KU LEUVEN CAMPUS BRUSSELS
FACULTY OF LAW
Academic year 2020-2021

Robotic-Assisted Surgery

Key aspects on liability in the EU and US

Promoter: Prof. A. VEDDER

Master's thesis, submitted by
Jan-Willem PAGE
as part of the final examination for the degree of MASTER OF INTELLECTUAL PROPERTY AND ICT LAW

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Plagiarism Declaration

I confirm that this thesis is my own work, that all ideas contained in the thesis are expressed in my own words, and that I have not literally or quasi-literally taken anything over from other texts, except for fragments cited between quotes for which I provided full and accurate bibliographical data.

Jan-Willem Page

Abstract

Robotic surgery has undeniably changed the operating theatre. Surgical robots' cost-reducing and quality-improving characteristics have made them a valuable addition to the surgical staff. Nevertheless, new risks for companies, patients, and physicians accompany their implementation, challenging the current legal frameworks regarding compensation for resulting damages.

Consequently, a critical review of these frameworks imposes itself to determine whether or not they are flexible enough to manage these adverse events. This aim is reached by exploring the current literature, in-depth analysis of legislation on medical malpractice, product liability, and medical devices, and consulting several stakeholders such as teaching institutions and manufacturers. To ensure exhaustiveness, this thesis compares and discusses European and American legislation and their application to surgical robots while simultaneously underscoring the encountered difficulties. For the moment, case law on this matter is limited; scholars and judges can only rely on sparse judicial texts, further highlighting the importance of said legislation.

The comparison of both frameworks indicates several issues in reconciling robotic-assisted surgery and traditional tort liability law: the imperatives to successfully file a claim under product liability or medical malpractice often require significant expertise in several domains such as medicine, engineering, and computer science. Undoubtedly, patients are mostly not well-versed in all of these disciplines. This translates into the complexity of surgical robots aggravating the burden of proof for them, potentially dissuading them from filing a claim at all. Even the application of strict liability does not mitigate this issue sufficiently. Moreover, multiple exemptions presented in both frameworks exonerate the otherwise liable party.

In conclusion, the feasibility of the frameworks is inversely proportional to the complexity of surgical robots. We are approaching the point where the legislation's pliability will no longer be sufficient to guarantee fair and balanced litigation to the injured patient. Therefore, more research into other mechanisms of compensation, such as a strict no-fault regime or national funds is needed.

Acknowledgments

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A special thanks goes to Korneel Vandenbroucke (ORSI Academy), Sara Skoczylas and Martin Woiczik (Intuitive Surgical), and Ann-Sophie Page (Department of Urogynecology UZ Leuven Gasthuisberg) for providing me with invaluable insights and guidance in the world of surgical robotics.

Last but not least, I am immensely grateful for the motivation, assistance, and reviews by Julie Matthys and Jens Claerman. Their support during the past year has helped me shape this thesis to what lays before you today.

Contents

List of Abbreviations

AI	Artificial Intelligence
AIMDD	Council Directive 90/385/EEC on Active Implantable Medical Devices
CIS	Computer-Integrated Surgery
EMA	European Medicines Agency
EU	European Union
FDA	US Food and Drug Administration
IVDMD	Directive 98/79/EC of the European Parliament and of the Council on in vitro Diagnostic Medical Devices
MDD	Council Directive 93/42/EEC on Medical Devices
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices
MIS	Minimally Invasive Surgery
PMA	Pre-Market Authorization
RAMIS	Robotic-Assisted Minimally Invasive Surgery
RAS	Robotic-Assisted Surgery
RASD	Robotic-Assisted Surgery Device
US	United States of America

Part I

Introduction

1.1. Context

As robotics were a mere futuristic concept just a couple of decades ago, society's constant pursuit of increased efficiency elucidates why robotics have become a substantial part of our daily lives and their overall importance continues to grow exponentially. Robotics facilitate the performance of detailed tasks and deliver high-quality results in less time. The benefits of robotics naturally paved the way for their use in healthcare. Currently, robotics has a myriad of applications in modern healthcare systems (e.g., exoskeletons, care robots, hospital robots, ...).[1]

The first robot-assisted surgery (RAS) took place in 1985, by way of the PUMA 560,[2] sparking the start of the operation room's robotization. In 2018, the milestone of 1 million robotic-assisted surgery with the Da Vinci Surgical Robot was reached and their usage increases by each year.[3] Surgical robotics aims to improve both the quality and precision of surgical procedures by providing for less invasive procedures, faster recovery, and a reduced rate of postoperative complications.[4] Consequently, it improves the quality of surgery for both surgeons (ergonomic advantages of robotic-assisted surgery) and patients, and thereby considerably reduces personal and social financial costs.

Nevertheless, the robotic industry is still at a nascent stage of development and understanding. The possibilities have only partially been explored and many more applications will be developed in the coming years. Since we are witnessing only the start of what many consider the fourth industrial revolution, now is the time for the regulators to understand the benefits and risks and take the necessary steps to provide a clear regulatory framework or reassess the current legislation.

Furthermore, a clear legislative framework is of the utmost importance for manufacturers, software developers, hospitals, and surgeons. Not only do they have to keep track of the rapid

[1] A. DONOVAN, *15 Medical Robots That Are Changing the World*, Interesting Engineering, 3 November 2020, https://interestingengineering.com/15-medical-robots-that-are-changing-the-world.
[2] The PUMA 560 is a robotic arm with six axes that uses computed tomography to guide the arm as it inserts a needle.
[3] V. LAVOUE "Quel rationnel médico-économique de la chirurgie robot-assistée pour les pathologies bénignes ?", *Société de Chirurgie Gynécologique et Pelvienne*, Webinar, 11 May 2021.
[4] A. LANFRANCO (et al.), "Robotic Surgery A Current Perspective", *Annals of Surgery*, 2004, vol. 239, no. 1, 16-17.

evolutions in their respective fields, but they also have to be aware of how regulation deals with these risks and liability issues. Moreover, liability implies damage to befall a person (i.c., the patients at risk of the wrongful use or malfunctioning of the robot), further stressing the need for a precise regulation on that matter. Such a framework offers the injured party the opportunity to be adequately compensated for the articulated damage. It also facilitates legal proceedings - of which we undoubtedly will see more in the coming years - and thus reduces litigation costs.

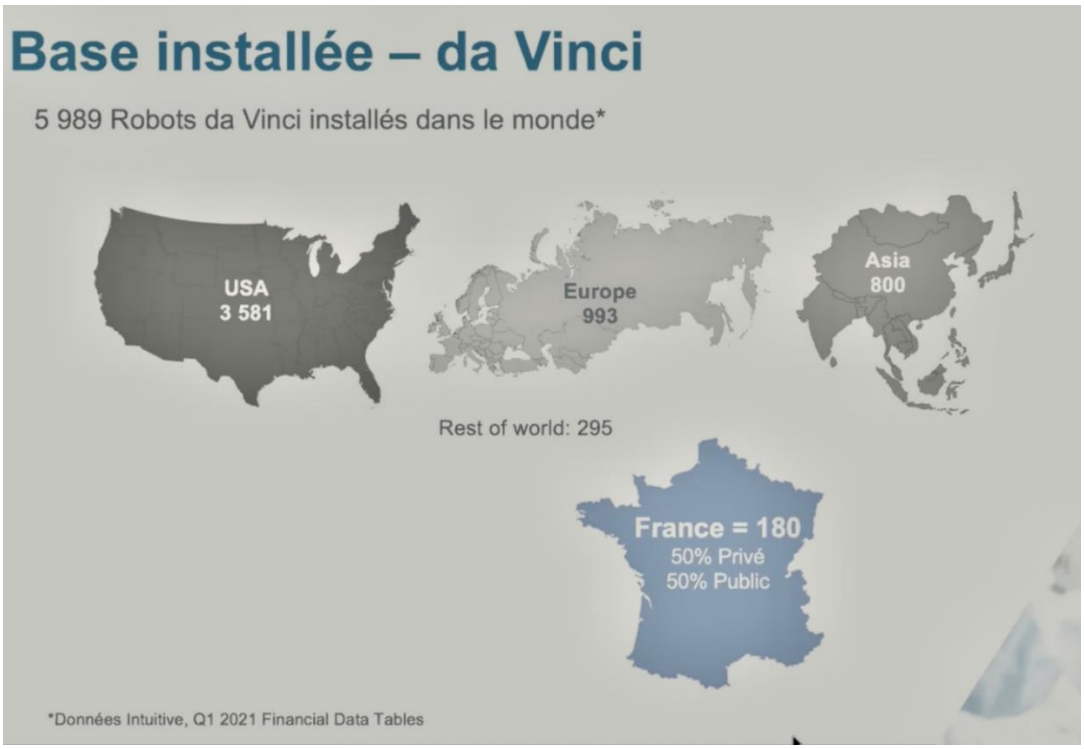

Figure 1: the amount of Da Vinci robots installed in different continents. Source: V. LAVOUE "Quel rationnel médico-économique de la chirurgie robot-assistée pour les pathologies bénignes ?", Société de Chirurgie Gynécologique et Pelvienne, Webinar, 11 May 2021.

1.2. Problem statement and relevance

Due to their transcendent characteristic, robots challenge our current society in many ways. From an ethical and social point of view, robots might increase inequality in our contemporary society. Some even denounce robotization as the "end of jobs". Others worry about how the wealth generated by robots will be distributed or how these machines will affect our behavior and interaction. However, these ponderings are subject to many other studies which are beyond the scope of this research. Legislators face challenges of a different nature. One of the biggest hurdles to tackle is the liability of robots. The lifecycle of a robot entails various stakeholders such as the manufacturer, the software developer, the operator, and the affected party. For RAS, this is no different. Furthermore, surgery deals with an even more delicate matter, the health of

patients. This is precisely why legislation needs to ensure that robots conform to safety standards and that their risks are well covered.

All of this brings us to the main research questions posed in this thesis. Before discussing the liability aspects of surgical robots, two elements have to be elaborated: the concept of surgical robots and how they may injure patients. Firstly, considering the myriad of robotic applications in healthcare, this thesis will clarify the sort of robotics that fall within the scope of this research. A clear demarcation of surgical robots is essential for its further discussion in this thesis. Likewise, an exposition of the possible failures that may occur with robots will be provided.

Secondly, no robot is the same. This is also true for surgical robots. All surgical robots in existence or development have different functionalities but also a varying degree of autonomy. This directly impacts questions on liability, as the surgeon's contribution is inversely related to the robot's autonomy. Although the fully autonomous "robo-surgeon" is still merely an idea, the development of surgical robots is accompanied by an ever-increasing degree of autonomy. Hence, there is a need to map out this autonomy.

The elaboration of the aforementioned elements induces the central question presented in this thesis. How suitable are the current liability frameworks in the EU and the US for the purpose of redress for injured patients of RAS? To give a clear answer to this question, several aspects of liability will be discussed. First of all, this thesis will provide an in-depth overview of medical device regulation, product liability, and medical liability, as these provide the regulatory fundament of risk management. This overview will ascertain the extent to which the respective legislations could be applied to surgical robotics, leading to a normative evaluation. At the same time, the difficulties in litigation regarding surgical robots will be highlighted.

Once the EU and US frameworks are expounded, a comparison between the two will be made to elucidate the patient's accessibility of redress in the case of RAS and how the complexity of surgical robots hampers litigation in both systems.

1.3. Methodology & Limitations

To ensure a thorough and critical analysis, an extensive study of European and American legislation, case law, and legal literature is mandatory. This analysis allows us to grasp the implications of said legislation for surgical robots. Regarding the legal literature, due attention

is given to select the most reliable and recent studies. Occasionally, online (news) articles may be consulted for the more recent findings in the field of robotics.

However, one of the main obstacles is the lack of in-depth legal studies on RAS. Robotics is undoubtedly a niche subject for legal scholars since it is a recent phenomenon. Moreover, comprehending the entirety of a surgical robot requires insights into many different fields of study such as medicine, engineering, and computer science. To tackle this interdisciplinary hurdle, ORSI Academy, the legal department of Intuitive Surgical, and a surgeon practicing RAS have been consulted to understand better the different approaches to surgical robots held by these three different stakeholders. ORSI is "*a unique center for surgical innovation and expertise in minimally invasive surgery*".[5] Its primary focus is providing adequate training in RAS for surgeons. Intuitive Surgical is the manufacturer of the Da Vinci Surgical Robot, the most used surgical robot worldwide. The consultation of these stakeholders gave the necessary insights from different perspectives (support, manufacturing, and medicine).

