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MOROCCAN LEGAL FRAMEWORK AND LIABILITY FOR MEDICAL ROBOTICS

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Abstract

The legal discussion regarding the policy for the use of medical robots, ethics, and its regulations was not opened significantly despite the seriousness of the subject when compared to comparative legal systems. This paper aims to study legal liability due to security issues for consumers of medical robot services, within the lens of Moroccan legal framework. It also investigates the standards for assessing the risks associated with the use of medical robots since they closely intersect with human rights standards. The right to health and the affordable access to quality health care, in all its aspects, is a major goal for medical profession; involving medical robots in treatment, diagnosis, or personal care, especially when coupled with artificial intelligence, is challenging. This article is a call for a national discussion that will contribute to the evolving legal land space by addressing critical gaps and challenges in the regulation of medical robotics within the Moroccan legal framework.

Keywords: Morocco, Legal liabilities, Medical robots, Ethics, Metadata.

Introduction

The growing digital evolution and people's desire to reach and maximize its benefits have triggered the creation of more industrial innovations that rely on three core components of the ongoing digital revolution: the Internet of Things, big data, and artificial intelligence, wish have a direct influence in all sectors, including medical sector.

This digital industrial progress creates a new domain for research and analysis, along with the legal discussion of conventional concepts and principles recognized by the law. Undoubtedly, this will lead to a convergence of disciplines such as engineering, medicine and technological industry, underscoring that the legal regulation of these domains is an indirect framework for emerging industries like robotics.

Indeed, robotics has infiltrated the medical industry, especially in surgery and human care, due to its varied benefits. Robotic surgery mirrors traditional surgery involving endoscopes, where surgical instruments are introduced through small incisions in the patient's body; the surgeon is controlling the procedure from the control unit in the operating room. The surgeon employs manual and pedal control tools to manipulate the surgical instruments connected to the robot's arms. This type of surgery results in swifter recovery, diminished infection risks, reduced blood loss and decreased patient discomfort in comparison to conventional surgical procedures conducted through larger incision [1].

According to reports from the MAUDE database, which is managed by the Food and Drug Administration (FDA), several incidents have occurred during robotic-assisted surgical procedures. A robotic hand for an example, does not allow the preservation of tissues captured during surgery. Additionally, a mechanical arm struck a patient on her face while she was lying on the operating table. These incidents have raised new legal issues, including concerns about medical responsibility, as there is ambiguity in the allocation of responsibility between the surgeon, “the robot” and the manufacturing company. [2]

And therefore, the integration of robots in the medical field has become a reality that asserts itself with its benefits and drawbacks. This necessitates

dealing with it based on the principles of human rights, which encompass a wide range of concerns related to the right to health. As a result, this raises the issue of legal security in the consumption of these robot services. Is it a boon for health and medical treatment, or a threat that could upset the balance between the right to health and industrial development?

The right to health must be highlighted as an optimal right, mentioned in Moroccan constitution as in legislations all over the world. By the 31's article of the Moroccan Constitution, the Kingdome of Morocco has introduced this element as a constant obligation of the state of Morocco. [3]

In this article, we will delve into the core of medical robotics to understand its features and characteristics that may influence its legal nature (first requirement). Then, we will examine its suitability for meeting the demands of the right to health, considering it as one of the international and national right (Second requirement).

The use of medical robotics & the necessity of a legal framework

To assimilate the essence of medical robotics, this section aims to explore aspects of the legal nature of medical robots. However, this cannot be done before understanding their concepts and traits.

The concept of medical robotics between law & standards

The mixture of intelligence with machines led to the invention of what is now known as artificial intelligence. The IVth industrial revolution in its digital form, which the world experiences today, is closely connected to the industrial revolution that accompanied the world during the XIIIth century. This revolution was characterized by replacing manual labor with mechanization, as machines moved away from their mechanical and traditional concepts towards simulating human intelligence and adapting to external reality.

Artificial intelligence is a set of theories and techniques used to create machines capable of producing intelligence [4]. Among the applications of this intelligence is the robot, which is regarded as a futuristic technology, owing to the capacity to supply services associated with mobility and task execution. However, its association with intelligence poses several challenges in a lot of aspects, and most importantly, the legal aspect.

