) or even a fully automated surgery would trigger a lot of discussion about who would take responsibility in these developing legal grey areas. On the other side of the case, human operators or institutions may claim that developers never produced adequately tested software or lied about the capabilities of the system, which is well documented where tort liability is concerned about software programs (Nazer et al. 2023).

The emerging domain also highlights the need to revise and expand the ISO standards in a bid to address such independent systems. In addition to the popular ISO 13485 quality management system related to medical devices and ISO 14971 risk management, there are other essential standards: ISO 62304, ISO 81001-1, ISO 60601, and ISO 25010. All of them deal with medical devices, specifically related to software development, risk management, electrical and functional safety, software maintainability, and reliability. Of equal importance are ISO/IEC 27001 on the security of information, which is critical to safeguard patient data used in training and real-time decision-making and ISO/TR 24028, which presents guidelines of trustworthiness in AI, which are needed to curb transparency and robustness that are needed in sustaining patient safety. Collectively, these are all very dynamic factors in legal doctrine, international protocols as well as ethical governance that will be key towards seeing to it that either military or civilian applications of autonomous surgical robots safeguard the patients, doctor professional accountability and the trust necessary to make the machines a part and parcel of the modern day surgery (Rus et al. 2023).

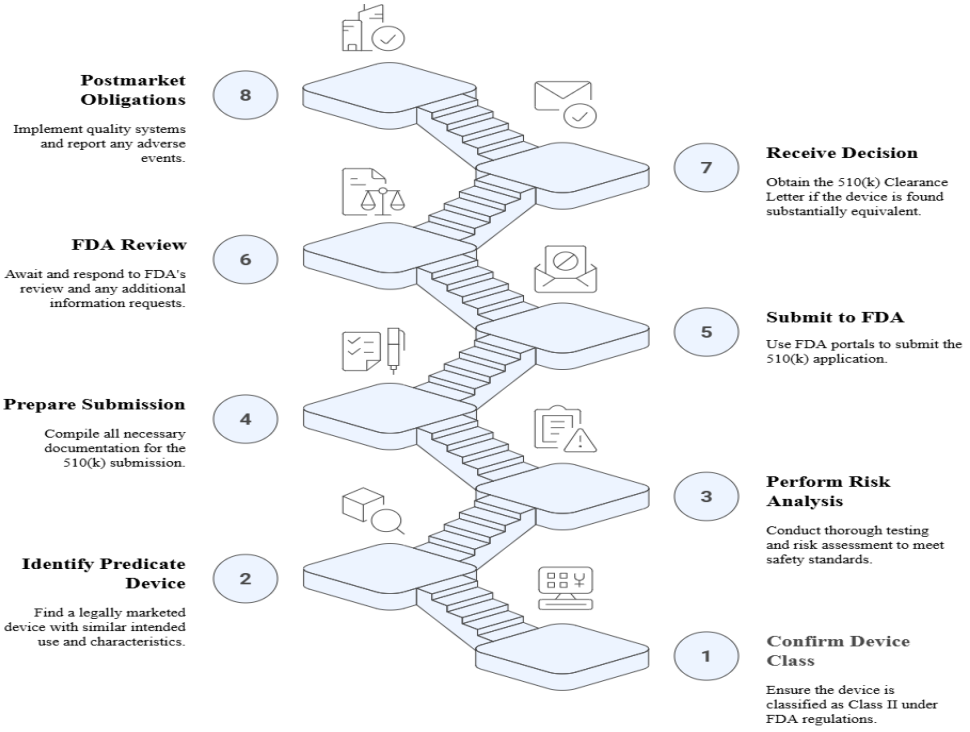

Fig 3: 510(k) notification pathway

10. HUMAN-IN-THE-LOOP AND MEDICAL MISTAKES

Robot-assisted tele-surgery, in a military environment, may be severely impeded by unstable communications, because of which these systems are relatively susceptible to any communication interference. As much as the medical frequencies, e.g., the ISM Band with international law protection, are under protection, they are still not immune to asymmetric risk of jamming or hacking by non-military rogue actors. In such cases, the capability to automatically transfer to autonomous searching mode may be lifesaving. As an example, when a remote procedure that takes place on a battlefield or aboard an orbiting platform loses its linkage in the event of power shortages, enemy jamming, or cyber-hack, the installed autonomous functionality would enable the confirmatory process to complete and possibly even save a life. Such an idea is the basis of such projects as the Trauma Pod, which was created to deal with such semi-automatic emergencies (Collier 2017).

