

Who Is Liable When the Algorithm Operates? A Legal Analysis of AI Accountability in Robotic Surgery

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Abstract

The integration of artificial intelligence (AI) into robotic surgical systems marks a transformative shift in modern healthcare. What began as surgeon-controlled robotic assistance has evolved into increasingly autonomous systems capable of real-time decision-making, tissue recognition, and predictive risk assessment. While these developments promise enhanced precision and improved patient outcomes, they also generate profound legal uncertainty. When harm occurs during an AI-assisted procedure, traditional liability frameworks struggle to identify a clear defendant. Is the surgeon liable for relying on algorithmic outputs? Does responsibility lie with the hospital that adopted the technology, or with the manufacturer and software developer who designed the system?

This article examines the doctrinal gaps in medical negligence and product liability law in the context of AI-driven robotic surgery. It analyses how adaptive algorithms challenge classical notions of breach, causation, and defect, particularly in light of algorithmic opacity and probabilistic decision-making. Through a comparative perspective drawing from regulatory developments in the United States and the European Union, the article highlights the absence of a coherent accountability framework in India. It argues that fault-based models alone are insufficient for high-risk autonomous medical technologies and proposes a layered and risk-based liability regime combining strict liability, institutional responsibility, and mandatory insurance mechanisms. The article concludes that proactive regulatory reform is essential to preserve patient trust while fostering responsible innovation in surgical AI systems.

INTRODUCTION

The Rise of Algorithmic Surgery and the Accountability Dilemma

In two decades, robotic surgery is no longer in the science fiction but rather in the common clinical practice. Telesurgery Systems like those in Intuitive Surgical had a telesurgery platform that allowed the surgeon to control a high precision robotic arm. During this initial stage, the robot was still just a tool, but a high-tech tool. The liability analysis was not that difficult: in case of any harm, the actions of the surgeon were judged using the known medical negligence standards. The modern stage of robotic surgery is however qualitatively different. The artificial intelligence is becoming more integrated into the surgical platforms. Machine learning algorithms help to identify tissues, detect anomalies on the fly, suggest points of incisions, and even suture automatically. It is not a passive system anymore but it is involved in decision making.

The shift to mechanical support to algorithmic autonomy is profoundly transformative of the traditional framework of accountability. Classical tort law makes the assumption of a human decision-maker whose actions may be judged in reference to a standard of reasonable care.

However, the AI systems work in a probabilistic manner and they are trained on data and produce outputs that might not be completely understandable even to their creators. This creates a central legal question: when the algorithm operates and harm occurs, who is legally responsible? The issue becomes more convoluted by the way the actors on the issue of AI-enabled surgery are distributed. The doctor carries out the surgery. The system is procured and maintained in the hospital. The hardware is designed by its manufacturer. The algorithm is trained and updated by software developers. Training datasets are provided by data suppliers. The system is sanctioned to be used in the market. Different human errors may not form the source of harm but rather the combination of interdependent technical and institutional systems. The legislation, nonetheless, is still to a large extent anthropocentric. It stands on safe soil in search of a culprit. AI challenges this premise.

Doctrinal Limits of Medical Negligence and Product Liability

A. Medical Negligence and the Problem of Reliance

According to traditional tort law, medical negligence must be shown to have existed with regard to duty, breach, causation and damage. The patient has a right to a duty of care on the side of the surgeon. Breach is occurring when the surgeon does not act within the accepted medical standards.

The role of the AI in assisted surgery, however, is that the surgeons are more and more guided by algorithmic recommendations. Assume that the system indicates a non-cancerous region and the surgeon removes it. Subsequently, malignancy appears in the pathology. Did the surgeon act carelessly in trusting to certified AI software? In case the dependence on AI becomes a rule, the loss of it can be regarded as negligence by itself. Therefore, the dependence on AI can and should be punished and supported by the law, paradoxically, basing on the results. This brings in uncertainty and defensive medicine. In addition, causation is hard to determine. Was this caused by the judgment of the surgeon or because of erroneous algorithm output? In the case where human and machine collaborate in decision-making, it is analytically complex to isolate breach.

B. Product Liability and Adaptive Algorithms

The defective products are treated by the product liability law on the basis of manufacturing defect, design defect and failure to warn. Nevertheless, AI systems are not similar to traditional medical devices. AI evolves unlike the situation with static products. The machine learning systems evolve as they are updated and fed with data. A system that has been found to be safe may act in a different way months later following the process of iterative learning. Is this dynamic behavior one that can be classified as a design defect? Also, AI judgments are stochastic as opposed to deterministic. An algorithm can work as it was designed, but with disastrous results in statistical ranges of error. Is statistical defect on a par with legal defect? The fact that complex neural networks are opaque also adds to the situation. When the developers themselves are unable to intelligently explain a course of decision, it becomes practically impossible to demonstrate defect in court.