Lastly, the application of medical and product liability is a rather theoretical exercise. This is precisely why case law is of great importance to understand the nuances within fully. If legislation would be too specific, it might render itself unusable in specific cases. Jurisprudence has the quality of filling in those gaps that are intrinsic to legislation. However, case law regarding surgical robots is limited in the US and completely absent in the EU. Although many medical malpractice and product liability claims appear in the US, they are often settled in mediation proceedings.[6] This is especially true for RAS injuries. Consequently, there are only very few case-based decisions to work with.

[5] See:. https://www.orsi-online.com/nl.

[6] See: X, *Da Vinci Robot Lawsuit – Settlement Info*, Drug Dangers, https://www.drugdangers.com/da-vinci/robot-lawsuit/: "*More than 3,000 cases of injury caused by use of da Vinci robot technology were settled in 2013 and two cases have gone to trial […] The second trial was settled during jury deliberations when the company offered a $30 million payout*". There are more claims pending, but it seems likely most of these will be settled as well.

Part II

Delineating Surgical Robots

2.1. General introduction to robotics

The earliest usage of the term "Robot" dates back to 1920 when used in the play "Rossumovi Univerzální Roboti" by the Czech writer, Karel Čapek.[7] It is the adaptation of the ancient Slavic word "Robota", which means forced labor. It was first introduced in the English language via this play, in which the "Roboti" were human-like machines doing the tedious work of humans.[8] Today, robots are even capable of doing tasks more efficiently or more quickly than humans. They extended humanity's possibilities, making us stronger or mitigating potential weaknesses. A century later, robots have evolved to much more than what Čapek's play depicted. This also challenges us in giving a thorough answer to the question "what is a robot?".

2.1.1. Defining a robot

Before addressing the different kinds of robots in healthcare, a basic understanding of 'robots' is needed. One definition can be found in the Oxford Dictionary, which describes a robot as "a machine—especially one programmable by a computer— capable of carrying out a complex series of actions automatically".[9] However, to be subject to legislation, a more legal approach to such definition is called for. Although the Commission of the European Union has, so far, avoided the issue of drafting a definition,[10] the European Parliament did propose five main characteristics to describe a robot[11]:

- the acquisition of autonomy through sensors or by exchanging data with its environment (inter-connectivity) and the trading and analyzing of that data;
- self-learning from experience and by interaction (an optional criterion);
- at least a minor physical support (as opposed to virtual robots, e.g., software);
- the adaptation of its behavior and actions to the environment; and
- the absence of life in the biological sense.

[7] T.R. KURFESS, *Robotics and Automation Handbook*, Florida, CRC Press, 2018, 3.
[8] E. FOSCH VILLARONGA and C. MILLARD, "Cloud Robotics Law and Regulation" in *Queen Mary School of Law Legal Studies Research Paper*, London, Queen Mary University of London, 2018, no. 295, 11.
[9] J.A. SIMPSON and E.S.C. WEINER, *Oxford English Dictionary*, Oxford, Oxford University Press, 2020.
[10] The European Parliament has called on the European Commission to define, among other concepts, "smart autonomous robots".
[11] European Parliament, Recommendations to the Commission on Civil Law Rules on Robotics, 2017.

In the United States of America, there is so far no corresponding attempt at legally defining a robot at a federal level. Instead, some definitions or interpretations are found in case law or scholarly articles. American literature often refers to the "sense, think, act"-paradigm, which implies that (i) a robot can sense its environment, (ii) has the capacity to process the information it senses, and (iii) is organized to act directly upon its environment.[12] Richards and Smart made another attempt at defining robots. They characterize robots as a constructed system that displays physical and mental agency but is not alive in the biological sense.[13]

For the moment, no consensus exists on how a definition of robots would increase or reduce certainty as to the scope of the law,[14] as questions arise on the feasibility to uphold a legal definition in a world of rapidly evolving technology. Hence, it might be opportune to take a less formal approach. By not formally setting in stone a stringent definition, but instead relying on a set of characteristics, similar to the European Parliament's, we are not only capable of clearly distinguishing robots and other technological concepts such as computer programs and artificial intelligence, but we also future-proof our theoretical framework, for it is widely known that the law lags behind on technological evolutions (also referred to as the pacing problem or regulatory disconnect).[15] Providing the possibility to quickly adapt the conceptual basis of a regulatory framework is indisputably advantageous in this rapidly changing field.

2.1.2. How robots differ from artificial intelligence

In the current state of the art, robots are often intertwined with artificial intelligence. Nevertheless, they are two completely different concepts. Artificial intelligence can be defined as "[…] computer systems able to perform tasks normally requiring human intelligence, such as visual perception, speech recognition, decision-making, and translation between languages".[16] Some well-known examples of artificial intelligence are Google's search algorithm and Facebook's Recommendation Engine. A significant difference with robots' characteristics is that artificial intelligence is not tangible. For a robot to act upon its environment, such tangible physical support is necessary.

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[12] R. CALO, "Robotics in American Law", *University of Washington School of Law Legal Studies Research Paper Series*, 2016, no. 2016-04, 6.
[13] N. M. RICHARD and W. D. SMART, "How should the law think about robots?" in R. CALO, A.M. FROOMKIN and I. KERR (eds.), *Robot law*, Cheltenham, Edward Elgar Publishing, 2016, 6.
[14] E. FOSCH VILLARONGA and C. MILLARD, "Cloud Robotics Law and Regulation" in *Queen Mary School of Law Legal Studies Research Paper*, London, Queen Mary University of London, 2018, No. 295, 12.
[15] See: G. MARCHANT, B. ALLENBY and J. HECKERT (eds), *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem*, Dordrecht, Springer, 2011 and R. BROWNSWORD, *Rights, Regulation and the Technological Revolution*, Oxford, Oxford University Press, 2008.
[16] https://www.oxfordreference.com/view/10.1093/oi/authority.20110803095426960.

Artificial intelligence and robots are often confused due to the existence of artificially intelligent robots or autonomous robots.[17] These kinds of robots form the bridge between both concepts. Artificial intelligence could be considered as the brain of the autonomous robot. Robots and artificial intelligence are often mingled because it allows the robot to achieve a higher functionality. A non-autonomous robot only functions per its programming (e.g., vacuum robots or other household robots). In comparison, artificially intelligent robots can determine how to achieve a specific goal with little to no human supervision or intervention.[18]

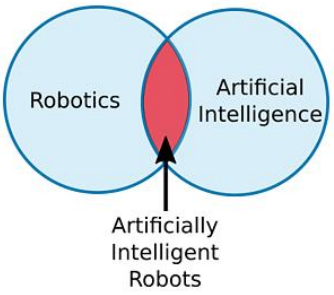

Figure 2: Source: https://blog.robotiq.com/whats-the-difference-between-robotics-and-artificial-intelligence.

2.2. Healthcare robots

Robots have found their way to many surgical domains, such as neurosurgery, orthopedic surgery, dental surgery, laparoscopy, and radiosurgery. However, not only surgery has been the target of robotization. For example, the rehabilitation of older adults or those with a dysfunction is also increasingly assisted by robots. The usage and application of robots differ profusely depending on the various work fields. A clear distinction will be made accordingly, in this chapter, to delineate this thesis's subject, namely surgical robots.

2.2.1. Exoskeletons

This first category of healthcare robotics resemble sci-fi soldiers from futuristic movies and videogames whose their abilities are buffed by exoskeletons. However, this is no longer a futuristic concept, as a wide range of industries is already using exoskeletons to boost productivity and safety. For example, military personnel uses exoskeletons to move heavy supplies and equipment in the field. Also, industries prone to significant manual labor, such as the agricultural industry and logistics firms, increasingly use exoskeletons.[19]

[17] W. BARFIELD, "Liability for Autonomous and Artificially Intelligent Robots" in *Paladyn, Journal of Behavioral Robotics*, 2018, vol. 9, no. 1, 193.
[18] *Ibid*.
[19] X, *How Exoskeletons Are Being Leveraged For More Than Healthcare*, Association for Advanced Automation, 1 June 2020, https://www.automate.org/blogs/how-exoskeletons-are-being-leveraged-for-more-than-healthcare.

Despite the benefits mentioned above, the incorporation of exoskeletons experienced some complications. Foremost, mobility has long been a significant design challenge. As exoskeletons remain an electronic device, they need to be tethered to a power source. Today, this has been partly resolved by lowering the power requirements and thus allowing the use of batteries. Next to mobility, latency was another challenge. The exoskeletons offer the user increased capabilities, but in return, they have slowed down the movements of said user. These users had to be trained extensively to use the exoskeletons successfully and efficiently. This hurdle was overcome by predictive algorithms and artificial intelligence, allowing the exoskeletons to function intuitively in real-time based on the worker's movements.

Figure 3: Hybrid Assistive Limb (HAL) suit by Cyderbyne.

Since exoskeletons enhance the abilities of the person using them, this also implies that they can allow people with paraplegia, amputees, and others to walk again.[20] Hence, exoskeletons can be considered as healthcare robotics as well.

However, the costs associated with this type of technology limit its adoption in the field of healthcare. Exoskeleton manufacturers have therefor started implementing Robotics-as-a-Service pricing models in an attempt to tackle this problem, thereby allowing facilities to implement exoskeletons without the upfront cost. Although this fee-based model takes away the upfront cost, it remains an expensive affair. For example, the monthly rental for a Hybrid Assistive Limb (HAL) suit by Cyberdyne amounts to 1,000 USD.[21]

2.2.2. Care robots

Care robots can be defined as "machines that operate partly or fully autonomously intending to support potential users, older adults, and relatives as well as professional caregivers, in providing physical, cognitive or emotional support".[22] To date, the number of robots used to provide care and support to elderly and disabled patients remains relatively low. The best-

[20] X, *How Exoskeletons Are Being Leveraged For More Than Healthcare*, Association for Advanced Automation, 1 June 2020, https://www.automate.org/blogs/how-exoskeletons-are-being-leveraged-for-more-than-healthcare.
[21] K. MARTENS, *Cyberdyne Bringing HAL Cyborg Exoskeleton to US Market*, Lexology 2018, https://www.lexology.com/.
[22] S. GLENDE, I. CONRAD, L. KREZDORN, S. KLEMCKE and C. KRÄTZEL "Increasing the acceptance of assistive robots for older people through marketing strategies based on stakeholders needs" in *Int J Soc Robot*, 2016, vol. 8, 355–369 and M. GOELDNER, M. HERSTATT and C. TIETZE, "The emergence of care robotics—a patent and publication analysis", *Technol Forecast Soc Change* , 2015, vol. 92, 115–131.

known examples of care robots mainly provide support regarding assistance in daily tasks, monitoring behaviors and health, and providing companionship (e.g., Care-O-Bot, Robot-Era, JustoCat, and Zora Bots).

A plethora of present barriers prevent care robots from being incorporated fully into this medical field. These barriers are either technological, ethical, legal, social, organizational, or market-driven.[23] However, in the case of care robots, moral and social barriers play a more vital role.[24] For example, Sharkey and Sharkey described the main ethical concerns: reduced human contact, loss of privacy, deception, infantilization, loss of control, and loss of personal liberty.[25] Furthermore, questions may arise about the responsibility if something goes wrong with the robot.

Figure 4: Visitors of the airport of Ostend (Belgium) are greeted by "Pepper", a Zora Bot.

2.2.3. Hospital robots

Hospital robots are nonsurgical robots that can be used in a vast array of implementations. These machines aim to complete or augment many everyday tasks of human employees in a hospital. Some of the most widespread hospital robots will be described.

