



MEDICAL LIABILITY ARISING FROM THE USE OF SURGICAL ROBOTICS

Julián Andrés Gaitán Reyes^{1*}, Alexander Correa Reyes², José Alejandro Vera Calderón³

^{1*}julian.gaitanr@campusucc.edu.co, master's degree in law, cooperative university of colombia

²alexander.correar@campusucc.edu.co, master's degree in law, cooperative university of colombia

³javerac@ut.edu.co, master's degree in administration, university of Tolima

***Corresponding Author:** Julián Andrés Gaitán Reyes

*julian.gaitanr@campusucc.edu.co, master's degree in law, cooperative university of colombia

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Abstract

This study aims to analyze the technological disruption caused by the integration of robotics in the field of medicine, as well as its legal implications in the Colombian legal context, focusing on civil liability. The question arises as to whether the current regulations of the Civil Code, Consumer Law, and Insurance Law adequately guarantee the right to full reparation for users affected by the use of this technology, or whether it is necessary to establish new regulations that address the ethical and legal challenges arising from the implementation of robotics in medical practice.

A documentary-type methodological design was proposed, using analytical and comparative law methods through the collection of a non-probabilistic sample of systematic information. This approach led to an exhaustive analysis of empirical research on the errors derived from surgical robotics.

To this end, it addresses the concept of health as a fundamental right, the impact of technological advances in the provision of medical services, as well as an exploration of the applications of robotic technology in medicine. It examines the possible medical errors associated with robotics and analyzes medical civil liability in the Colombian context regarding the use of intelligent robots in clinical practice. This research aims to provide a comprehensive analysis of the legal and ethical implications derived from the convergence between robotics and medicine, with the purpose of creating the regulatory framework that guarantees the protection of patient's rights and safety in the provision of health services assisted by robotic technology in Colombia.

In conclusion, the integration of robotics in medicine offers significant advances but also poses challenges in terms of civil liability. Although the Colombian legal framework appears to be prepared to address the use of surgical robots, the lack of specific regulations underscores the need to reflect on measures to ensure the safety and protection of patients.

Keywords: Consumer law, artificial intelligence, medical errors, medical civil liability, surgical robots.

Introduction

The convergence between health and the legal field has raised concerns about tort law and liability arising from using technologies. This paper reflects on tort law in the civil liability associated with

the use of intelligent surgical robots, questioning whether Colombian law adequately addresses the legal needs in the face of adverse events, ensuring full compensation to the victims of such procedures.

It highlights the relevance of the fundamental right to health, a complex right that safeguards various aspects of human life, and the need to guarantee its effective enjoyment. In addition, the crucial role of medicine in society is addressed, from the historical doctor-patient relationship to the interaction between biotechnology and patient. The impact of technology, particularly robotic surgery with artificial intelligence, on this fourth industrial revolution in medicine is examined, exploring its benefits for medical practice.

Despite the benefits of surgical robotics, errors or adverse events due to technical or human failure have been documented, resulting in harm to patients. According to tort law theory, these should be compensated. The civil liability associated with the use of surgical robots in the Colombian legal framework is analyzed, raising questions such as whether the intelligent robot possesses legal personality, whether it should be considered as a corporeal object or as a product under consumer law. It also underlines the importance of insurance law in its use and discusses who assumes the final responsibility: the manufacturer, the surgeon, the hospital or the clinic.

It concludes by examining the current positions on medical liability and consumer law in the use of surgical robots. Mention is made of the opposing doctrine that advocates the application of the strict liability regime in the field of medical civil liability for the use of these robots. In addition, the following are identified doctrinal developments concerning the possibility of modifying laws to prevent injustices when requesting full compensation for the use of this technology.

Methodology

A documentary methodological design was proposed, using analytical and comparative law methods. This approach allows a comprehensive analysis of the technological disruption caused by the integration of robotics in medicine and its legal implications in the Colombian legal context, focusing specifically on civil liability.