C. The Black-Box Problem and Evidentiary Challenges

The opacities of algorithmic nature, also what many call the black-box problem, have harsh evidentiary impediments. The plaintiffs have to demonstrate causation. However, when the logic of decision making is not available, how are they supposed to show that they were harmed because

of the malfunction of the algorithm? This can be asymmetry of information in which the manufacturers have access to technical information which patients do not. Devoid of procedural modifications, including burden-shifting or compulsory audit books, victims might not be remedied.

The traditional doctrines were not shaped to suit distributed and opaque learning systems. The larger the autonomy of AI, the less effective the liability in the form of faults.

Comparative Regulatory Responses and the Indian Gap

The risky nature of AI in healthcare is recognized within the regulatory trends across the world. In the US, AI-based medical devices are regulated by the Food and Drug Administration (FDA), which uses a risk-based approach to classification. Recent instructions deal with adaptive AI systems and life cycle monitoring. Nonetheless, the liability is highly subject to state tort law which yields inconsistent results. The EU has taken an even more inclusive strategy by the EU AI Act. Healthcare AI systems fall into the high-risk category, which elicits the requirement of strict conditions, such as human supervision, transparency requirements, risk management systems, and conformity evaluations. Though, it is rather regulatory than compensatory in nature, this framework represents an indication of acknowledgment that AI medical tools need to be governed more adequately.

India, on the contrary, does not have AI-specific healthcare laws. The Consumer Protection Act, 2019, or court-developed medical negligence jurisprudence would probably apply to settling liability disputes. These models presuppose recognizability of the service providers or defective goods, and not algorithmic co-worker autonomy. Regulatory silence brings about uncertainty. There is a risk that hospitals fear using the new advanced systems because of liabilities. Patients might have no conception of rights and remedies. An irresponsible innovation would lead to loss of trust among the people. The urgency of regulatory clarity is also increased by the constitutional obligation of India in the right to life and safe healthcare under Article 21. In areas that deal with human lives, technological advancement can never keep up with the legal protection.

Toward a Reconstructed Accountability Framework

An alternative model of AI responsibility in robotic surgery needs to be constructed because the current doctrines are limited. This paper suggests a bi-polar structure which is based on four pillars.

1. Layered Liability Allocation

Liability is to be spread among actors according to functional control:

- Surgeon: The person is in charge of unprofessional behavior or unreasonable use of AI results.
- Hospital: Responsible on the areas of procurement, failure in maintenance, lack of proper training and institutional control.
- Manufacturer/Developer: Responsible of algorithmic errors, lack of proper testing, biased data, and is not able to give proper warnings.

This is a layered model that identifies distributed responsibility as opposed to singling out an individual defendant.

2. Risk-Based Strict Liability for High Autonomy

A strict liability regime can be reasonable where there are few human controls on how the AI systems work. No-fault compensation obligations should be triggered when a manufacturer or operator operates in the high-risk autonomous surgical functions (e.g. automated suture or tissue excision). Strict liability achieves this, as it incentivizes thorough testing of safety and insurance cover without necessarily asking plaintiffs to show fault in non-transparent systems.

3. Mandatory AI Insurance and Compensation Fund

An obligatory insurance system of the AI-controlled surgical devices would guarantee timely indemnification of victims. As with the models of motor vehicle insurance, manufacturers and hospitals would actually have a contribution to an AI Medical Compensation Fund. This method is a compromise between innovation and patient safety because it does not suppress technological innovation but instead socializes risk.

4. Explainability and Audit Mandates

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Conclusion

Robotic surgery that is AI-powered is one of the radical changes in the field of modern medicine. However, the legal frameworks used to regulate medical harm are rooted in the assumptions of the agency of man and non-mobile products. Since algorithms are getting involved in surgical decision making, liability is undetected, fragmented, and uncertain. Where the use of AI becomes a norm, fault-based medical negligence doctrine strives. The challenges that face product liability law in the face of adaptive, probabilistic systems are fatal. In the absence of reform, patients will have an overwhelming evidentiary barricade, and innovators will have to face the threat of unpredictable litigation.

A new model of accountability, which could include layered liability, strict liability based on the risk, mandatory insuring, and explainability, is a middle ground. This would maintain innovation incentives and protect patient rights and constitutional obligations of safe healthcare. The law should not abdicate as the algorithm can work. Legal intelligence has to evolve alongside surgical intelligence as the intelligence increases. It is only at this point that the society can reap the advantages of AI-driven medicine without jeopardizing justice and accountability.

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