The Aethon TUG robot - capable of transporting supplies, meals and lab samples, medical supplies, and other materials around the hospital - is one of the most widely used robots in hospitals. One estimate, provided by Aethon, shows that a typical 200-bed hospital moves aforementioned items the equivalent of roughly 82 kilometers per day.[26]

Another promising hospital robot is the Xenex Germ-Zapping Robot. Many hospitals have to deal with hospital-acquired infections (HAI). These infections are the result of insufficient decontaminated rooms. Often, this results from a lack of time or simply because the contaminated surface(s) are not visible. Hospital employees can use the Xenex robot "to

[23] N. LINZER "An ethical dilemma in home care" in *J Gerontol Soc Work, 2002*, vol.37, no. 2, 23–34.
[24] R.M. JOHANSSON-PAJALA, K. THOMMES, J.A. HOPPE *et al.* "Care Robot Orientation: What, Who and How? Potential Users' Perceptions" in *Int J of Soc Robotics*, 2020, vol.12, 1104.
[25] A. SHARKEY and N. SHARKEY, "Granny and the robots: ethical issues in robot care for the elderly" in *Ethics Inf Technol*, 2012, vol.14, no. 1, 27-40 and R.M. JOHANSSON-PAJALA, K. THOMMES, J.A. HOPPE *et al.* "Care Robot Orientation: What, Who and How? Potential Users' Perceptions" in *Int J of Soc Robotics*, 2020, vol.12, 1104.
[26] www.aethon.com/tug/tughealthcare/.

disinfect entire hospital rooms in minutes using pulsed, full-spectrum UV rays that kill a range of infectious bacteria".[27]

2.2.4. Surgical robots

The previously mentioned robots are used either before or after surgery. Surgical robots, on the other hand, are used during the surgery itself and, in that way, differ from the aforementioned, having different goals and fields of applications. As it is these sorts of robots that will form the main subject of thesis' research, a closer look at these robots and their history and applications is warranted.

a. A short history of surgical robots

The first surgical robot, the PUMA 560, was first used in a stereotaxic operation in 1985 and marked the beginning of the era of surgical robots.[28] The PUMA 560 eliminated the operating surgeon's possible hand tremor by using computed tomography, which guides the robot to insert a needle into the brain for biopsy. Only three years later, the PROBOT, a robot for prostate resection, was developed at the Imperial College of London and applied in transurethral prostate surgery.

Another phenomenon that pioneered in the same period was laparoscopic surgery, more commonly referred to as minimally invasive surgery (MIS).[29] It entails all operations performed in the abdomen or pelvis using small incisions with a camera's aid. Because the camera allows the surgeon to see within the abdominal and thoracic cavities without performing open surgery, it drastically decreased the patients' recovery time and hospital stays.[30] In 1994, the AESOP was the first robot to be introduced as a laparoscopic camera holder. Later on, the Zeus robotic surgical system (Computer Motion) and the Da Vinci surgical system (Intuitive Surgical) were developed and used in MIS. In 2003 Computer Motion was purchased by Intuitive Surgical, which stopped the Zeus system's further development and opened the doorway for the Da Vinci robot, the most widely used robotic surgical system worldwide.

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[27] X, *5 Medical Robots Making a Difference*, Case School of Engineering, 28 December 2017, https://online-engineering.case.edu/blog/medical-robots-making-a-difference.
[28] E.J. MOORE, *Robotic surgery, medical technology*, Encyclopaedia Britannica, 18 November 2015, https://www.britannica.com/science/robotic-surgery.
[29] T.N. ROBINSON and G.V. STIEGMANN, "Minimally Invasive Surgery" in *Endoscopy*, Stuttgart, Thieme Medical Publishers, 2004, vol.36, no. 1, 48.
[30] *Ibid.*

In the following paragraphs, some of the most studied applications of surgical robots are shortly presented.

b. Robots for navigation

The navigational robots can define a narrow plane in which the medical instrument has to be used (e.g., a bone saw for a bone cut).[31] Before the surgery, the surgeon defines the narrow area of operation. Once the intervention starts, the robot will move the medical instrument in the predefined area. The surgeon will then be able to use the instrument only in this field of operation. It reduces the motion of the device and thus provides much higher accuracy.

Another example of navigational robots are those that track moving targets.[32] It is often the case in radiosurgery when removing long tumors, the tumors move as the patient breathes. Given that it is impossible for the surgeon to effectively move the radiation source, which can easily weigh 200 kilograms, robotic assistance can be instrumental. In this case, the robot will track the tumor motion and compensate.

c. Computer-integrated surgery (CIS)

Computer-integrated surgery is an entire process that starts with the medical information about the patient (e.g., CT, MRI, PET, lab results, …), combining it with statistical information about human anatomy and physiology.[33] As a result, it creates a comprehensive computer representation of the patient, used to provide an optimized interventional plan. If the surgeon approves the plan, he will then further monitor if the system correctly executes it. TSolution One Surgical System (previously known as ROBODOC) by THINK Surgical is one example of CIS.

d. Robot-assisted minimally invasive surgery (RAMIS)

For now, no surgical robot acts independently of the surgeon. The idea of a robot operating on a human might even be off-putting for some and would undoubtedly give rise to an even more considerable debate on ethics. For now, this is not the case. The most advanced surgical robots use motion replication, which means the robot only replicates a surgeon's acts on a real-time basis.[34] For example, the surgeon uses a magnified 3D high-definition vision and controls

[31] A. SCHWEIKARD and F. ERNST, "Medical Robots", Dordrecht, Springer, 2015, 2.
[32] A. SCHWEIKARD and F. ERNST, "Medical Robots", Dordrecht, Springer, 2015, 6.
[33] H. RUSSELL, A. MENCIASSI, G. FICHTINGER and P. DARIO, "Medical Robotics and Computer-Integrated Surgery" in B. SICILIANO and O. KHATIB, "Handbook of Robotics", Dordrecht, Springer, 2008, 1200.
[34] A. SCHWEIKARD and F. ERNST, "Medical Robots", Dordrecht, Springer, 2015, 16.

that strap to his wrists and hands. The robot then replicates the surgeon's motions on the patient's body (i.e., the Da Vinci Surgical System developed by Intuitive Surgical Inc.).

It allows precise and delicate interventions to be performed with very high accuracy because it can down-scale the surgeon's hand's motion range and replicate the same motion. The patient's benefits are a shorter hospital stay, less risk of infection, less blood loss and fewer blood transfusions, less pain, and a faster recovery.[35] Another interesting fact is that it allows the surgeon to operate remotely, enabling the so-called telesurgery.

[35] A. SCHWEIKARD and F. ERNST, "Medical Robots", Dordrecht, Springer, 2015, 16 and E.J. MOORE, "Robotic surgery, medical technology" in *Encyclopaedia Britannica*, 2015, https://www.britannica.com/science/robotic-surgery.

Part III

Autonomy and failures of surgical robots

3.1. Degrees of autonomy

The fictional "Roboti" in Čapek's play portray fully autonomous robots. They can act upon their environment and make decisions on their own without human input of any kind. Although technology is progressing significantly, most modern robots do not achieve this autonomy yet.[36] For example, the Society of Automative Engineers recognized that not all self-driving cars are alike. Hence, they proposed a five-level classification, ranging from non-autonomous cars (where the driver has sole control) to vehicles that handle all driving decisions without any human input. Much like self-driving cars, surgical robots can be classified into different categories of autonomy. One proposition hereto was made by Yang (et al.):[37]

Degree	Definition	Context
0	No autonomy	Robots that solely respond to and follow the operator's command
1	Robot assistance	Robots that provide mechanical guidance or assistance during a task. The operator maintains continuous control.
2	Task autonomy	Robots that perform specific operator-initiated tasks. The operator maintains discrete control.
3	Conditional autonomy	Robots that generate task strategies, but the operator selects the method or approves the autonomously chosen process.
4	High autonomy	Robots that make medical decisions. The operator maintains supervision.
5	Full autonomy	Robots that can perform an entire surgery, replacing the surgeon entirely, hence being granted the term "robotic surgeon".

Another proposal by Parasuraman, Sheridan, and Wickens consists of 10 levels[38]:

Degree	Context
1	The computer offers no assistance: human must take all decisions and actions
2	The computer offers a complete set of decisions/action alternatives, or
2	Robots that perform specific operator-initiated tasks. The operator maintains discrete control.
3	Narrows the selection down to a few, or

[36] G.Z. YANG (et al.), "Medical robotics – Regulatory, ethical, and legal considerations for increasing levels of autonomy", *Sience Robotics*, 2017, vol.2 no. 4, 2.
[37] *Ibid*.
[38] R. PARASURAMAN, T. B. SHERIDAN and C. D. WICKENS, "A model for types and levels of human interaction with automation", *IEEE Transactions on Systems, Man, and Cybernetics - Part A: Systems and Humans*, 2000, vol. 30, no. 3, 286-297.

4	Suggests one alternative, and
5	Executes that suggestion if the human approves, or
6	Allows the human a restricted time to veto before automatic execution, or
7	Executes automatically, then necessarily informs the human, or
8	Informs the human only if asked, or
9	Informs the human only if it, the computer, decides to
10	The computer decides everything and acts autonomously, ignoring the human.

Legislators should not minimize the importance of this classification, especially with regards to rules on liability. The current state of the art contains robots up to level 3 (conditional autonomy).[39] Surgical robots classified between levels 1 and 4 are still under the control of the operating surgeon. On the other hand, level 5 (and in some cases level 4) robots are operating at their own discretion. In this case, it is no longer the surgeon but the robot that is practicing medicine.[40] This is uncharted legal territory because, as described later on, European law and American federal law regulate medical devices but omit the practice of medicine by such devices. As a result, the respective national and state legislator will need to address this legal lacuna.

3.2. Distinction of failures

Robots malfunction for a variety of reasons. Hence, a clear distinction is necessary to separate the failures caused by the robot's correct operation as per the specification from those caused by an active adversary. The latter are referred to as adversarial failures, the first as non-adversarial failures. This division is of great importance in the correct designation of the applicable legislation. The liability differs depending on whether the failure is induced or stems from the robot's malfunctioning.

3.2.1. Adversarial failures

Although the adversarial failures will not be further discussed within the scope of this thesis, some of these failures will nevertheless be briefly touched upon as they underscore the distinction with non-adversarial failures. As mentioned above, adversarial failures entail any

[39] G.Z. YANG (et al.), "Medical robotics – Regulatory, ethical, and legal considerations for increasing levels of autonomy" in *Sience Robotics*, Washington, American Association for the Advancement of Science, 2017, vol.2, no. 4, 2.
[40] *Ibid*.

failure induced by an active adversary who intends to achieve a specific goal.[41] The WannaCry-ransomware attack on healthcare systems recently accentuated the magnitude of the risks with these kinds of failures. This attack disrupted services in nearly one hundred countries at an unprecedented level, locking up computers and holding users' files for ransom.[42] Even during the duress of the COVID-19 pandemic, ransomware attacks on hospitals were skyrocketing.[43] Since robots are likewise often connected to networks, similar assaults are imaginable. Ludvigsen and Nagaraja composed a security taxonomy that defines six distinct adversarial failures:[44]

1. Manipulation attacks, where the adversary modifies the robot's instructions to achieve a different response.
2. Subverting robotic control, in which case the adversary makes changes in the robot's control.
3. Reprogramming the robot, consisting of changes in software on any level.
4. Theft of trade secrets.
5. Poisoning the feedback loop, where the adversary modifies the outputs (camera/sensory) that are sent to the surgeon.
6. Software vulnerabilities, meaning any vulnerability that can be exploited by an adversary (e.g., the ransomware attack as mentioned above).

3.2.2. Non-adversarial failures

Contrary to the adversarial ones, non-adversarial failures occur when an unsafe outcome results from the correct operation. In this case, no external adversary hampers the robot's functioning, but the cause of the malfunction stems from the robot itself. K. Ludvigsen and S. Nagaraja also provided a brief overview of what these failures may consist of:[45]

1. The robot works in unintended ways because of failures in motor calibration or sensory defects.
2. The robot causes a denial of service on itself while legitimately trying to accomplish the assigned task.
3. The robot has an incremental bias that creeps in due to shifts in belt tensions, gear wear-and-tear, and other electro-mechanical reasons.

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[41] K. LUDVIGSEN and S. NAGARAJA, "Dissecting liabilities in adversarial surgical robot failures: A national (Danish) and European law perspective", *ArXiv*, 2020, 6-7.
[42] See: X, Ransomware cyberattack : *UK's health system recovered from hacking, interior minister says*, ABC News, 13 May 2017, https://www.abc.net.au/news/2017-05-13/ransomware-cyberattack:-technicians-work-to-restore-systems/8524170 and D. GAYLE, A. TOPPING, I. SAMPLE, S. MARSH and V. DODD, *NHS seeks to recover from global cyber-attack as security concerns resurface*, The Guardian, 13 May 2017, https://www.theguardian.com/society/2017/may/12/hospitals-across-england-hit-by-large-scale-cyber-attack.
[43] Europe and North America saw the ransomware-attacks increase with respectively 67% and 37% in November of 2020 (see: X., *Attacks targeting healthcare organizations spike globally as COVID-19 cases rise again*, Check Point Blog, 5 January 2021, https://blog.checkpoint.com/2021/01/05/attacks-targeting-healthcare-organizations-spike-globally-as-covid-19-cases-rise-again/).
[44] K. LUDVIGSEN and S. NAGARAJA, "Dissecting liabilities in adversarial surgical robot failures: A national (Danish) and European law perspective", *ArXiv*, 2020, 6-7.
[45] *Ibid*., 9.