The collection of a non-probabilistic sample of systematic information related to the topic of study was carried out. Various sources, such as academic literature, jurisprudence, laws, regulations, and policies, were used to collect relevant data on the implementation of robotics in medical practice and its legal impact. A comprehensive analysis of empirical research on errors arising from the use of surgical robotics was conducted using an analytical method. Potential medical errors associated with the use of robotics will be examined and medical civil liability will be analyzed. The concept of health as a fundamental right was addressed and the impact of technological advances on the provision of medical services was evaluated. In addition, an exploration of the applications of robotic technology in medicine was conducted, highlighting the ethical and legal challenges that emerge from its implementation.

Results

Health as a right

The concept of health is the result of a complex historical process, as pointed out by De Lellis and Mozobancyk (2009), characterized by its multifaceted nature, encompassing physical, psychological, social, and environmental aspects. This concept is intrinsically linked to the continuous and mutually transforming interaction between the individual and his or her human, psycho-cultural, and economic-political environment. These elements constitute a complex system that structures the very essence of life.

Historically, the concept of health has been the subject of debate and evolution. In earlier times, health was conceived as a divine gift, while disease was considered a punishment. Later, in the context of Western medicine, which originated in ancient Greece, health was understood as a state of “order”, while the disease was perceived as a state of “disorder”. Health was equated with happiness, in harmony with the natural order, while disease and suffering were seen as unnatural disturbances (Garcia, 2021).

Over time, the concept of health was predominantly linked to the biological paradigm until, in 1946, the World Health Organization (WHO) defined health in its founding charter as “a state of complete physical, mental and social well-being and not merely the absence of disease”. These definitions laid the foundation for theoretical models that explain the health of a population. However, there are essential concepts that surround the understanding of health as a product of the interaction between multiple factors that can increase, preserve, or deteriorate it, as proposed by Lalonde (1974) with the concept of the “health field”, which comprises four major categories: lifestyle, environment, human biology and organization of health services. The conceptual definition of health is not a simplistic process, but rather a dynamic, complex concept subject to constant changes in reality.

The concept of health is situated within the framework of a human right, recognized as such in our regional human rights system by the Inter-American Court of Human Rights. This right is considered fundamental and indispensable for the full exercise of other human rights. It guarantees the right of every individual to enjoy the highest attainable standard of health, understood as a complete state of physical, mental, and social well-being, derived from a lifestyle that promotes an integral balance. The State's obligation to protect health translates into ensuring people's access to essential health services, providing quality and effective medical care, and promoting the improvement of the population's health conditions.

In the Colombian context, the right to health is considered complex due to its conception and the various obligations it entails, as well as the breadth and variety of actions and omissions that its fulfillment requires from the State and society in general. The full guarantee of this right is conditioned, in part, by the material and institutional resources available. This right is based on human dignity, including timely, effective, and quality access to health services to prevent, improve, and promote health.

It is clear that the right to health is fundamental and its content has been defined by constitutional jurisprudence and the legislator. Current debates focus on how to effectively and sustainably guarantee its enjoyment. Medicine stands as a fundamental pillar within the structure of this right, dedicated to the diagnosis, prevention, and treatment of diseases, to preserve health and improve the conditions for a dignified life.

Medicine and technological advances

In general terms, medicine is conceptualized as a discipline that combines artistic and scientific elements, oriented towards the preservation and restoration of health. According to Bernard (1944), medicine is oriented towards two main goals: the preservation of health and the cure of diseases. This approach has given rise, as pointed out by Canete Villafranca et al. (2013), to a doctor-patient relationship that has been universally recognized as a fundamental aspect of medical practice.

Throughout history, the physician-patient dynamic has been predominantly paternalistic, implying that the physician assumed a role of authority and paternal care towards the patient. This approach was justified in part by the fact that illness places the person in a position of vulnerability, affecting his or her capacity for discernment and decision-making due to pain and emotional disturbance. In this context, the patient was subordinated to the moral authority of the physician, who determined which medical decisions were right or wrong.