Nevertheless, despite the theoretical benefits of emergency autonomous activation, it brings along with it severe accountability issues. Until the autonomous functions come into effect, a surgeon or operator is undoubtedly the one in charge of all the actions carried out by the robotic component. However, when the system converts itself to absolute autonomy, the following issues come to prominence: who is legally or ethically responsible in case of mistake? Robots are not able to understand any blame, penalty, or fault, like humans can. In a military activity, human resources can be court-martialed or even charged with crimes such as manslaughter in case a human error results in the death that was avoided. When autonomous robots are out on the road, where does the chain of liability start and end? The existing law provisions still presume that the supervising human is mostly to blame even in cases where the process is being directed by a machine, yet such a gray area is also a growing legal controversy.

The problem is even more pressing once we notice that even the traditional, human-implemented medical practice, despite what some of its proponents may claim, is nowhere near error-free. Indeed, medical errors remain the third-leading cause of death in

the United States, with Makary and Daniel making such a rigorous estimate many times (Shademan et al. 2016). Under unexpected happenings, human clinicians become susceptible to personal prosecution by a court in the case of their judgment resulting in injury. Nonetheless, when a robot (on its own accord) makes or performs a surgery, it raises questions regarding our key principles in terms of what we consider liability and malpractice.

To make this even more complicated, the new debate regarding the safety and explainability of AI poses the necessity to develop systems that not only work properly but are also capable of explaining their decisions. Standards bodies and ethicists are making a more and more compelling case that human-in-the-loop controls, layered fallback protocols, and transparent algorithmic reports and explanations should be incorporated. This would most preferably place humans in the ethical and legal chain of events, even in autonomous interventions, and thus harmonize the novel medical device technology down the road of responsible medical practice ethics and patient trust down the line.

11. JUSTIFYING THE NEED FOR AI AND AUTONOMOUS ROBOTIC SURGERY

Utilizing AI and autonomous robotic surgery has a solid legal and ethical case on the use of robots and autonomous surgery especially under remote or dangerous settings where a human surgical team cannot reach because of logistical or safety issues like in the case of battlefields, research stations or space missions with extended duration (Mohammad 2013). In such cases, robotic systems with machine learning (ML) capabilities could both save the patients and spare medical personnel against infection, given that during previous epidemics, the SARS, in particular, intubation and suction procedures were in direct contact with the infected patients (Hung Tomlinson, and Cockram). As an example, ML-supported robotic bronchoscopy could safely detect lung lesions at reduced risks to clinicians. Even though the present-day systems, such as the Monarch platform approved by the FDA, do not feature autonomous functions yet (FDA K173760)[43], it is possible that future integration of ML-based image analysis processing with autonomous navigation will help minimize the contamination hazard since the carrying employees would not be physically near infected airways.

In addition to infection control, AI and ML possess the enormous potential to boost the diagnostic capabilities of others, including ENT and bronchoscopic examinations, to identify faint lesions that the human eye cannot (Ullman and Malle 2017). Still, more sophisticated ML algorithms, such as deep neural networks, have already been able to rival dermatologists in terms of skin cancer classification (Makary and Daniel 2016), which shows how pattern recognition can achieve better accuracy than standard analysis, particularly on large data sets.

Nevertheless, the potential of AI also indicates the usefulness of interactive machine learning (iML), which involves the continued participation of human experts to teach learning and support context-oriented decision making (Steinert 2014; Stahl and Coeckelbergh 2016). This is essential because mere automatic ML systems tend to be opaque black boxes, and it is difficult to find out why a decision was reached, which is a severe problem in safety-sensitive medical practice. Combining human understanding and AI, we can develop systems that both detect disease, but do so clearly and responsibly, that instill greater confidence by doctors and patients alike (Stahl and Coeckelbergh 2016).

In general, whether it is in highly specialized autonomous procedures required in hostile environments or minimally invasive endoscopic or laparoscopic surgeries, robotic systems using AI are of huge potential in outcome improvement, protecting clinician-level healthcare workers, and in extending surgical capacity to areas that humans cannot venture into or where doing so is dangerous. But their use should be very cautious in its balance between independence and responsibility, and it should never leave humans out of the loop in a meaningful way (Holzinger 2016).

12. Responsibility

12.1. Accountability

Accountability means the capacity to justify what a system is doing. In surgery AI, that refers to the ability to track decisions back to records of inputs, internal states, and outputs, analogous to an aircraft flight recorder or black box. It is by using such devices that one can be able to reconstruct events to a post-failure activity, although it is still not fully clear that such devices will be able to elicit the reasoning of complex machine learning systems. Wachter et al. accentuate the fact that design decisions must incorporate the accountability requirement, despite the existing discussions concerning transparency, trade secrets, and intellectual property (Wachter et al. 2017). This varies in different regions: the EU emphasises the regulatory rights (GDPR), whereas in the US, ethical self-regulation is favored (Pagallo 2018).