4. The robot fails to handle shifts in lighting, shadows, tilt of surface level, noise, mist, or other environmental noise in the visual or acoustic plane.
5. The robot fails to perform due to its inability to function in poor network conditions or being operated in network conditions (jitter, throughput, and bandwidth) that are quite different from what it was tested on.

Studies confirm the likelihood of the occurrence of these failures. One of these studies, dated from 2016, extracted its data from the "Manufacturer and User Facility Device Experience"-database as maintained by the FDA.[46] This study examined the outcome of 10.624 instances of adverse events in robotic surgery between 2000 and 2013. It reports 144 deaths (1,4%), 1.391 patient injuries (13,1%), and 8.061 device malfunctions (75,9%). The most frequent malfunctions are: falling of burnt/broken pieces of instruments into the patient (14,7%), electrical arcing of instruments (10,5%), unintended operation of instruments (8,6%), system errors (5%), and video/imaging problems (2,6%). In many cases, the surgeon had to interrupt the surgery to restart the system or even convert to open surgery. This data highlights that RAS is still facing a non-negligible number of technical difficulties and complications during procedures.

3.2.3. Wrongful use

The currently used surgical robots are merely tools for surgeons. Consequently, not all harmful occurrences regarding surgical robots are failures but may instead be the outcome of the surgeon's wrongful use. In such a case, the 'failure' lies with the surgeon and not the robot. It takes specific knowledge to carefully decide whether or not RAS is feasible on a case-by-case basis. If a surgeon did not have the necessary training, RAS might be wrongfully used to the detriment of the patient.[47]

[46] H. ALEMZADEH, R. IYER, Z. KALBARCZYK, N. LEVESON and J. RAMAN, "Adverse Events in Robotic Surgery: A Retrospective Study of 14 years of FDA Data", *PLoS One*, 2015, vol. 11, no. 4, 2.
[47] Circuit Court of Cook County, 17 February 2012, Lenika Fernandez, etc. v. George Salti M.D., et al., no. 08 L 1117 and P. MILHIZER, *Family gets $7.5 million in death after spleen removal*, Chicago Daily Law Bulletin, 21 February 2012, https://www.personalinjurylawchicago.com/documents/Spleen.pdf.

Part IV

European legal approach towards surgical robots

4.1. Regulation on medical devices

One of the European Union's main principles is to ensure the smooth functioning of its internal market. It does so by providing a clear and understandable regulatory framework. Hence, the European Union has a competitive and innovative medical devices sector (with over 500.000 types of medical devices on the said market).[48] The underlying basis for this framework regarding medical devices is a balance between a high level of health protection for both patients and users and ensuring the safety and efficacy of medical devices while facilitating patient access. As a result of this rationale, the regulatory framework solely regulates medical devices' function, design, and construction requirements. It does not provide any rules on the risks involved in robotic surgery. Still, these requirements help prevent malfunctioning and thus further reduces the possibilities of risks.

Up until recently, three directives were in place to ensure the goals above: (i) Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990), (ii) Council Directive 93/42/EEC on Medical Devices (MDD) (1993) and (iii) Directive 98/79/EC of the European Parliament and of the Council on in vitro Diagnostic Medical Devices (IVDMD) (1998).

In 2017, the European Union adopted two new regulations to replace the previous directives:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices (MDR)
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

Both regulations are characterized by a transition period. The Medical Devices Regulation governs licenses for medical devices granted after 26 May 2021.[49] All licenses granted before

[48] https://ec.europa.eu/health/md_sector/overview_en.
[49] Originally, the deadline was set on 27 may 2020. However, following the outbreak of the COVID-19 pandemic, the regulation was amended, postponing the deadline for one year. This decision was made to take the pressure off national authorities, notified bodies, manufacturers and other actors to allow them to focus on urgent priorities related to the coronavirus crisis.

that date (thus governed by the directive) will remain valid until 26 May 2024 or until the end of the period indicated on the certificate issued by the Notified Body.

As the deadline of 26 May 2021 approaches while writing this paper, it seems appropriate to have a closer look at how surgical robots fit in this framework.

4.1.1. Robots and the Medical Device Directive

The MDD defines medical devices as:

"*any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: (i) diagnosis, prevention, monitoring, treatment or alleviation of disease, (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, (iii) investigation, replacement or modification of the anatomy or of a physiological process, and (iv) control of conception*."

Due to this broad definition, surgical robots fall within its scope, thus qualifying them as medical devices. The directive further classifies medical devices according to the risks that come with them. Surgical robots are considered medium to high-risk devices, therefore ranking them as Class IIb medical devices (based on Annex IX of the MDD).[50] This classification means the MDD treats them the same way as any other medical device used during surgical operations, such as defibrillators, surgical lasers, scalpels, and scissors.

To place a Class IIb device on the market, the manufacturer will have to obtain a CE certificate from the Notified Body.[51] This testing institute will grant the certificate if the device conforms with the regulation's assessment procedures. This procedure can either be the procedure for the declaration of conformity (Annex II) or the type-examination (Annex III).

As soon as the manufacturer has obtained a CE certificate and the device has subsequently found its way to the market, it remains subject to ongoing vigilance procedures. Once a Member State regulator becomes aware of a specific medical device incident, it will take all necessary steps to protect patients. Some of the measures a regulator can take are the withdrawal of non-

[50] C. HOLDER (et al.), "Robotics and law: Key legal and regulatory implications of the robotics ages (part I of II)", *Computer Law & Security Review*, 2016, vol. 32, no. 3, 389.
[51] A notified body is a third party, designated by a Member State and notified to the Commission, with the task to assess the conformity of medical devices under the MDD (art. 16 MDD).

compliant devices and the prohibition or restriction of their distribution. The action taken will depend on the nature of the incident.

4.1.2. Robots and the Medical Device Regulation

Those familiar with European law know that EU regulations are directly binding for all Member States and, contrary to directives, do not need to be transposed into national law. Regulations allow the European Union to achieve a higher degree of harmonization within the Member States. One of the main catalysts for the new regulation is that many counterfeit products have found their way into the medical devices' supply chain. Some reports estimate that 8-10% of all medical devices are of fake origin.[52] Consequently, some scandals emerged (e.g., the breast implant scandal and the vaginal mesh device scandal).

Although the MDR does not explicitly include any new provisions or restrictions on surgical robots, some provide some exciting rules, such as the explicit codification of the manufacturer's obligations in article 10. Next to the legal requirement of having in place systems for risk management, quality management, and the obligation to conduct clinical evaluations,[53] article 10 stresses the responsibility of the manufacturer when damage occurs. The last paragraph of said article stipulates that "*natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law*".[54] Moreover, "*manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law*".[55] The MDR does not give any further details on the liability of manufacturers but refers to Union and national law for this matter.

4.1.3. EU Regulation on Artificial Intelligence

In April 2021, the European Commission unveiled its proposed regulatory framework for artificial intelligence and machinery products.[56] Much like the regulation on medical devices, the AI-regulation adheres to a risk-based approach, establishing a four-tier system: (i) minimal

[52] B.D. GLASS, "Counterfeit drugs and medical devices in developing countries", *Research and Reports in Tropical Medicine,* 2014, vol. 5, 11-22.
[53] Medical Device Regulation, article 10, paragraph 2, 9 and 3 respectively.
[54] Medical Device Regulation, article 10, paragraph 16
[55] *Ibid*.
[56] Respectively: Proposal for a Regulation Of The European Parliament And Of The Council Laying Down Harmonised Rules On Artificial Intelligence (Artificial Intelligence Act) And Amending Certain Union Legislative Acts, COM(2021)206, 21 April 2021 and Proposal for a Regulation Of The European Parliament And Of The Council On Machinery Products, COM(2021)202, 21 April 2021.

risk, (ii) limited risk, (iii) high risk, and (iv) banned. The regulation clarifies that risk is to be interpreted as a risk to society and not a risk as in liability costs for the manufacturers of these devices.

- Banned – The devices that manipulate human behavior to circumvent the users' free will, systems for 'real-time' biometric identification, as well as "social-scoring" systems for governments, are flat out banned.
- High risk – an AI-system is considered high risk when it "*is intended to be used as a safety component of a product, or is itself a product*". The Commission further clarified that this entails the AI application in robot-assisted surgery.[57]
- Limited risk – AI-systems that (i) interact with humans, (ii) are used to detect emotions or determine association with (social) categories based on biometric data, or (iii) generate or manipulate content are bound to certain transparency obligations. These are, for example, chatbots and deepfake content.
- Minimal risk – Any AI-system that does not fall within the scope of any of the previous categories is not regulated, as these systems represent only minimal or no risk for citizens' rights or safety - for example, AI-enabled video games or spam filters.

As the European Commission has clearly stated that AI applications in robot-assisted surgery are high-risk systems, manufacturers of these applications will have to bear in mind several requirements (art. 24):

- Adequate risk assessment and mitigation systems (art. 9);
- High quality of the datasets feeding the system to minimize risks and discriminatory outcomes (art. 10);
- Detailed documentation providing all information necessary on the system and its purpose for authorities to assess its compliance (art. 11);
- Logging of activity to ensure traceability of results (art. 12);
- Clear and adequate information to the user (art. 13);
- Appropriate human oversight measures to minimize risk (art. 14);
- High level of robustness, security and accuracy (art. 15).

[57] European Commission, "Europe fit for the Digital Age: Commission proposes new rules and actions for excellence and trust in Artificial Intelligence", Press release, Brussels, 21 April 2021, https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1682.

Furthermore, the proposed Regulation on Machinery Products explicitly refers to the Regulation on AI to ensure the safe integration of the AI system into the overall machinery.

> *"Where machinery products contain an artificial intelligence system, to which the essential health and safety requirements of Regulation (EU) .../... apply, this Regulation shall, in relation to that artificial intelligence system, only apply with regard to its safe integration into the overall machinery, so as not to compromise the safety of the machinery product as a whole."*[58]

However, these regulations are not in effect yet and will not be for a couple more years. Its earliest effective date would be in 2024. Nevertheless, two conclusions which directly impact AI-enhanced surgical robots are apparent already.

Firstly, the required audits to assess conformity will require a considerable amount of experts in the field of AI and engineering who have an "*in-depth understanding of artificial intelligence, technologies, data and data computing, fundamental rights, health and safety risks, and knowledge of existing and legal requirements*".[59] Consequently, manufacturers of surgical robots will have to invest considerable amounts in hiring such a team. Although this seems straightforward, establishing a team of these AI-risk managers who possess all the necessary knowledge will be problematic due to the 'AI-talent gap'. A 2021 report by O'Reilly on the adoption of AI in enterprises found that 19% of its respondents experienced difficulties in finding skilled people.[60] The proposed regulation on AI will most likely further increase this rush on AI-talent.

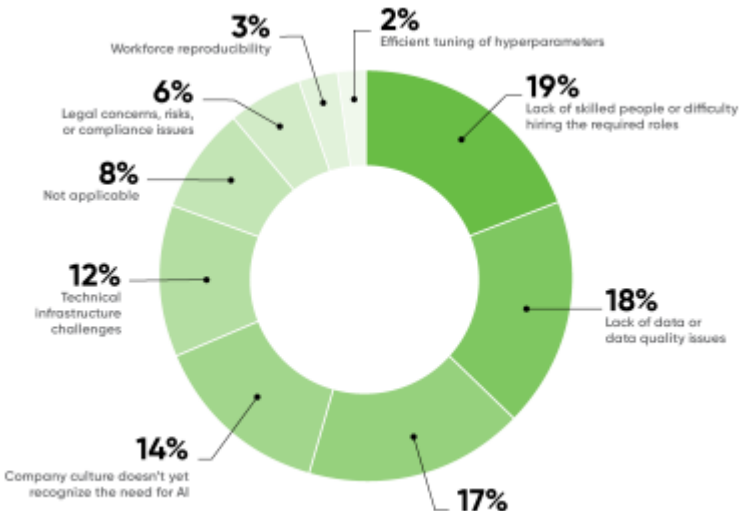

Figure 5: Source: LOUKIDES, "AI Adoption in the Enterprise 2021", O'Reilly, United States of America, 2021.