In 1969, the American Hospital Association (1973) presented the first compendium of patients' rights, known as “A Patient's Bill of Rights,” in response to demands raised by patients themselves. The advance of new technologies in the medical field, such as the development of artificial organs, renal dialysis devices, life support equipment, and intensive care units, led patients to question who should have the authority to decide on the implementation of these innovations and what their rights were about such decisions. This questioning, which Entralgo (1964) called the “rebellion of the subjects,” marked the emergence of the principle of patient autonomy and, ultimately, the establishment of informed consent. This principle recognizes the fundamental right of the patient to make predominant decisions about his or her health after receiving a clear, sufficient, and adequate explanation of the diagnosis and treatment proposed by the physician.

The evolution of the patient-physician relationship has led to growing concern about depersonalization in the provision of medical care. Previously, this relationship was characterized by trust, with family or “primary care” physicians maintaining a close bond with their patients. However, the expansion of health services and the widespread use of technology have contributed to the depersonalization of this relationship, giving way to more traditional models of care.

In Colombia, with the implementation of the General Social Security System Law (Congress of the Republic of Colombia, 1993), the practice of medicine ceased to be an individual task and became a business, collective, and institutional activity. This gave rise to what today is called “macro medicine”, where the patient is no longer considered a patient but a client within an economic system. This has led to a system-patient relationship and the depersonalization of medical care. (Supreme Court of Justice, Civil Chamber, 2016).

In this same context, great advances in science and technology appear, which have been revolutionizing humanity, what has been called (Schwab, 2016) “the fourth industrial revolution”, which converges with digital, physical, and biological technologies that will fundamentally change the way we live, work and relate to each other. This industrial revolution has brought great technological and scientific advances in the area of health, contributing to guaranteeing the right to health, in search of timely access and quality of medical service. However, they have also contributed to the emergence of an obsession in contemporary society: the utopia of health and the perfect body, (De Freitas, 2008) which, through the development of biotechnology, genetic engineering, medically assisted reproduction, stem cell cloning, regenerative medicine, predictive medicine, precision medicine, and the use of new technologies, has led to the emergence of the utopia of the perfect body (De Freitas, 2008).

This has caused concern among health and judicial authorities around the world. This problem has been addressed as a priority in recent years by health authorities in several countries, especially in the United States of America (USA) and Australia; and more recently in Great Britain and Canada. For example, in the USA, the report *To Err is Human*, (Kohn, Corrigan, & Donaldson, 1999), concluded that between 44,000 and 98,000 people die each year in hospitals in that country as a result of errors that occur in the care process. In the same line and based on the previous study, 2016 Johns Hopkins University, (Makary & Daniel, 2016), concluded that between 210 thousand to 400 thousand deaths are associated with medical errors, calculating an average death rate due to medical error of 251,454 per year, making medical error the third leading cause of death in the USA.

In the European Union, according to the World Health Organization Europe for the year 2010, adverse events with hospitalized patients amounted to around 5 thousand deaths per year. In this sense, the (World Health Organization, 2010) determined that the estimated risk of dying from a preventable medical accident while receiving medical care is 1/300, 1 in 10 patients suffers harm while receiving hospital care, which causes 2.6 million deaths per year.

In the Colombian context, a study conducted by Pérez (2016) reveals the alarming frequency of safety problems faced by people during hospitalization. According to this study, approximately 9 million people were admitted to hospitalization services, which represents more than 70%, that is, around 180 thousand people, suffer deaths attributable to alleged cases of negligence, safety problems, and medical errors, among others. Statistics show that 13% of accidents occur during the performance of medical procedures. These findings suggest, as Barsky, Olson, and Astik (2022) point out, that medical errors are a frequent occurrence. These errors can manifest themselves in the form of adverse events, delays in care, incidents, late diagnoses, unexpected outcomes, omissions, or erroneous actions by medical personnel, all of which have a significant impact not only on patients and their families but also on medical professionals and the healthcare system as a whole.