12.2. Liability

According to the existing legislation, robots cannot be held responsible. By default, responsibility is often assigned to either the manufacturer (of a defect), the operator (who has misused or committed a medical error), or maintenance providers (Sheriff 2015). Since robots are becoming adaptive, researchers are concerned that liability rules are not likely to cope with unexpected behaviours. However, unexpected behaviours are still unusual in the current day and age. In case the robots turn out too unpredictable, they may be labeled unsafe and taken out of the market, with insurance being considered the most important risk management instrument. Where certain proposals in the EU even considered robots to have access to liability through the assumed endowment of electronic personhood, some objections to the proposal say that the inability to assign liability to an electronic person prevents accountability and also strips humans of the right to control.

12.3. Culpability

Culpability is associated with blame and punishment, and it cannot be connected to robots because they are not conscious of free will. Rather, there is the responsibility of the criminal that always lies on human beings, whether designers, manufacturers, or those who operate it. The human element is regarded as guilty when the harm that occurs because of the rattle of a robot is directed at human subjects in the case of surgical robotics (Wachter et al. 2017). The fact that raises more questions about autonomy in cases of tele-surgery signal loss is the fact that by making AI the last alternative, the responsibility of humans inevitably gets eroded. Either way, the law will always demand the human in the loop to tie liability and ethical responsibilities.

13. Ethical Concern

Since robotic and AI technology can be used in medicine, either in surgery, in rehabilitation, and in additional practices, ethical issues arise as the weight of responsibility should be given to the problem of informed consent and the attitude to the patients and doctors autonomy. Much of the urgency revealed in these ethical debates was reflected in the special issue of IEEE Technology and Society Magazine in March 2018, which made blatantly clear the increasing ripeness of ethical issues in robotics in the absence of clear timeframes (Ullman and Malle 2017). Extended AI research in the military, such as DARPA and the FORWARD research into robotic surgery, has previously given considerable thought to the topic of ethics, which can provide a starting point in the field of healthcare robots. On the one hand, Coeckelbergh studied ethical aspects in military robotics, and Rosen et al. and Lin et al. gave wider considerations of surgical robotics and robot rights.

The moral panic in the development of AI, the possibility of weakening human autonomy or subjecting them to physical and mental harm, is gaining speed. Steinert divided ethical challenges in robotics into two groups: robots as tools, robots as agents with moral capacity, including the fullness of concern on how misunderstanding leads to over-hyped expectations of what the robots can do (Stahl and Coeckelbergh 2016). This kind of analysis can promote the creation of what can be called an ethical impact factor to estimate the social ramifications of robotic technologies at large (Steinert 2014).

Other academicians believe such ethical dilemmas are not all new. An example of this was given by Datteri, who proposed that the issue of responsibility in the context of medical robotics was mostly accommodated by the current sets of engineering and law. Nonetheless, Stahl and Coeckelbergh proposed built-in ethical judgments within the engineering practice, i.e., fostering such a notion as responsible research and innovation in the realization of healthcare robots (Grasso 2025).

With non-autonomous surgical systems, such as the majority of the robotic surgical assistants on the market today, however, moral objections persist. The proper training of a surgeon is instrumental, considering that outcomes may be affected by differences in the robotic systems. Although manufacturers provide the training and simulators, supervised practice in the real world may be needed to reduce the harm to patients. In addition, informed consent and patient education are primary. Before agreeing to operate, patients need to know that besides the advantages, there could be negative aspects, to surgery time is longer, or there is the risk of sterility, or there is no sense of touch (Makary and Daniel 2016).

The more you move towards partially or fully autonomous systems, the more complex ethical issues become. Is it possible to train an AI that will make ethical decisions in such situations as battlefield triage? Are such decisions only to be made based on chances of survival, or should they include positions and wider implications, such as choosing a medic over a soldier? The complexity of accountability is presented when opaque machine learning models are proposed by scholars like Wallach and Allen, who suggest a combination of both top-down (rule-based) and bottom-up (data-driven) approaches (Holzinger 2016). Despite the presence of the ethically aware AI, human control, liability, and responsibility cannot be neglected.