Due to the variety of definitions given to intelligent robots, the closest to reality is the one provided by the International Federation of Robotics (IFR) [5]. The IFR defines a robot as "a programmable mechanism with one or more degrees of freedom, capable of autonomous movement within its environment to perform intended tasks. [6]

This definition suggests the following:

- Although it mimics human intelligence, an intelligent robot does not possess human sensibility.
- The intelligent robot, often mistakenly referred to an ''artificial human'', cannot embody the diverse aspects that define humanity.

Therefore, associating it with human description is not suitable for all types of artificial intelligence.

It is acknowledged that jurisprudential and technical definitions often differ from legal definitions. The regulation of medical robots has not received sufficient attention in international systems, save for some exceptions. Law in south Korea defines a robot as a mechanical tool that perceives the external world, distinguishes conditions and moves automatically or voluntarily. The definition closely coordinates with the one established by the international organization for standardization (ISO) for intelligent robots used in both industrial and non-industrial settings. A robot is able of performing tasks by perceiving its environment or interacting with external sources and adapting its behavior. [7]

The field of artificial intelligence exhibits variations in its scope, composition and applications in the medical domain, a particular type of artificial intelligence stands out, characterized by a collection of features because of its association with human health. This has led to a keen interest in its legal framework. The utilization of artificial intelligence in the medical field has undergone several phases, evolving with scientific innovations. The field has witnessed the introduction of surgical medical robots, rehabilitation robots, bio-medical robots, telepresence robots, companion medical robots, sterilization robots and more. The first medical robot was used in 1983 in Vancouver, Canada, named" Arthrobot" specifically designed for hip joint surgery; it was used for the reconstruction of the hip joint. Later, the field witnessed the emergence of various types of medical robots such as Da Vinci, Puma-560 robot, Hugo and Robodoc. [8].

Interestingly, the Moroccan legislative system is still deficient in regulation for governing civil matters related to medical robotics [9]. This makes it challenging to define the nature of these robots within the national context which is different when referring to comparative law, especially the rules issued by the European Union, particularly in the field of medicine.

The expression of the medical robot involves a multitude of non-biological components, such as limbs, grippers, sensors, computers, and propulsion units, among others. All these components aim to simulate the human body and mind. Thus, the structural framework of the robot, its power source, and its operating program or electronic operation

must be in place [10]. These components are significant because they collectively determine the functionality, safety and credibility of medical robots, which immediately influence their use in sensitive fields like healthcare.

The legal quest for the legal security of consumers of medical robot services elevates several issues, such as its legal nature and its detachment from human senses. This pursuit leads to legal and ethical considerations that concern the human entity both materially and morally.

Aspects of the legal status of medical robotics

Before exploring this section, it's important to emphasize that medical services can only be supplied by individuals recognized by public authorities for their ethical and professional qualifications. This also includes various equipment and tools that assist in the practice of medicine. In some cases, scientific advancements may play a role, including the adoption of medical robots.

Although the concept of medical robots may suggest solutions that replace or complement human roles in healthcare, Moroccan legislation does not explicitly mention these entities within the healthcare, system. Most legal regulations focus on humans, whether as physicians, institutions, or healthcare facilities. However, it is worth noting that several clauses also apply to medical robots. This includes issues, such as professional secrecy, ethics, neutrality, integrity, non-discrimination and linking responsibility to accountability. [11] The use of medical robots today extends to self-diagnosis, precise surgery and the execution of repetitive treatments.

Investigating the legal personality of the medical robot is an integral part of the research into the legal adaptation of all consequences resulting from the intervention of 'the machine' in the healthcare domain. Is it something, or what is it, especially given its tangible physical presence and the existence of a tangible mind? While it can be conclusively stated that the medical robot is not a human, as this characteristic is associated with natural beings, it cannot be decisively stated that it lacks legal personality. Recognition of legal personality is not solely tied to humans; there are legal entities such as companies, contractors, institutions and associations.

Given that legal recognition of personality is linked to either the natural person (human) or the legal person, as known in legal systems, considering the robot as a natural or legal person is challenging. The characteristic of a natural person cannot be attributed to the robot because it is non-human. Furthermore, its tangible and perceptible existence distances it from the concept of a legal person.