In the context described above, medical liability is framed as an integral part of civil liability, which arises when the practice of the liberal professions results in the transgression of the fundamental principle of not causing harm to others. medical liability carries a significant cost at both the personal and institutional level, with significant repercussions on the doctor-patient trust relationship, the

erosion of the credibility of healthcare institutions, and, even more relevantly, an impact on society as a whole.

Uses of technology in the practice of medicine. An approach to robotics.

The impact of technological advances in the field of healthcare is undeniable, with significant transformations in areas such as biotechnology, genetic engineering, precision medicine, data analysis, artificial intelligence (AI), and robotics. In this study, we will focus on understanding in depth the concepts of artificial intelligence and robotics, as these terms are often confused and used interchangeably.

When we talk about artificial intelligence, we refer to the ability of machines to mimic human intelligence, performing tasks such as learning, problem-solving, pattern recognition, and decision-making. Although there is no absolute consensus on the definition of artificial intelligence, the “Turing Test” proposed in 1950 by Alan Turing has been fundamental in the evaluation of the ability of machines to simulate human behavior. This test seeks to determine whether an AI is capable of thinking and acting like a human being, thus establishing a common framework of concepts and definitions in this field.

Artificial intelligence encompasses various subfields, such as natural language systems, machine learning, sensory stimulation, neural networks, computer games, expert systems, and, of course, robotics. Robotics refers to the design, construction, and operation of robots, which are machines capable of performing tasks autonomously or semi-autonomously, either in controlled or uncontrolled environments. The intersection between artificial intelligence and robotics is becoming increasingly evident, as advances in AI allow robots to become more autonomous, adaptive, and capable of interacting more naturally with their environment and with humans.

In summary, artificial intelligence and robotics represent two key areas in the evolution of technology applied to healthcare, offering opportunities to improve diagnosis, treatment, and patient care, as well as to automate repetitive tasks and improve the efficiency of healthcare systems in general. However, they also pose ethical, legal, and social challenges that must be carefully and thoughtfully addressed to ensure their responsible and beneficial implementation for society.

En oncología, los algoritmos de inteligencia artificial pueden diagnosticar el cáncer con gran precisión en histopatología computacional, permitiendo a los anatomopatólogos centrarse en otras tareas importantes (Campanella et al., 2019). En radiología, el uso de software de aprendizaje profundo ha demostrado avances significativos en el diagnóstico basado en imágenes (Liu et al., 2019).

Artificial intelligence developers aim to teach computers to emulate human intellect, which involves skills such as learning, reasoning, and self-correction. To achieve this goal, they rely on principles such as problem-solving through search, knowledge representation, machine learning, natural language processing, and artificial neural networks (Tadiou, 2014).

Artificial intelligence is becoming an integral part of everyday life, encompassing more and more social and occupational aspects of humans, and healthcare is no exception. AI has permeated medicine, providing answers to fundamental questions such as diagnosis, prediction, and prescription in various medical specialties.

For example, in cardiology, artificial intelligence is used to predict fibrillation and cardiovascular disease risk (Huang, Chan, & Dong, 2017). In pulmonology, it helps in the interpretation of pulmonary function tests (Topalovic et al., 2019), while, in endocrinology, it facilitates continuous monitoring of blood glucose levels (Lawton et al., 2018).

In gastroenterology, neural networks process endoscopy and ultrasound images to detect abnormalities such as colonic polyps (Yang & Bang, 2019), and in neurology, it helps in seizure detection, thus improving seizure management (Campanella et al., 2019).

In addition, robotics also plays an important role in medicine, as in the case of Da Vinci's robotic surgery, which has revolutionized surgical procedures by allowing greater precision and control by the surgeon.

In short, the integration of artificial intelligence and robotics in the healthcare field is transforming the way diseases are diagnosed, treated, and prevented, offering significant benefits for both patients and healthcare professionals.