[58] Article 9, Proposal for a Regulation Of The European Parliament And Of The Council Laying Down Harmonised Rules On Artificial Intelligence (Artificial Intelligence Act) And Amending Certain Union Legislative Acts, COM(2021)206, 21 April 2021.

[59] Article 59, §4, Proposal for a Regulation Of The European Parliament And Of The Council Laying Down Harmonised Rules On Artificial Intelligence (Artificial Intelligence Act) And Amending Certain Union Legislative Acts, COM(2021)206, 21 April 2021.

[60] M. LOUKIDES, "AI Adoption in the Enterprise 2021", *O'Reilly*, United States of America, 2021, p. 7. Note: the majority of the respondents are from the US, but the same barrier is present in Europe as well. Moreover, many

Secondly, article 14 establishes an obligation of human oversight. This eliminates the idea of the "robo-surgeon". In any instance, a human will remain in the loop who is able to interpret the AI and intervene when necessary.[61] Nevertheless, "*although surgeons may remain, the world is likely to change dramatically around them*".[62]

4.2. Rules on liability

4.2.1. Medical Liability

The European Member States hold primary responsibility for organizing and delivering health services and medical care. The European Union rather complements the national policies to ensure health protection in all EU policies (for example, legislation on medical devices and patients' rights in cross-border healthcare). Medical liability, however, remains a national affair. Although most European countries approach medical liability similarly, many differences remain, such as the specific characteristics of each legal culture and tradition.[63] Next to these cultural differences, the entire infrastructure might diverge as well. While some countries only consider private law relevant, others use administrative law (e.g., France). There is also the distinction between the traditional negligence-based liability doctrine and the no-fault regime (e.g., Nordic countries).

To further elaborate on the concept of medical liability, Belgium's legislation and practices will be used. The reason for this is that the Belgian regulation on medical liability is considered private law and adheres to the traditional negligence-based liability doctrine. Nevertheless, the Belgian legislator in 2010 adopted a variation of a no-fault regime for when the healthcare provider is not liable and the harm suffered is abnormal, sufficiently serious, and a result of the

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of the European graduates who are well-versed in AI are recruited by the tech giants situated in the US. See: https://www.technologyreview.com/2017/12/04/147323/europe-is-struggling-to-keep-local-talent-for-its-homegrown-tech-scene/ and X, *The presence of tech giants in Europe is changing the dynamics of the region's talent pool*, State of European Tech Report, 2017, https://2017.stateofeuropeantech.com/chapter/talent/article/big-tech-giants-are-growing-presence/.

[61] Article 14, 4, (a)-(e), Proposal for a Regulation Of The European Parliament And Of The Council Laying Down Harmonised Rules On Artificial Intelligence (Artificial Intelligence Act) And Amending Certain Union Legislative Acts, COM(2021)206, 21 April 2021.

[62] A. SAYBURN, "Will the machines take over surgery?", *Royal College of Surgeons of England*, 2017, vol. 99, no. 3, 90.

[63] A. PANAGIOTOU, "Medical Liability in Europe at the Dawn of Cross-border Healthcare: Time to Reflect on the Possibility of Harmonising the Policies Regarding Medical Liability?", *European Journal of Health Law*, 2016, vol. 23, no. 4, 360.

healthcare delivered.[64] Therefore, the Belgian system can be regarded as a "not only fault" system, striking a balance between the two dominant regimes in Europe.[65]

a. The contractual liability of the operating physician or hospital

According to the Belgian legislation, three criteria need to be addressed in case of legal action against a health care provider.[66] First, harm must befall the patient. Secondly, the mistake must be committed by the healthcare professional. Last but not least, there must be a strict[67] connection between the error and the harm. These principles apply to any medical act and, therefore, to RAS as well. The burden of proof of these three criteria lies with the moving party, i.e., the patient.

A physician performing medical acts has certain legal result obligations towards the patient. In case of such obligation, the patient does not have to prove fault, but only that the agreed result was not achieved.[68] One obligation is not to leave any foreign object (needles, tools, but also small parts or pieces of a machine such as a medical robot) in the patient's body by error.[69] This rule knows no exceptions. The falling of burnt/broken pieces of instruments into the patient is one of the more frequent malfunctions regarding RAS (14,7%), which further highlights the relevance of this obligation.[70]

However, to invoke the operating physician's contractual liability, an agreement between said physician and the patient is essential. In Belgium, the patient often enters into a contract with the physician as well as the hospital. In this respect, the hospital is accountable for the lodging, food distribution, personnel, and infrastructure, while the physician remains responsible for the medical treatment.[71] In some cases, the agreement is solely made with the

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[64] E. HONDIUS, "Comparative medical liability in Europe" in *Festschrift für Hans Stoll zum 75. Geburtstag*, Mohr Siebeck, Tübingen, 2001, 193.
[65] T. VANDERSTEEGEN, W. MARNEFFE and D. VANDIJCK, "Physician Specialists' Perceptions of the Medical Malpractice System in Belgium", *European Journal of Health Law*, 2015, vol. 22, no. 5, 483. The predecessor of the 2010 act was abrogated as it entailed an extensive no-fault system, similar to the one used in Sweden. Consequently, patients would have no longer been able to go to court for medical malpractice.
[66] Robotgeassisteerde chirurgie: health technology assessment, KCE reports 104A, Federaal Kenniscentrum voor de Gezondheidszorg, 2009, 64.
[67] The Belgian Court of Cassation has further elaborated on the interpretation of the "strict connection", clarifying that the connection must be indisputably established (Cass.12 May 2006, *Arr.Cass.* 2006, 1084) and irrespective of the risk/benefit considerations (Cass. 17 September 2003, *J.T.* 2003, 95).
[68] Robotgeassisteerde chirurgie: health technology assessment, KCE reports 104A, Federaal Kenniscentrum voor de Gezondheidszorg, 2009, 65.
[69] Cass. 28 September 1995, *Arr. Cass*. 1995, 828.
[70] See: previous chapter on non-adversarial failures.
[71] T. VANSWEEVELT, "De civielrechtelijke aansprakelijkheid van ziekenhuizen en ziekenhuisgeneesheren", in H. CLAASSENS, H. COUSY en J. HERBOTS (eds.), *De aansprakelijkheid in ziekenhuisverband*, Gent, Mys en Breesch, 1994, 65.

hospital ('all-in-agreement'), in which the hospital is responsible for the medical acts performed by its physicians.[72] In more rare incidents, no contractual basis exists[73]. Evidently, the physician cannot be sued based on this liability regime if he is not a party to the agreement.

The fault criterium:

In an obligation of means, the physician undertakes to achieve the desired result with all reasonable and available means and efforts.[74] To prove a breach of contract in this case, the patient must show that the doctor made a mistake by not making sufficient efforts to achieve the desired result. If the agreement is considered to be a result obligation, the doctor undertakes to achieve a specific outcome. As mentioned before, the patient does not have to prove fault but instead needs to demonstrate that the agreed result was not realized.

When a surgical robot performs a non-adversarial failure during the operation, the outcome of both liability regimes might differ. In the case of a result obligation, the malfunctioning of the robot is irrelevant. The unachieved guaranteed outcome triggers the liability of the physician or hospital. Conversely, a similar failure might not bring about the same answer when it occurs in the case of a means obligation. The patient will have to prove that the physician induced the malfunctioning, willingly or unwillingly, to fulfill contractual liability requirements. Thence it would no longer be an apparent non-adversarial failure.

b. The non-contractual liability of the operating physician or hospital

When the patient has entered an agreement with the physician or hospital, his possibility of invoking non-contractual liability is excluded. This exclusion forms the principle of prohibition of concurrence as confirmed by the Belgian Court of Cassation.[75] Nevertheless, some circumstances might overrule this principle; the patient may hold the physician non-contractually liable if:

1. both the fault and the damage are alien to the contract's performance, or;
2. the contractual default also constitutes a criminal offense.

Regarding RAS, the second exception is crucial. When surgeons commit a harmful error while performing an operation, they consequently commit the crime of unintentional assault

[72] H. VANDENBERGHE, "Medische aansprakelijkheid" in H. VANDENBERGHE (ed.), *De professionele aansprakelijkheid*, Brugge, Die Keure, 2004, 12.
[73] For example, when the patient is brought to the hospital in an unconscious state after an accident.
[74] H. VANDENBERGHE, "Medische aansprakelijkheid" in H. VANDENBERGHE (ed.), *De professionele aansprakelijkheid*, Brugge, Die Keure, 2004, 27.
[75] Cass. 7 december 1973, *Arr. Cass*. 1974, 395

and battery,[76] allowing the patient to choose between contractual or non-contractual liability. Whether one applies the contractual or non-contractual liability significantly impacts the extent of the damages compensated. The contractual debtor is only obliged to compensate the foreseeable damage at the time of the contract's conclusion unless the malpractice was perpetrated willfully. In the case of non-contractual liability, the entire loss shall be compensated, irrespective of whether there was intent or not.[77]

The fault criterium

To invoke the non-contractual liability when no criminal offense has occurred, the patient will have to prove the fault, harm, and the causal link between them. The fault can manifest itself in two forms of unlawful behavior:

On the one hand, an error is committed when a legal rule or standard is violated. For example, the physician must obtain the patient's free and informed consent before carrying out any intervention.[78] Failure to do so constitutes an error on behalf of the doctor, which the patient must prove. However, the Belgian Court of Cassation underlined that the doctor must prove the patients' informed consent in the case of a complex or sensitive surgical procedure.[79] RAS can likely be considered as such a procedure and thus reverses this burden of proof.[80] In a more recent case on informed consent, the Court of Cassation highlighted the rule that the burden of proof is upon the moving party in case of non-contractual liability.[81] It is to be seen if the Court might uphold this approach for good.

On the other hand, the violation of a general standard of care can also constitute an error. The standard of due care requires that one considers others' interests and takes precautions to prevent physical damage. The physician should act as a "*bonus medicus*"[82] and be adequately trained to operate surgical robots. Performing RAS without the necessary training or education will constitute a breach of the standard of care.[83] Considering that ~30% of the surgeons are

[76] Article 418-420, Strafwetboek of 8 June 1867, *BS* 9 June 1867.
[77] H. BOCKEN en I. BOONE, *Inleiding tot het schadevergoedingsrecht: buitencontractueel aansprakelijkheidsrecht en andere vergoedingsstelsels*, Brugge, Die Keure, 2011, 36.
[78] Cass. 14 December 2001, *Arr.Cass*. 2001, nr. 10, 2200, concl. J. DUJARDIN.
[79] Cass. 28 February 2002, *T. Gez* 2002-03, , nr. 1, 12.
[80] Robotgeassisteerde chirurgie: health technology assessment, KCE reports 104A, Federaal Kenniscentrum voor de Gezondheidszorg, 2009, 65.
[81] Cass. 11 January 2019, *T. Gez*. 2018-19, nr. 5, 314-322.
[82] T. VANSWEEVELT, *De civielrechtelijke aansprakelijkheid van de geneesheer en het ziekenhuis*, Antwerp, Maklu, 1997, 136-137.
[83] *Per analogiam*: Rb. Brussel 12 mei 1997, *T.Gez*. 1999-00, 289.

deemed inadequate for independent surgery after classical training,[84] let alone RAS, the need for intensive training can hardly be overstated.

4.2.2. Product Liability

a. The strict liability of the operating physician or hospital

The physician or hospital can also be held liable for using defective products, as provided by the Civil Code.[85] This provision allows the patient to hold a physician responsible for damage caused by tools in his safekeeping (such as surgical material, *inter alia* surgical robots). A patient who brings a claim under this liability regime will have to prove the defect in the product, the damage, and a causal link between the two. The application of the objective liability for defective products bears two more prerequisites; (i) the person addressed is the custodian of the object,[86] and (ii) the object that caused the damage is defective.

Regarding the first prerequisite, it is presently unlikely that the surgeon will be the owner of a surgical robot, considering their steep pricing. Therefore, in most cases, the hospital will be liable because the doctor uses the surgical robot on behalf of the hospital. Nevertheless, an independent doctor working at a hospital can also be regarded as the custodian of the defective robot, even though the hospital owns the robot. In order to define the custodian, the decisive element shall be who can supervise, direct, and control the robot.