Determining the legal nature of the medical robot is crucial in several areas. On a general level, medical intervention involves significant interactions with human rights. Therefore, defining the legal status of the medical robot is essential for understanding how to handle real-world issues related to preserving the right to health, the right to privacy and preventing violations of bodily autonomy. It also helps to determine responsibility for medical interventions performed by robots.

It is crucial to note that the legal nature of medical robots is determined by their types. Referring to comparative legal systems, it is noted that they often discuss the concept of 'legal personhood,' as exemplified in Europe. In the European context, the European Union has acknowledged a distinct form of personhood for artificial intelligence, especially for systems using deep learning. However, it is important to emphasize that this form of legal personality remains at a lower level compared to the legal personality of humans. This recognition justifies its non-independence leading to two observations in this regard**:**

- **1st Observation**: The non-recognition of legal personality for artificial intelligence outcomes in considering the robot as an extension of humans. Consequently, establishing a legal formula for holding it accountable becomes challenging, as it is regarded subordinate and non-independent. This underlines that the absence of legal personality for the medical robot is more likely than considering it as independent from humans.
- **2nd Observation:** The non-recognition of independent legal personality for the robot resulted from the inability to ensure the consequences arising from such recognition of independence. On the contrary, doing so would be a reckless move, especially in the medical field, which is complexly connected to human rights in all aspects. The world has not guaranteed boundaries for the robot's intervention in human life to recognize it as an independent entity.

Looking at the Moroccan legislative system, regardless of its adaptation to economic and technological developments, it remains confined to recognizing two types of legal personality: natural and moral personality. It has not extended to include electronic personality, sentient entities, or same concepts. Moroccan law includes provisions concerning animals and things, in addition to penal provisions related to both natural and moral persons. Thus, within the framework of Moroccan law, the legal adaptation of the robot cannot transcend its traditional role as a 'thing' that remains under human supervision.

Returning to the contemporary legal and jurisprudential discussion about the legal personality

of robots, it can be observed that the discourse is separated into two main directions:

The direction opposing recognition of legal personality for robots:

It becomes clear that the debate over granting legal personality to robots has intensified, especially following tangible cases like that of the robot "Sophia," which obtained Saudi citizenship in 2017. This incident garnered global attention and ignited discussions about the legal recognition of the robot's status. [12] Some voices seem to reject the idea of granting legal personality to robots, considering it a threat to traditional concepts of legal personality, as robots are seen merely as intelligent tools used by humans. There may be attempts to adapt legal systems to tackle these new challenges and to define the rights and responsibilities of robots in a legal context. [13]
Founded on the refusal to grant legal personality to medical robots due to their danger to humans, voices rose in Europe in defense of this, as the European Economic and Social Council (CESE) refused on May 31, 2017, due to moral risks, to recognize the robot's legal independence [14]. The International Committee for the Ethics of Scientific and Technological Knowledge (COMEST) also rejected this because the robot is devoid of human qualities of free will, self-awareness, moral sense and sense of personal identity. [15]

The trend supporting the idea of recognizing the legal personality of the robot.

We must announce from the beginning that legal personality is not limited to humans only but extends to other legal entities. Perhaps the recognition of legal entities and granting them personality is merely the result of a group of developments. This fact does not limit human responsibility for this recognition because personality remains non-independent. It is subject to supervision and management. A differentiation must be made between recognition of legal personality and recognition of independent legal personality.

Medical robotics & the applications to the right to health:

The right to health is considered as a national and an international right, like other universal rights that do not accept hierarchy, because it is linked to the right to life. It also comprises a large human rights lexicon linked to several guarantees, such as the right to treatment, the right to choose, the right not to infringe upon physical integrity, the right to confidentiality and not to infringe upon private life. For individuals, the necessity of framing the industry and intervention of robots in the medical field have a very rigorous standards (first), for the simple reason that this intervention is linked to a group of risks wish leads to a lot of challenging and promising repercussions (second).