By way of colophon, AI has been developing, among others, medical diagnostics with early identification of degenerative diseases or some types of cancer, pharmacological treatments that offer an advance in the work of the researcher for the analysis of genetic development in the creation of vaccines, medical and imaging analysis with a large amount of data and medical tests such as MRI, the detection of genetic disorders through mobile applications that recognize anomalies through facial features, the monitoring of pregnancy with a better view of fetal development, and prostheses adaptable to the needs of patients. (Sanchez-Fernandez de la Vega, J. , 2020)

Robotics in medicine

AI is a basic component of robotics because AI is what enables a robot to make decisions and perform complex tasks. It can be stated that not all AI is a robot. The word robot was massified with the success of the science fiction play called *Universal Robots* Rossum, written by Karel Capek in 1920. The word Robot has the meaning of the Czech word “robot” which means hard work, having characteristic features because it executes tasks

in an automated way, with a variable level of autonomy, with the ability to interact with its environment or as defined by (Murphy, 2000), an intelligent robot is a mechanical creature that can function autonomously. Also, the RIA, the Robotic Industries Association, defines it as a reprogrammable multifunctional manipulator capable of moving materials, parts, tools, or special devices (hardware), according to variable trajectories, programmed to perform various tasks (software).

Assistive robots: also known as collaborative robots, these are devices designed to manipulate objects in collaboration with a human operator. Initially developed by Colgate, Wannasuphoprasit and Peshkin in 2019, these robots have undergone a remarkable evolution thanks to the advancement of Artificial Intelligence, especially in areas such as machine vision and pattern identification to anticipate or detect errors.

Nowadays we find different kinds of robots such as the so-called androids, zoomorphic, mobile or rolling robots, and poly poly-articulated robots, among others. In the field of health they can be classified according to (Garcia, 2018, p. 207), between grades groups, the first called:

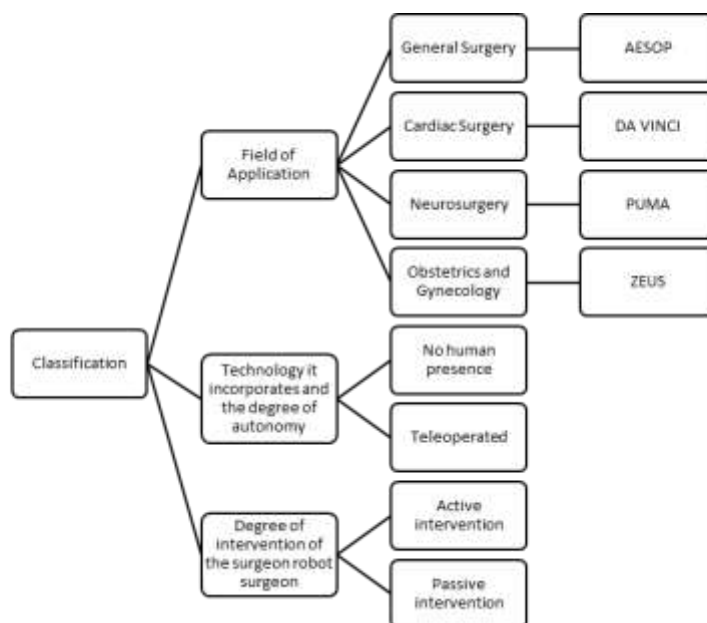
In addition, they have improved their ability to intercommunicate with other robots. A prominent example of their application is in the field of laboratory testing and analysis, where they are capable of handling around 3,000 samples per day, which has resulted in a significant improvement in turnaround time, as evidenced in the case of Gentoft Hospital in 2019. Similarly, in the nursing field, there are examples such as Robear, developed by Martinez in 2006, a bear-shaped robot designed to assist patients with reduced mobility. Other notable examples include Spot, developed by Kim in 2020, and Tommy, developed by Sclazo in 2020, both intended to reduce the workload of doctors and nurses