The Civil Code considers a product defective if it displays any abnormal characteristic, making it susceptible to damage in certain circumstances.[87] The fact-finding court consistently assesses the existence of such a defect. Given the ever-growing complexity of robots, concluding on the existence of a defect can be a challenging exercise for the court. According to the Court of Cassation, this requires a comparison "*with products of the same kind and type in order to determine the requirements of the product to which the victim could normally expect to be subject*".[88] Considering that the sector of surgical robotics is still fully developing, defining a "*product of the same kind and type*" might even be close to impossible. Even if two different robots aim for the same result, their operations and programs can diverge. Moreover, when comparing a robot with other robots of the same type and brand, the said robot's abnormal

[84] B. C. GEORGE, J. D BOHNEN, R. G. WILLIAMS (et al.), "Readiness of US General Surgery Residents for Independent Practice", *Annals of Surgery*, 2018, vol. 267, no. 3, 582–594.
[85] BW, art. 1384.
[86] Cass. 20 March 2003, *Arr. Cass*. 2003, no 3,, 691, concl. DE RIEMAECKER
[87] Cass. 1 December 1994, *Arr. Cass*. 1994, 2, 1032.
[88] Cass. 25 April 2005, *Arr. Cass*. 2005, no. 4, 928.

characteristic(s) (for example, a software bug) might be present in all identical robots, rendering the qualification as abnormal impossible.

Belgian jurisprudence deems the deviation from the normal expectations of society sufficient to qualify a product as defective.[89] This bypasses the previous difficulties regarding the abnormal characteristic but provides for a whole new issue. Since there is no European jurisprudence on faulty surgical robots yet, determining said societal expectations is arduous. Even so, considering the sensitivity that is patient health, the absence of any potential harmful defect might be considered as a standard societal expectation. Nevertheless, one might wonder whether it is realistic and economically feasible to set forth such a high standard. Technological improvements might narrow this gap but might also turn out to be a double-edged blade, given that as the amounts of lines of code in a robot's software keep growing, so does the likelihood of bugs and their potentially harmful consequences.

b. Directive on liability for defective products

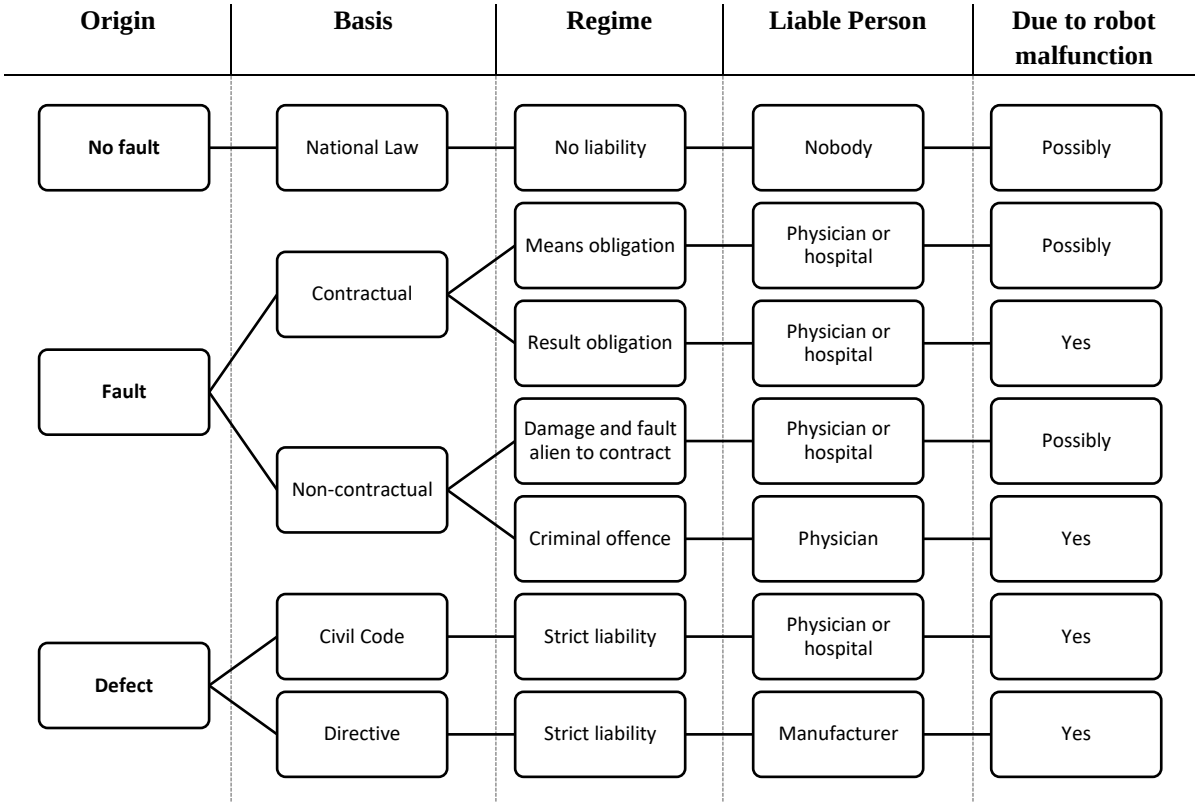
When a patient suffers damage due to a defective product, he may also bring an action against the producer of the defective product. The legal basis for this lies within the Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products. Products in this directive are "*all movables […], even though incorporated into another movable or into an immovable*". As such, this also applies to surgical robots.

A defect is deemed to exist when the product does not provide the expected safety, taking into account its presentation, foreseeable use, and the time when the manufacturer put it into circulation (i.e., the *consumer expectations test*). It adheres to a similar approach formulated by the Belgian jurisprudence on defective products based on article 1384, paragraph 1 of the Civil Code. The consumer expectations test takes into account the legitimate expectations of the public. This renders the distribution of information a crucial element. Information (or the lack thereof) to the public may qualify a non-dangerous robot defective and vice versa. Additionally, information other than from the manufacturer (e.g., television shows, radio, and magazines) may raise expectations as well.[90]

[89] J. DE BRUYNE and J. TANGHE, "Software aan het stuur: Aansprakelijkheid voor schade veroorzaakt door autonome motorrijtuigen", in T. VANSWEEVELT en B. WEYTS, *Nieuwe risico's in het aansprakelijkheids- en verzekeringsrecht*, Antwerpen, Intersentia, 2018, 51.
[90] T. VANSWEEVELT and B. WEYTS, *Handboek Buitencontractueel Aansprakelijkheidsrecht*, Antwerp, Intersentia, 2009, 498-499.

4.2.3. Interim Conclusion on Belgium & the European Union

The patient has a plethora of legal action grounds to see his damages compensated by the physician or the hospital. Even when the robot malfunctions despite the doctor's good care, the patient is not left empty-handed. Nonetheless, all of these legal provisions are drafted disregarding the emergence of robotics. Especially with regards to the directive on defective products, this might give rise to several issues.



Foremost, information can relieve the manufacturer of his liability. As stated before, a producer can willingly include the dangerous nature of surgical robots in the information he distributes, thereby changing the consumers' expectations and consequently avoiding his liability.[91] This exception has merit, but only to a certain extent. The requirement of sufficient and clear information is desirable and thoroughly needed, but the question remains whether it should exonerate the producer of any liability, regardless of the error's severity? Although a

[91] H. JACQUEMENT and J.B. HUBIN, "Aspects contractuels et de responsabilité civile en matière d'intelligence artificielle" in H. JACQUEMENT and A. DE STREEL, *L'intelligence artificielle et le droit*, Brussels, Larcier, 2017, 133.

limitation on his liability is understandable, a complete vindication is not - especially when dealing with patients' health and well-being.

Moreover, if the manufacturer can prove that the state of scientific and technical knowledge at the time when he put the robot into circulation was not such as to enable the existence of the defect to be discovered, his liability cannot be engaged.[92] AI-enhanced surgical robots further complexify this. These robots are capable of learning and making decisions according to newly learned information. The defect resulting from its learning capability is unknown when entering into circulation, which triggers the exception.[93] The same reasoning applies to the updating of the robot's software, possibly creating new functionalities.[94]

Determining the defect forms another issue. The directive approaches robots as mere tools, but new generation robots exhibit a behavior and can no longer be regarded as a simple object. In these cases, the question arises on how to apply this directive if the damage is not derived from a defect of the robot but from its behavior.[95] One example is Watson, a question-answering computer system.[96] Watson's hypothesis generation and evidence-based learning capabilities are being investigated to evaluate how Watson may contribute to clinical decision support systems.[97] If the behavior was set as a standard by the manufacturer, the directive could be applied with little difficulty. In contrast, when the behavior results from the robot's capability to learn, such application would be far less evident.[98]

Finally, understanding these emerging technologies, such as surgical robots, is an onerous task, considering the steep learning curve. Judges who are little-versed in emerging technologies may struggle with comprehending the subtleties of these.[99]

Irrespective of these issues, the question remains whether or not the existing liability pathways are practicable for sufficient and accessible compensation of damages. Many of these schemes, especially the non-contractual ones, place a significant burden of proof on the patient. The complexity of surgical robots further aggravates this burden, and perhaps, a new liability

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[92] Article 7(e) Defective Product Directive and C. HOLDER (et al.), "Robotics and law: Key legal and regulatory implications of the robotics ages (part I of II)", *Computer Law & Security Review*, vol. 32, no. 3, 2016, 390.
[93] H. JACQUEMENT and J.B. HUBIN, *op. cit.*, 135.
[94] H. JACQUEMENT and J.B. HUBIN, *ibidem*, 136.
[95] C. LEROUX (et al.), "Suggestions for a green paper on legal issues in robotics", *euRobotics*, 2012, 55.
[96] https://www.ibm.com/watson.
[97] https://www.ibm.com/watson-health.
[98] C. LEROUX (et al.), "Suggestions for a green paper on legal issues in robotics", *euRobotics*, 2012, 55.
[99] Directorate-General For Internal Policies , European Civil Law Rules in Robotics, Study for the JURI Committee, 2016, https://www.europarl.europa.eu/RegData/etudes/STUD/2016/571379/IPOL_STU(2016)571379_EN.pdf.

scheme would be more feasible. One proposition hereto was made by C. HOLDER (et al.)[100]. They suggested a 'no-fault scheme' where the producer is exempt from all liability, while an automatic compensation mechanism covers all damages. This mechanism could be funded by contributions from all producers active in this sector. As a result, the patient will see his damages compensated without lengthy and complex litigations.

In any case, the degree of certainty in the current liability schemes does not always seem to meet expectations one can reasonably expect fully. The existing legal framework is well sufficient to deal with the current surgical 'robots'. However, the well-established use of these robots and, consequently, the incentivized rapid development might soon outpace the framework and perhaps even the capacity to legislate all aspects of it.[101]

[100] C. HOLDER (et al.), "Robotics and law: Key legal and regulatory implications of the robotics ages (part I of II)", *Computer Law & Security Review*, vol. 32, no. 3, 2016, 390.
[101] *Ibid.*, 391.

Part V

American legal approach towards surgical robots

5.1. Regulation on medical devices

5.1.1. Introductory remarks

By 2017, approximately 175.000 different medical devices on the US market were overseen by the FDA Center for Devices and Radiological Health.[102] The FDA defines a medical device as "*an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article*" intended for diagnosing, curing, mitigating, treating or preventing medical conditions.[103] This definition has a high degree of similarity with the definition upheld by the European MDR. The device classification is also very similar to that of the EU: class I (lowest risk), class II (medium risk), and class III (high risk).[104]

Nevertheless, two significant differences exist between both systems. One of the most elicited differences between both systems is the time from concept to market for drugs. Drug review times are significantly shorter at the FDA than the EMA. About 63,7% of the drugs that were brought to market in both the US as the EU, entered the market of the US first and only 90 days later (by average) the European market.[105] There is insufficient data available to verify whether this also applies to surgical robots.

Another notable difference is the transparency of drug approval data. Not all data generated for drug approval is submitted for publication. While the FDA makes said information available for review online and by request, EMA only discloses this data in case of an overriding public interest.[106] This is because, at EMA, the non-published information is considered commercially sensitive.