Medical robot industry standards & the necessity of patient safety

The medical field cannot be isolated from the notable industrial development in the world. It is no secret that the robot industry remains subject to a set of standards and restrictions, even though the law frequently lags industrial development, as it is more regulatory than predictive, which is reflected in the components of the principle of legal security [16]. This is what jurisprudence expressed as the law's pursuit of science and technology.
Like other industries, medical robots are subject to a framework specific to the requirements of their industry. In February 2014, a technological framework was presented for safety requirements and standards for healthcare robots (ISO 13482/2014), founded on risks related to human care, with the aim of providing guidance to its industry, taking preventive measures, especially related to three types, namely mobile servant robots, physical assistant robots and personal carrier robot. [17]
Determining the standards for the medical robot industry is connected to the element of risk, which is something that is not achieved, but it is the most important factor of causing moral or physical harm, which urges the adoption of less serious requirements in robot production by anticipating the most dangerous possibilities, especially in the field of microsurgery and perhaps this is the difficult challenge confronting the producer. The manufacturer and the law as well, especially when matching the robot with artificial intelligence, attempt to give it independence in decision-making.
Even if the engineer and the scientist are ones who have the most important role in managing sciences, but we can't ignore the huge role and the intervention of AI and the digitalization in creating a marge of facilities that influence the management side in all sectors.
The standards for the medical robot industry suppose finding logic legal justifications that are legal and ethical framework that stems from the rules of human rights and basic freedoms, which are important to the medical profession, such as sensitivity and non-offending, which entails the presence of guidelines and instructions on aspects the legal implications of human care robot technology are essential. [18]
Medical robot engineering must follow a series of phases, starting with defining the system's core elements, functions, and interfaces. This evaluation

forms the foundation for all safety activities, beginning with risk analysis to identify potential hazards. Potential and classified, then safety functions can be defined to mitigate the risk of the hazard, with a safety level commensurate with that risk, then finally the implemented comportment of the system is tested according to the safety requirements to build confidence that the system achieves the level.

In addition to the above, what urges the adoption of more stringent standards in the medical robot industry is that the speed with which these mechanisms carry out their tasks. It is being carried out in a responsible and an ethical manner, which some jurisprudence has considered a prelude to not exempting the robot user from moral responsibility, This guides us to the conclusion that industry rules are just the beginning of legal compliance, as although the robot contains standards respecting human rights, the latter remains legally and morally obligated towards the patient, which undoubtedly initiates the lack of independence of the medical robot and limits the chances of recognizing its legal personality to hold it accountable.

To restrict the spread of medical robot risks to humans, the legal mechanism is effective in imposing strict standards in its industry by specifying them precisely and issuing detailed regulations of a technical nature that undermine the authority to interpret the law. This must also be followed by examining guidelines, instructions and everything having a relation to information and insight on how to deal with the robot by medical devices, as is the case for example in surgery, or by the consumer directly as the example of a human care robot.

It can be said that the medical robot industry remains fraught with risks, as it is important to take into consideration the agreed-upon concepts in this field, especially ethics, the duty of confidentiality and professional secrecy. This will help to ensure the continuity of the public facility, and preserve the property of work equipment and means. It is also crucial to calculate the most accurate hypotheses based on the fact that the robot would be unable to react when technical surprises occur during its therapeutic intervention.

There is no doubt that the reference to human rights, especially the right to dignity, is rooted in international references. Therefore, manufacturers, programmers and users must prepare medical robots to respect the human body according to the general legal framework regulating the idea of human rights internationally, nationally and regionally; the most important is the obligation to refrain from every action that harms the right to health in its broad sense. [19] This applies to all extensions of robot intervention in the medical field.

Indeed, the European decision on robotics proposed that each robot should be equipped with a black box containing information related to the data it stores, and the used algorithmic mechanisms in order to maintain the security and the data confidentiality [20]. It's worth mentioning that during its forty-first session in Paris from November 9 to 24, 2021, the General Conference of the United Nations Educational, Scientific and Cultural Organization (UNESCO) issued a recommendation on the ethics of artificial intelligence. This recommendation includes a set of principles that must be respected before the use of artificial intelligence, including the avoidance of harm, preservation of safety and security, non-discrimination, the right to privacy, data protection and human oversight. It is noteworthy that Morocco actively participated in implementing this recommendation, as evidenced by a consultative meeting and decision-making held with UNESCO on July 24, 2023. Even if the medical robot is tied by the ethics of the medical profession, it requires a human supervision to avoid anything that might vary from these ethics. As independence increases, the risk of ethical gap expands further [21]. Referring to the Moroccan legislation, it is prohibited to display unsafe products. In the second chapter of Law No. 24.09 concerning the safety of products and services, particularly in its fourth article, it is stated: "Producers, importers, and service providers are committed not to market anything other than products or services that are conform to the provisions of this chapter.