Prosthetic and rehabilitative: these are the so-called exoskeletons, which are intended to restore locomotion; they are prostheses that can replace missing or damaged limbs of the locomotor apparatus. For example, researchers have already used a wireless “brain-spinal interface” to prevent spinal cord injuries in a pair of rhesus macaques, restoring the intentional movement of walking in a temporarily paralyzed leg. (Capogrosso et al., 2016), Another great example is the different models of hand prostheses in continuous evolution and improvement to increase functionality as cited (Avila-Tomás, Mayer-Pujadas, & Quesada-Varela, 2020). The 2 generations of DLR® hands, the TUAT/Karlsruhe®, the Blackfingers®, the robotic hand with extensor mechanism, the hand composed of proprioceptive sensors or the Iowa® hand, the result of a collaborative work between American, Spanish, and Swedish universities, among others.

Surgical robots: originated in 1986, when the first neurosurgical procedure assisted by a Puma 560 robot arm, used to perform neurosurgical biopsies with greater precision, was performed (Kwoh et al., 2010).

Subsequently cites (Avila-Tomás, Mayer-Pujadas, & Quesada-Varela, 2020), the first robots, purely surgical, began to be designed as assistants to the surgeon in multiple organ and device operations. Some models of surgical robots are: AESOP® (acronym for automated endoscopic system for optimal positioning) used as a voice-controlled robotic assistant for endoscopic surgery, the NeuroMate® stereotactic robot which is a system used in neurosurgical centers to administer treatments and perform deep brain stimulation procedures, neuroendoscopy, stereoelectroencephalography, biopsies and research; the now defunct ZEUS® robotic system with which the world's first tele-surgery was performed in 2001, known as the Lindbergh operation, a successful two-hour laparoscopic cholecystectomy performed on a patient in a hospital in Strasbourg, France, by a surgical team in New York, USA. USA, The da Vinci® Surgical Robotic System, which in its most recent version, the da Vinci Xi®s System allows 3D vision with a magnification of up to 10 times and eliminates physiological tremor, mainly used in urology, general surgery and gynecological oncology, but also in oral and maxillofacial surgery, pediatric surgery, thoracic surgery and cardiac surgery; Probot®, designed to perform prostatectomies, Robodoc® for orthopedic surgery, Acrobot® for knee surgery and CyberKnife® robotic radiosurgery system designed to treat tumors located throughout the body in a non-invasive manner, among others.

Graph 1



Own elaboration. Classification of the use of surgical robots. Source Taylor (2003)

From the above classification it can be inferred that most surgical robots are manipulated, teleoperated by the surgeon, under systems such as master slave, preprogrammed or replacement. Except for STAR, which according to (De Momi & Segato, 2022) is the robot with the greatest autonomy so far.

Medical errors due to the use of surgical robots

As mentioned above, surgical robots, according to (Kobara, 2016), are cyber-physical systems, which seamlessly integrate computing, AI and physical components in their functions, where they are connected or linked to a control system network, in addition to the human-machine interface, which in the end is who operates the robot. However, there have been situations that have put the lives of patients at risk by the use of this technology, after all, the robot surgeon is a machine that can also present technical failures, for example, Alemzadeh et al., (2016), conducted a retrospective study of 14 years on adverse events in robotic surgery, having the finding was that 10.4% of the surgeries had

to be performed in interrupted by some technical failure that forced to reprogram the robot, restart the system or directly continue with the surgery by conventional procedures without the assistance of the robot.

In accordance with the above, experts such as Kaspar and Nagaraja (2022) examined the responsibilities in cases of adversarial failures in robotic surgery from a national (Danish) and EU perspective, making the taxonomy of failures or adverse, which are: first; attacks, manipulation errors: is that error where the instructions are modified by mistake, obtaining a different desired response, the effect of this failure would be unintended movements or that the robot would stop completely. Second; subverting the robotic control: this is the manipulation of the signals that the robot receives, allowing the robot to be “hijacked”, which could cause harm to the patient. Third; reprogramming the robot, means that whoever has access to the robot from its network can alter the software, the fault consists of changes to the software at any level, or poisoning of the feedback circuit, which consists, for example, of modifying the camera or other sensory outputs, which puts the patient's health at risk, in addition to the above, the surgical robot can be vulnerable to cybernetic attacks. However, frequent errors are those that occur due to failures caused by incorrect operation of the robots, according to specifications, which generate unsafe results generating harm to patients, such as: the robot operates in an undesired way due to failures in the motor calibration or sensory defects.