[102] US Food and Drug Administration Center for Devices and Radiological Health, *Progress in Achieving Our Vision of Patients First*, 2017, 1, https://www.fda.gov/media/104262/download.
[103] Section 201(h) of the Food, Drug & Cosmetic Act. (FD&C Act).
[104] T. MAAK and J. WYLIE, "Medical Device Regulation: A Comparison of the United States and the European Union", *Journal of the American Academy of Orthopaedic Surgeons*, 2016, vol. 24, no. 8, 538.
[105] G. VAN NORMAN, "Drugs and Devices: Comparison of European and U.S. Approval Processes", *Journal of the American College of Cardiology: Basic to Translational Science*, 2016, vol. 1, no. 5, 402.
[106] G. VAN NORMAN, *op. cit.*, 402.

5.1.2. The Da Vinci robot as a landmark

In 2000, the Da Vinci robot by Intuitive Surgical was the first surgical robot to be approved by the FDA. As is the case in the EU, the Da Vinci robot was qualified as a class II device. Apparently, the FDA deemed that "*the leap from hands-on mechanical control of tools to master-slave computer-mediated control did not raise significant new questions about the safety and effectiveness different than those asked for existing devices*".[107] This is also why the FDA does not refer to it as a robot but rather as a robotically-assisted surgical device (RASD).[108] The FDA considers a robot to be able to move within its environment to perform tasks with some degree of autonomy, in line with the ISO definition of a robot.[109] As a result, according to the FDA, "*there are no surgical robots on the market*".[110] Consequently, surgical robots such as the Da Vinci are approved through the 510(k) clearance process and do not require a pre-market authorization (PMA), unlike class III devices.[111] "*Future clearances may require only 90 days versus a PMA approval which can typically take up to a year or more*".[112]

The division between RASD and an autonomous robot is far from clear in many instances, and borderline systems might further challenge the feasibility for a distinctive definition of the word 'robot'.[113] An example of such a 'semi-autonomous' robot is being developed by the Vanderbilt Institute for Surgery and Engineering under the project 'Robot-Enabled Natural Orifice Prostatectomy'.[114] This robot has the shape of a tentacle, formed by extending and rotating curved, concentric tube segments. These help to navigate the needle on the end of the arm along a curved path. Sensors along the tube give the necessary input for the software to avoid touching nerves and blood vessels autonomously. The physician, on the other hand, will be in control at the point of interest.

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[107] D. BRITTON, "Automating Surgery: The Law of Autonomous Surgical Robots", *Life Sciences Innovation: Law 321*, 2016, 15.
[108] X, *FDA Authorizes First Robotically-Assisted Surgical Device for Performing Transvaginal Hysterectomy*, U.S. Food & Drug Administration, 1 March 2021, https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-robotically-assisted-surgical-device-performing-transvaginal-hysterectomy.
[109] ISO 8373:2012.
[110] D. BRITTON, *ibidem.*, 5.
[111] The 510(k) premarket submission has to demonstrate that the to be marketed device is as safe and effective, i.e. substantially equivalent, to a legally marketed device; section 513(i)(1)(A) Food Drug & Cosmetic Act. See also the second paragraph of the next page for an elaboration on this procedure.
[112] Quote by Fred Moll, medical director and co-founder of Intuitive Surgical, in U. JONES, *FDA Clears Robotic Surgical System*, 12 July 2000, https://www.meddeviceonline.com/doc/fda-clears-robotic-surgical-system-0001.
[113] D. BRITTON, *ibidem.*, 6.
[114] M. BUKOWSKI, *VISE affiliates to develop hand-held surgical robot for minimally invasive prostate surgery*, Vanderbilt University, 2 April 2019, https://www.vanderbilt.edu/vise/vise-affiliates-to-develop-hand-held-surgical-robot-for-minimally-invasive-prostate-surgery/.

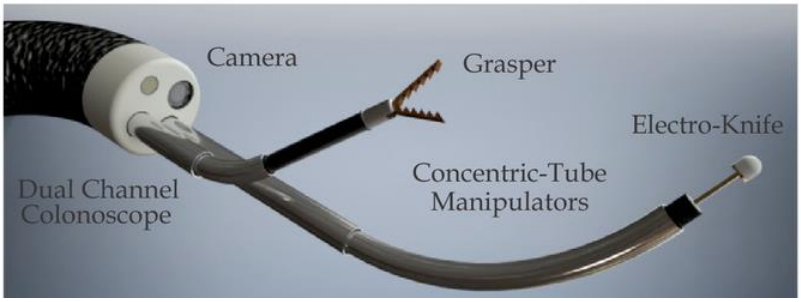

Figure 6: Concentric-tube robot design. Source: R. PONTEN, C. BLACK, A. RUSS and D. RUCKER, "Analysis of a concentric-tube robot design and feasibility for endoscopic deployment", Proc. SPIE, 2017, vol. 10135.

Unlike the Da Vinci robot's master-slave control, the computer algorithms of the concentric tube robot are autonomously making and executing safety-critical control decisions, exhibiting a certain degree of autonomy. It is yet to be seen how (i) the FDA will deal with autonomous robots and (ii) how their level of autonomy will impact this analysis.[115]

The 510(k) procedure requires the demonstration of substantial equivalence to another legally US marketed device. Substantial equivalence means that the new device is as safe and effective as the predicate device.[116] The criteria of this test, set forth by 21 CFR § 807.100(b)(ii)(A), are the following: the medical device

- (b.1.) has the same intended use as the predicate; **and**
- (b.2.i) has the same technological characteristics as the predicate;

  or
- (b.2.ii.A) has the same intended use as the predicate; **and**
- (b.2.ii.B) the information submitted to FDA demonstrates that the device is as safe and effective as the legally marketed device; **and**
- (b.2.ii.C) has different technological characteristics and does not raise different questions of safety and effectiveness.

An autonomous surgical robot will fail this test. On the one hand, no predicate device has autonomous functions. On the other hand, the autonomous capability would be a different technical characteristic that raises a different question of safety and effectiveness compared to master-slave RASD. Especially the last reason would appear to quell any chance of using the 510(k) procedure.[117] The errors triggered by an autonomous device's decision do not necessarily require the physician's misuse or mistake.

[115] See: part III of this paper on the levels of autonomy.
[116] https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k.
[117] D. BRITTON, *op. cit.*, 16.

However, D. BRITTON states that it is plausible that "*federal regulators under pressure to keep regulatory costs low and confronted by these borderline systems might be willing to let more and more automation slide into devices through a series of De Novo*[118] *and 510(k) applications*".[119] For the moment being, it seems manufacturers of autonomous surgical robots will have to follow the PMA-procedure.

5.1.3. The link of the Medical Device Act with liability

As is the case in the European Union, tort liability offers another means for post-market regulation. The liability for defective products is typically governed by state law in the US. Due to the increase of state law regulations on medical devices to deal with injuries and deaths caused by the Dalkon Shield IUD[120], Congress adopted a pre-emption provision in the Medical Device Amendments in 1976. It implies that federal law, when the requirements of 21 US Code § 360k are met, overrules state law and thus state common law tort:

"[…] no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

> *(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and*
>
> *(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."*

In Riegel v. Medtronic, the Supreme Court held that 21 US Code § 360k expressly pre-empts personal injury lawsuits at the state level that challenge the safety or effectiveness of medical devices and only if the device reached the market via a PMA-approval.[121] As a result, the choice

[118] FDA: "*The De Novo process provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device*.", https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request. General controls are regulatory requirements under sections 501, 502, 510, 516, 518, 519, and 520. Special controls are further regulatory requirements specific to class II devices for which general controls alone are deemed insufficient to provide reasonable assurance of safety and effectiveness of the device (e.g. performance standards, postmarket surveillance, special labelling requirements, …) https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls.
[119] D. BRITTON, *op. cit.*, 17.
[120] Approximately 200.000 women made claims against A.H. Robins company, the producer of the Dalkon Shield intrauterine device. Most of these claims were associated with pelvic inflammatory disease and loss of fertility, but also deaths and other injuries occurred; G. KOLATA, *The sad legacy of the Dalkon Shield*, New York Times, 6 December 1987, https://www.nytimes.com/1987/12/06/magazine/the-sad-legacy-of-the-dalkon-shield.html.
[121] Supreme Court of the United States, 20 February 2008, Riegel v. Medtronic, no. 451 F. 3d 104..

between the 510(k)- and PMA-procedure also directly determines how state law will apply to the robot, leaving the FDA with significant discretion regarding new technologies.[122]

Moreover, although a PMA-procedure might be considerably more expensive than a 510(k)-[123] or *De Novo*-procedure,[124] the costs manufacturers can face via tort claims may easily exceed this difference. For producers of autonomous surgical robots, the PMA-path becomes ever more interesting. This potential evolution has a significant drawback for patients in the US. As will be discussed in the following paragraphs, the patient has two options to see compensation for his injuries. First, they can sue the surgeon for medical malpractice (e.g., injury due to the wrongful use of the robot by the surgeon). Second, the patient can go for the manufacturer of a defective product (e.g., when the robot fails and injures the patient). Nevertheless, an autonomous surgical robot may remove the medical malpractice route entirely since the surgeon no longer controls the autonomously executed task. Consequently, a PMA-approved robot would leave the patient without any legal action to find compensation for his injuries.

5.2. Rules on liability

5.2.1. Medical Liability

Medical liability law, in the US referred to as medical malpractice, has been under the authority of the individual states and was developed by rulings in state courts. From the '60s onward, medical malpractice claims in the US started surging to the point that today 99% of physicians in high-risk specialties face at least one lawsuit by age 65.[125] Other sources state that the average physician spends over 10% of his or her career dealing with litigation.[126] More recent reports note even steeper increases than ever before, suggesting that this phenomenon will not stop any time soon. As a result, medical malpractice is a very present yet delicate matter.

a. Essential elements of medical malpractice

In common law, the harmed patient must establish four elements of the tort of negligence:[127]

[122] D. BRITTON, *op. cit.*, 15.
[123] The estimated difference in cost to manufacturers is $60 million; D. BRITTON, *ibidem*, 18.
[124] Cf. footnote 118.
[125] A. JENA, S. SEABURY, D. LAKDAWALLA and A. CHANDRA, "Malpractice Risk According to Physician Speciality", *N Engl J Med*., 2011, vol. 365, no. 7, 365.
[126] https://www.rosenbaumfirm.com/medical-malpractice-statistics.html.
[127] B.S. BAL, "An Introduction to Medical Malpractice in the United States", *Clin Orthop Relat Res.*, 2009, vol. 467, no. 2, 339.

1. duty of care: a legal duty exists whenever a hospital or health care provider undertakes care or treatment of a patient,
2. breach of duty: the provider failed to conform to the relevant standard care (negligence),
3. causation: the breach of duty was a proximate cause of the injury, and
4. harm or damages: without damages (pecuniary, physical, or emotional losses), there is no basis for a claim.

To a certain extent, the first requirement is similar to the criterium used in the Belgian system to distinguish contractual liability from extra-contractual liability. In the US, however, this is an essential requirement to file a medical malpractice complaint. Such legal duty of care is assumed whenever a physician undertakes the care of a patient.[128] This duty of care is not only assumed when a physician is treating patients at a hospital, but also when he provides emergency services to a victim along the road who was in a car accident.[129] If the physician treats the patient outside the hospital or in a more social setting, there is no legal duty owed.

A breach of duty can only exist if the physician did not meet the standard of care. This standard of care can differ among the various states in the US, but a certain similarity exists with the "*bonus medicus*"-approach. It refers to the level at which an ordinary, prudent professional with the same training and experience in good standing in an identical or similar community would practice under the same or similar circumstances. For this, courts focus on the methodology rather than the result.

The third and fourth requirements are causation and harm. As is the case in the Belgian system, the breach of duty is legally meaningless unless it caused damages to the patient. The patient has to prove that a direct link or legally sufficient relationship exists between the breach of duty and the injury. Causation is the most challenging criterium to establish for a patient. Especially in surgery, many complications may develop although the surgery was performed within the standard of care. These are the "accepted risks" of the procedure.

[128] B.S. BAL, *ibidem*, 342.
[129] In these cases, state law may provide for limitations on the liability of the physician providing healthcare services.

b. Medical malpractice and hospitals

As is the case in the Belgian system, hospitals in the US can face liability claims as well. Their liability is triggered by their own negligence or the negligence of one of its employees (i.e., vicarious liability).

A hospital's direct negligence often consists of negligence in the hiring or supervision of its medical staff. In hiring members of this staff, the hospital must make reasonable inquiries into e.g., the applicant's education, training, and specialization. Failing to do so will trigger the "corporate negligence"-doctrine, rendering the hospital liable. Next to that, a hospital has to make sure it is sufficiently staffed at all times to provide the necessary quality healthcare. Moreover, it is also responsible for maintaining and repairing the equipment used at the hospital, which could include surgical robots. For example, if the physician uses the hospital's surgical robot, which the hospital did not maintain properly, both the physician and hospital were negligent, and both will face liability.