Legal liability in the use of medical robotics and the necessary adaptation to metadata

The issue of liability in the medical field raises a few problems both in terms of determining its basis, as well as in terms of the concept of the leading medical error, which is a traditional facet of legal debate. However, when it comes to liability for medical robot errors, here we are talking about a recent debate, most of its features have not become clear due to the ambiguity of nature. It's obvious that we can underscore the complexity of attributing legal responsibility in cases involving robots [22].

Based on the previous discussion regarding the consideration of a medical robot as independent for granting legal personality, permitting it to be personally held accountable, we emphasize the distinction between natural personality and legal personality. Natural personality is granted to a person from the moment of conception, considering him a human being from the womb, while legal personality is granted based on the acquisition of rights and the presumption of responsibilities. This necessitates distinguishing between the capacity for obligation and the capacity for performance. Regarding personal responsibility, Article 77 of the

Law of Obligations and Contracts states: "Every act committed by a person intentionally and by choice, without legal permission, causing material or moral harm to others, obliges the perpetrator to compensate for this harm, provided that the act is proven to be the direct cause of the damage." Additionally, Article 78 of the same law stipulates: "Every person is responsible for the moral or material damage caused not only by his actions but also by his mistakes when it is proven that this mistake is the direct cause of the damage".

It is noted, then, that the Moroccan legislator distinguishes between the human and the person, which shows that the traditional legislative organization is valid and legitimate to include all natural and legal persons, but it is not possible to attribute responsibility to another entity, such as a robot or an electronic person, since the legislator has not made any attempt to regulate this field–till the moment of writing this article. In light of the luck of recognizing the legal personality of the robot, it is difficult to consider it other than that. The Chapter 85 of the Law of Obligations and Contracts talks about the concept of the legal person to assume responsibility for the actions of others, which remains with it.

In reference to the efforts of the European Parliament, it is moving towards creating an insurance fund to deal with the damages that could occur because of the legal activity of the robot, provided that this fund is financed by the robot's makers, for example, to compensate for the damages it causes, and thus it is concluded that there is a legal liability that occurs as a result of its intervention. Legal scholars argue that the European Parliament's approach should not be construed as an acknowledgment of the financial independence of the robot. This perspective has implications for recognizing the legal personality of a robot operating on the concept of deep learning. Deep learning is intricately connected to human needs and remains subject to human authority to avert potential dangers in the future [23]. In connection with preventing the danger of medical robots, the legal basis for the various protection systems forms the rules of the public health system, which requires preserving the life and safety of individuals and not harming them. Whatever the basis of responsibility for the errors of the medical robot, the forms of this error are exposed in several aspects. Within the framework of the doctor's supervision of the robot machine, he is responsible for errors caused to the patient, as the French judiciary has previously raised the issue of the existence of a defect in a machine that helps the surgeon. The French Court of Cassation held the doctor accountable for burns that occurred to the patient due to the flame coming out of the electric scalpel during the operation, as well as for the explosion of the flying sparks from the anesthesia machine. Additionally, responsibility was assigned when a patient fall from the examination table due to its sudden movement or when getting on or off it. [24]

Basically, a medical robot is considered something that is subject to the same considerations that things are subject to, with the idea that it remains guarded under the hands of its owner. However, in the contemporary time and due to the development of industrial production related to robots, product descriptions apply to it. It's considered that the product, in accordance with Article 3 of Law no. 24.09 related to the safety of products and services, is: «Everything presented or offered in the context of a professional or commercial activity, with or without compensation, whether new or used, whether expendable or not. It is subject to transfer or packaging, or it is not subject to that. Liability for a consumer of services medical robots is based on risks and the obligation to ensure safety in order to allow error presumption; the injured party only has to prove the damage, the defect and the causal relationship.