The robot causes a denial of service on itself while legitimately attempting to perform the assigned task. The robot has incremental bias creep due to changes in belt tensions, gear wear and other electromechanical reasons. The robot cannot handle changes in lighting, shadows, surface level tilt, noise, fog or other environmental noise visually or acoustically. The robot does not function due to inability to operate in poor network conditions or when operating in network conditions (instability, throughput and bandwidth) that are quite different from those tested.

Medical liability. Surgery using surgical robots

Between 2007 and 2013, 1.7 million robotic medical procedures were performed in the United States, according to Kaspar and Nagaraja (2022). During this period, surgical robots were implicated in the deaths of 144 patients. The study also identified that adverse events in robotic surgery, occurring between 2000 and 2013, fell into four categories: sparks during surgery that caused burns to patients; broken or burned parts that were accidentally inserted into patients; uncontrolled robot movements; and loss of video transmission. Of the more than 10,000 reports related to robotic procedures, it was found that more than 60% of these incidents were caused by equipment failure, while the rest were due to human error and the risks inherent in any surgery.

These adverse events and other accidents have raised concerns about the legal liability of robots. As a background, the European Commission developed the Robolaw project in 2014, to develop guidance for legislating on the field of robotics. The project suggested a civil liability scheme of a strict or quasi-strict liability nature, similar to product liability. It also established that not all robotic technologies are the same and that it is necessary to work on technical safety standards to design safe devices. States must come up with solutions from new liability frameworks or adapt existing ones.

In 2017, the European Parliament issued resolution P8_TA (2017) 00051, questioning whether current liability regimes can comprehensively redress damages caused by the use of robots. The resolution emphasized that, under current legal conditions, robots cannot be held liable for acts or omissions that cause damage to third parties, ruling out any possibility of granting them cyber legal status or personality. In addition, he suggested the establishment of a registration system for intelligent robots, a mandatory insurance regime, and a compensation fund for damages.

Civil liability for the use of robots, especially in the medical field, is a complex and evolving issue. More specific legal regulations will likely be developed in the future to address the challenges of robotic autonomy and its ethical and legal implications. As noted, the main precedents come from the European Union, although countries such as the United States, Germany, and Japan are also generating precedents in regulating the use of robotics, as Muñoz (2019) states.

Civil liability for the use of surgical robots in Colombia.

The constant evolution of society regularly poses legal challenges that generate questions about how the law addresses these new challenges. In this context, surgical robotics is no exception and questions arise in the field of tort law, highlighting who assumes civil liability in case of adverse events and damages caused by the use of surgical robots.

Since the inception of the Robolaw project, it has been questioned whether it is possible to bring legal action against a robot and whether it would be appropriate to grant them a cyber legal personality or an electronic personality (e-personality). The European Parliament Resolution of February 16, 2017, proposed the creation, in the long term, of a specific legal personality for robots. This would imply that more complex autonomous robots could be considered e-persons with the liability to repair any damage they may cause, especially in cases where robots make intelligent autonomous decisions or interact independently with third parties.

However, in the 2019 Resolution, the idea of granting legal personality to robots was abandoned. Currently, it is held that however autonomous and complex a robot may be, there is always a natural or legal person behind its operation, be it a programmer, a manufacturer, or an operator, among others, who may be liable for damages caused by the robot. In this context, the importance of having liability insurance in this area is emphasized.

Most surgical robots require programming and manipulation by surgeons since autonomous robots are practically non-existent at present.

However, this does not rule out the possibility that in the future technology will be developed that allows the complete autonomy of robots, as is the case of the Robot Star.