14. PERFORMANCE OF AUTONOMOUS ROBOTIC SURGICAL SYSTEMS

Medicine is being led into new territory by the performance of autonomous robotic surgical systems, and fundamental questions are being asked: are we measuring these systems simply by average success rates when some patients may be better off getting a traditional procedure led by a surgeon? Advances and systems commonly adopted, such as da Vinci robot- the da Vinci robot, together with other platforms such as the Mako, ROBODOC, CyberKnife, and Renaissance provide astonishing precision to surgeons so that surgery performance on the prostate, colon kidney, and heart is highly precise and involves the least possible invasiveness. Nevertheless, these robots cannot make their own decisions as they are not autonomous mechanisms rather, they are completely combined with experienced surgeons who can act manually in the event of some complications. In the future, it is forecasted that semi-autonomous and fully autonomous robots will eventually be approved, and this may constitute an integral part of surgical practices in the future. One already gets a preview of this future with systems such as the Smart Tissue Anastomosis Robot (STAR): the vision-based laparoscopic suturing made by the robot hand has proved faster, more consistent, and stronger than even the most talented human hands (Shademan et al. 2016).

This progress brings great legal and ethical concerns. Assuming that autonomous robotic surgery is statistically safer, would the possibility of malpractice standards eventually change, to expect surgeons to perform robotic surgery, or at least tell patients about a possible alternative treatment with robotic surgery, that would be better? Legal scholars claim that current systems might become loose enough to manage this, but as the success rate of robots goes up, any failure may be even more scrutinised, which really sets the bar even higher on both human and robotic care (Moustris et al. 2011). Nevertheless, not every hospital would be able to afford such expensive systems, and in these situations, physicians may only need to explain or direct the patients to those places where robotic surgery is offered.

The equally vital matter is explainability and trust. The majority of robots being used today, and even new autonomy systems, are unable to explicitly describe the reason behind some of the decisions. This constrains the aspect of transparency, which may hurt the trust of both the patients and the surgeons. Human-robot trust researchers emphasize that the future systems require the development of the ability to reveal the types of how decisions were reached, e.g., by highlighting the most decisive aspects of the data that prompted an action (Makary and Daniel 2016). In the meantime, regulatory agencies such as the FDA are only concerned with approving the safety of the devices and have nothing to do with what physicians learn or how they use the devices in their everyday practice, letting hospitals, physicians, and manufacturers do that. With the advance of the nature of the field to increasingly autonomous and decision-making systems approaching human-level judgment, the need to define standards of accountability and legal liability and, in particular, transparency emerges, which will guarantee that these advanced machines will act in the best interests of the patients and will not dilute the trust of human professionals with whom they will be working.

15. Challenges in Robotic Surgery

15.1 Cost and Accessibility

High cost is the main barrier to adopting robotic surgery, particularly in low-resource settings. Such systems as Da Vinci and Versius incorporate high purchasing costs, as well as constant expenditures on maintenance, equipment, and special education. The cost-effectiveness of the robot procedures has been controversial despite the fact that a shorter period of stay and complications occur during the stay of patients in hospitals.

15.2 Ethical Challenges

The use of AI in robotic surgery introduces a complicated issue of responsibility, informed consent, and liability should the surgery become complicated. It is hard to determine whether the error should be blamed on the surgeon, the institution, or the AI developer. This has encouraged regulators to consider ethical guidelines that would ensure transparency and that AI applications have the welfare of the patients at heart.

15.3 Role of Surgeons in an Automated Future

Even though there are current solutions to intraoperative decision-making, complication management, and patient-individualization, which the existing AI-related solutions solve at best, surgeons are still needed because it is impossible to automate all these tasks (Alemzadeh et al. 2016). The focus of today's research is on the cooperation of AI tools and human experience, not the desire to achieve full independence.

15.4 Training and Certification

The other significant issue is the achievement in training and certification across nations. The surgery by robo has highly specialized skills, whereas ununiformed credentialing may jeopardize patients. There are such solutions as proctoring and mentorship, but they are effective at different institutions.

15.5 Regulatory Challenges

Current regulatory pathways, such as the 510(k) by the FDA, were largely created to support nonadaptive or self-learning systems, which means that they are poorly suited to support self-learning or adaptive AI systems. Such a post-market, independently-updating AI still lacks an accepted framework for its approval. This puts manufacturers and healthcare organizations in the situation of not knowing whether their applications of advanced forms of autonomy will be approved or not (Stahl and Coeckelbergh 2016).

CONCLUSION

This can radically change the field of medicine because artificial intelligence, when incorporated in robotic surgical systems, provides greater accuracy, effectiveness, and patient-centered care. Although the present systems continue to be mostly under the control of the surgeons, the progressive transition to autonomous abilities presents a lot of potential an especially in risky or distant settings. Nonetheless, such an evolution is accompanied by serious issues concerned with safety, accountability, regulation, and ethical responsibility. Patients should be assured of their safety against strong legal systems, cybersecurity practices, explainable artificial intelligence, and the extended human supervision of the system. With the technological development, an appropriate balance between innovation and ethical governance will be instrumental to the responsible adoption of autonomous surgical robots both in civilian and military healthcare systems.

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