The Moroccan judiciary has deliberately confirmed a presumption of causal relationship between the produced good and the damage, considering that the producer remains presumptively responsible and bears the burden of proving his lack of responsibility for the product despite the transfer of his physical possession to the consumer, because the manufacturer is responsible and obligated to verify the safety of the product.

Despite the legal guarantees there are several difficulties that could face the patients in proving the required elements of liability, especially the difficulty of obtaining the medical file and the difficulty of relying on medical expertise, the results of which are often the decisive factor in directing the judge's ruling. Within the difficulty of proving the presence of a flaw in the medical robot, the American judiciary has previously ruled on a series of cases related to the medical robots. In these cases, plaintiffs often struggled to win their lawsuits due to a lack of evidence and weak proof. Among them, we mention the following:

The case of Taylor against Intuitive Surgical Company in Washington in 2012, when he faced a lawsuit for being endangered by the marketing of machines to doctors without providing proper training, putting individuals' lives at risk [25].

- The case of Siliverstrini against Intuitive Surgical Company, where he claimed to have received inadequate care in October 2010 during his thyroid surgery. Siliverstrini chose to undergo a thyroidectomy using a robot because she had been informed that the procedure would be much less invasive than traditional surgery. However, during the surgery, the robot malfunctioned, and the procedure had to be

completed by the medical team, leaving her with a scar on her neck that required cosmetic surgery to repair. Siliverstrini's claim was based on the assertion that the mentioned company had not provided adequate training for the hospital staff on how to use the robot, and that the hospital failed to maintain the robot, with the staff unable to resolve the malfunction that occurred during the surgery. Additionally, the mentioned company had an agreement to address such emergencies. Siliverstrini claimed to have suffered physical and psychological harm, but the court dismissed the lawsuit on the grounds of insufficient evidence to support the claims [26].

- The case of Obrien against Intuitive Surgical Company, where he claimed that the robot manufactured by the mentioned company was defectively designed, malfunctioning during the plaintiff's pancreatectomy, causing him severe injuries. The plaintiff considered this as medical negligence, but the court dismissed his claim due to lack of evidence [27].
- The case of Dulski against Intuitive Surgical, where Thomas claims that he underwent surgery using the Da Vinci robot, but during the surgery, a gap was created in his colon. He based his lawsuit on medical malpractice against the surgeons in the New York State Supreme Court, Erie County, due to negligence and recklessness in the manufacturing, repair, and planning of the robot. However, the court dismissed his lawsuit due to lack of evidence [27].

Thus, given that proving the defect poses a challenge in terms of exercising the right to litigation and obtaining compensation, some mechanical engineers have considered that the solution lies in adopting descriptive data for the manufacturing, production, or distribution of the medical robots. These descriptive data, which will later serve as a means of proving damage, will act like the black box found in aircraft. Once accepted by the judiciary, this data will function as a record of events.

In this regard, we applaud that the adoption of the metadata standard for medical robots is a starting point that finds its basis in the compatibility of the use of the robot with human rights standards, which was previously approved by Law no. 24.09 when it stipulated in Article 9 that the competent administration determines, in accordance with a regulatory text, the characteristics of the product in terms of its safety, its composition features and the conditions for its production (assembly, installation, use, maintenance, reuse, recycling, transportation, distribution, storage, display, packaging, wrapping, and labeling). Additionally, the characteristics of the product depend on the measures related to evaluating its conformity with the safety requirements applied to it, which are the standards for production or importation in Moroccan law. [28]

Conclusion

All in all, we applaud that the adoption of the metadata standard for medical robots is a starting point that finds its basis in the compatibility of the use of the robot with human rights standards, which was previously approved by *Law No. 24.09* when it stipulated in Article 9 that the competent administration determines, in accordance with a regulatory text, the characteristics of the product in terms of its safety. The manufacturer should include its composition features and the conditions for its production, assembly, installation, use, maintenance, reuse, recycling, transportation, distribution, and storage, as well as its naming, display, packaging and labeling, in addition to the measures related to evaluating its conformity with the safety requirements applied to it.

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