The civil doctrine of civil family law, as expressed by Lacruz (2020), holds that robots, although not simple things, are singular things endowed with apparent intelligence and consciousness. Under Colombian legal regulation, the subjective imputation of liability to the robot itself is forbidden, i.e., it is not allowed to attribute subjective liability to a robot as if it were a person with intentions and knowledge of its own.

In the case of damage caused by the use of surgical robots, various liability possibilities arise the liability of the owner, of the manufacturer for defective products, and of the user. This entails the possibility of joint and several liability on the part of the Health Care Provider Institution (IPS), together with the option of suing the physician for medical malpractice. As the electronic personality of the robot is ruled out in the legislation, in terms of civil liability, robots are considered within the legal category of things. According to the Colombian civil code, a system of civil liability for the fact of things is not established in a general way, but by exercising the powers inherent to the domain, the holder or guardian who has intellectual power, direction and control over the thing that causes damage compromises its liability (Supreme Court of Justice, Civil Chamber, Sentence SC4750, 2018).

The manufacturer's liability is based on the defective product theory, which holds that the manufacturer is liable for any damage caused by the defective product. In Colombia, Law 1480 of 2011 on consumer law establishes a special liability for manufacturers, who must ensure the suitability, safety, and quality of products. The legal definition of defective products includes manufacturing, design, and information defects, and this liability is objective and joint and several.

Regarding the medical civil liability for the use of surgical robots, in Colombia it is configured, as a general rule, under the proven fault regime according to the constant precedent of the Supreme Court of Justice and the majority doctrine, applying both in the contractual and extra-contractual modality (Supreme Court of Justice, Civil Chamber. Judgments CSJ. SC2506, 2016 and SC003 of 2018). However, there is the possibility of applying a strict liability regime, especially to prevent the victim from bearing damage without compensation.

Some doctrinarians suggest the need to update civil or consumer law regulations to adapt to the new reality of surgical robots, while others consider that the current liability rules are sufficiently flexible. Solutions put forward to address the challenges of robot autonomy and its ethical and legal implications include: establishing a mandatory insurance regime, creating a compensation fund, implementing a robot registration and monitoring system, and ensuring civil liability coverage.

In Colombia, although there is no special law for AI or intelligent robotics, in 2021 the national government created the “Ethical Framework for Artificial Intelligence in Colombia”, offering a guide of recommendations and suggestions for the formulation and management of projects that include the use of AI, and establishing ethical principles for their adoption.

Conclusions

The fourth industrial revolution, characterized by the convergence of physical, digital, and biological technologies, promises to improve the well-being and quality of life of the population. In the field of medicine, from early advances such as the electrocardiogram in 1903 to modern surgical robots such as Da Vinci and Star, we have witnessed significant progress. These robots have provided valuable support to surgery, offering precision, safety, smaller incisions, and faster recovery. However, they also pose challenges in terms of medical liability and the need to adapt existing regulations.

In the Colombian context, the civil liability regime, consumer law, and insurance law seem to be adequately prepared to deal with the use of highly autonomous surgical robots. Although Colombian civil law does not recognize the electronic personality of robots, it considers them as tangible property, which focuses liability on the manufacturer, the operator, or the remote manipulator.

In this regard, the applicable civil liability regime is generally based on proven fault, focusing on the liability of the operator, i.e. the surgeon. In addition, considering the robot as a product, there is the possibility of manufacturing, design, or information defects. In such cases, the consumer statute provides for special strict liability based on the risk to which users or third parties are exposed. Insurance law also plays an important role in allowing for comprehensive redress in case of adverse events during robotic surgical procedures.

However, the doctrine has also explored the possibility of considering the use of these intelligent robots as a high-risk activity, which could lead to the application of the objective liability regime. Although in Colombia and many legislations there are still no specific rules regulating the use of intelligent robots in medicine, it is essential for society to reflect on possible measures to address civil liability issues that may arise due to their use in medical procedures.

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