When the malpractice by an employee of the hospital injured a patient, the hospital may be held vicariously liable under the legal doctrine of '*respondeat superior'*. Similar to what is known under the Belgian system, the employer can be held liable for the negligent acts of its employee, as long as the employee was acting within the scope of the employment during the negligent act or omission. However, if the physician operates at a hospital as an independent contractor, the '*respondeat superior*'-doctrine does not apply, and thus the hospital can not be charged for vicarious liability.

c. Medical malpractice as a criminal case

Although rarely tried as a criminal case, medical malpractice may very well be a criminal offense when it is proven that the physician or hospital exhibited gross negligence in performing his or her health services.[130] Gross negligence entails extreme indifference to or reckless disregard for the safety of others.[131] For example, a surgeon using a robot during surgery while he has no prior experience with RAS would constitute such recklessness. Moreover, when gross negligence is proven, the prosecutor may ask for punitive damages.[132] If the patient would decease due to the gross negligence of the physician, the latter can be charged for involuntary manslaughter as well.

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[130] The requirements for civil medical malpractice still apply as well.
[131] G. HILL and K. HILL, *The People's Law Dictionary*, New York, MJF Books, 2002, https://legal-dictionary.thefreedictionary.com/gross+negligence.
[132] *Ibid*.

d. Medical malpractice due to RAS and (semi-) autonomous surgical robots

The principles of law that are binding upon professional liability in medicine are precisely the same for robotic surgery. Currently, no real autonomous robots are used in healthcare, nor are they available on the market. Following the definition of the FDA, the 'robots' used today are merely RASD. This implies they can only be regarded as a tool for the surgeon, much like a scalpel or any other surgical device. Nevertheless, once robots enter the market with a certain degree of autonomy, applying medical malpractice principles will become more complex. This is mainly due to the standard of care and what it entails.

Since robotic surgery is still in its infancy, determining whether a particular method or technique is acceptable within the medical society and validated in clinical practice is complicated. Furthermore, suppose the surgeon incorrectly operates the device. In that case, the patient will have to prove that the robotic malfunction risk would have been lower had the procedure been performed by a different surgeon.[133] Finding proof for this might be even more challenging since every robot has a potential risk of malfunctioning.

Next to that, establishing the causal link between the harm and the negligence is also more problematic concerning surgical robots, especially when the malfunction is due to a software problem.[134] It would require significant expert input to prove this causality. Moreover, in the case of robots, other alternative causes may come into play. Robots most likely will be interconnected with many different technologies and rely upon external input and data. This raises the question of whether the damage was triggered by a single original cause or by the interplay of multiple.[135]

5.2.2. Product Liability

While the medical malpractice law of the US shows many similarities with the medical liability laws of the EU, product liability in the US has a broader application. Section 2 of the Restatement (Third) of Torts: Products Liability distinguishes between three major types of product liability claims: (i) marketing defect, (ii) design defect, and (iii) manufacturing

[133] A. FERRARESE (et. al), "Malfunctions of robotic system in surgery: role and responsibility of surgeon in legal point of view", *Open Med (Wars)*, 2016, vol. 11, no. 1, 289.
[134] Expert Group on Liability and New Technologies, "Liability for Artificial Intelligence and Other Emerging Digital Technologies", 2019, 20. Even though this reasoning comes from an European perspective, the same applies mutatis mutandis for the causation theory in the US.
[135] *Ibid*., 22.

defect.[136] These categories are not legal claims in themselves but are pleaded in terms of legal theories, namely: (i) strict liability, (ii) negligence, and (iii) breach of warranty.

Product liability claim	**Legal theory**
Marketing defect	Negligence
Design defect	Negligence
Manufacturing defect	Strict liability

The product liability claim and the respectively legal theory they are most often pleaded in.

a. Marketing defect: failure to warn

Manufacturers of medical devices have an obligation to provide the intended users with the necessary warnings for inherent foreseeable dangers. These are the kind of hazards present with the everyday use of the device, regardless of how well the device was manufactured/designed. To successfully claim a failure to warn, the patient would have to prove that (i) a proper warning was not given and (ii) if such warning were given, the foreseeable harm would not have occurred.[137] However, this obligation lies with the manufacturer, which implies that the patient who would receive robotic surgery must be informed by both the physician (due to the informed consent) and the manufacturer. Such duality may give rise to confusion when the patient weighs the risks and benefits of robotic surgery.

Therefore, product liability law adopted the Learned Intermediary Doctrine.[138] According to this doctrine, the physician is in the best position to decide on the surgical intervention. Consequently, it considers the physician as the end-user, not the patient. As a result, the manufacturer only has to adequately warn and inform the physician of the device's intended use. If done correctly, it further absolves the manufacturer of the obligation to provide the patient with further warnings and shifts the duty to warn and inform to the physician. If the physician would neglect this obligation, he may face medical malpractice claims while the manufacturer goes free.

b. Design defect

When the design of a product is inherently dangerous, regardless of how well it was manufactured, the patient may sue the manufacturer on the grounds of a faulty design.[139] A

[136] T. MCLEAN, "The complexity of litigation associated with roboticsurgery and cybersurgery", *Int J Med Robot*., 2007, vol. 3, no. 1, 25 and F.J. VANDALL, *A History of Civil Litigation: Political and Economic Perspectives*, Oxford University Press, Oxford, 2011, 91.
[137] T. MCLEAN, *op. cit.*, 25.
[138] T. MCLEAN, *ibidem.*
[139] F.J. VANDALL, *op. cit.*, 91.

faulty design claim will be successful if the patient proves that (i) the manufacturer should have known that the design was faulty, (ii) the defective product harmed him or her, and (iii) a safer alternative design was feasible.[140] This might seem straightforward, but more complicated devices require considerable knowledge of software and other engineering skills. It is unlikely in those cases that the patient will experience swift litigation. Some jurisdictions follow the consumer expectations test rather than the alternative design test (also the risk-utility test). Under this test, the product will be considered defective if a reasonable consumer would find it defective. However, considering the complexity of advanced medical devices, the question of what a reasonable consumer can expect may be challenging to answer as well.

c. Manufacturing defect

Manufacturing defects occur when the product departs from its intended design, even though all possible care was exercised in the preparation and marketing of the product. As is the case with design defects, proving a manufacturing defect can be rather tricky since it requires a similar amount of expertise and knowledge, especially with more complex products.

d. Product liability or medical malpractice and the impact of tort reform

It may be well worthwhile for patients to pursue a product liability claim since the damages they can see compensated are much higher than is this case for compensation under a medical malpractice claim. In a successful product liability claim, "*the sky is the limit on the amount of damages that can be recovered*".[141] A manufacturer can face both unlimited economic and non-economic damages. Moreover, punitive damages are possible and act as a deterrence for other manufacturers to refrain from making similar risky products.

Conversely, the compensation for medical malpractice is more limited due to the tort reform. These tort reforms reduce the ability of injured parties to file lawsuits or even reduce the recovery these parties may receive. These reforms are deemed necessary as litigation costs started to increase insurance costs, increasing healthcare costs altogether. The most noteworthy tort reform measure is the caps on non-economic damages. Roughly half of the US states have adopted caps ranging from $250.000 to $750.000 or more.[142] Thirty states have placed a cap on malpractice damages.[143]

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[140] T. MCLEAN, *op. cit.*, 26.
[141] T. MCLEAN, *ibidem*, 27.
[142] See: https://www.millerandzois.com/malpractice-damage-caps.html and https://centerjd.org/content/fact-sheet-caps-compensatory-damages-state-law-summary.
[143] The tort reforms are heavily criticized and even found unconstitutional in several states such as Illinois, Alabama and New Hampshire. Some states (e.g. Kentucky, Arizona, Pennsylvania, …) prohibit caps altogether.

State	Cap on non-economic damages in medical malpractice
Alaska	$250.000 or $400.000 (in case of death or severe disability)
California	$250.000
Colorado	$300.000
Florida	$500.000 or $1.000.000 (in case of catastrophic injury
New York	None
Illinois	$500.000 (but was found unconstitutional)

Some examples of non-economic damages caps in medical malpractice cases

Moreover, some states have accepted absolute caps, limiting the total compensation a patient may receive with a medical malpractice lawsuit (economic and non-economic). Consequently, the state is of critical importance for the patient when filing a lawsuit for medical malpractice. Although eight states accepted non-economic damages caps for product liability cases,[144] this pathway is, compensation-wise, often more beneficial for the patient.

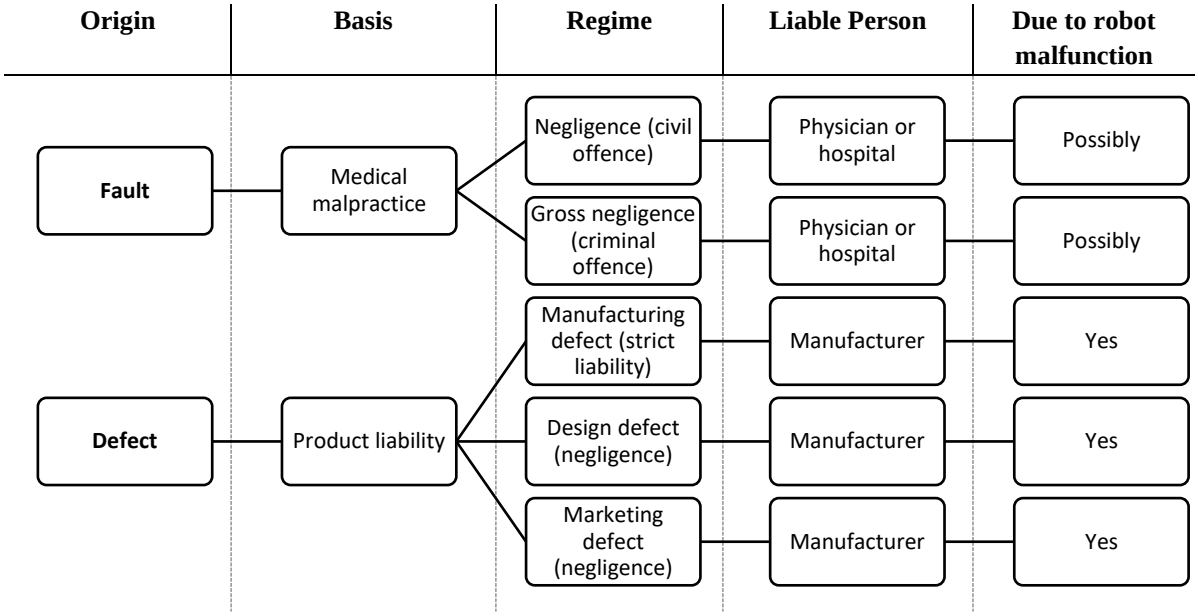
5.2.3. Interim Conclusion on US liability

While the patient has four legal actions at his disposal, applying these schemes to surgical robots with an autonomous component is not straightforward. Especially the design and manufacturing defect impose new hurdles for the patient. More advanced surgical robots would consist of many different parts, technologies, and software. It requires considerable expertise to successfully establish such a claim as the non-adversarial failure is often far from clear. As the burden of proof lies with the patient, it may further deter patients from suing the manufacturer of an autonomous surgical robot. Moreover, product liability might even be exempted if the robot was PMA-approved, leaving the patient uncompensated.

With regards to medical malpractice, surgeons will have to be prudent. On the one hand, they must carefully decide whether or not a RAS is more beneficial for the patient and duly inform the latter. Furthermore, the physician needs to provide the patient with sufficient warnings for the robotic device due to the learned intermediary doctrine. In the future, this might become problematic as a physician will have to understand engineering and programming to a certain extent to comprehend the risks associated with surgical robots entirely. On the other hand, the surgeon must be proficient at RAS since inadequate training might lead to medical malpractice claims.

[144] Alaska, Colorado, Hawaii, Idaho, Maryland, Mississippi, Ohio, and Tennessee, see: https://centerjd.org/content/fact-sheet-caps-compensatory-damages-state-law-summary.

To conclude, the US liability laws provide the patient with a clear framework of pathways to invoke liability from the physician or manufacturer or both. Nevertheless, the system is hampered by the same difficulties encountered under the European approach; when surgical robots become more complex tools or even fully autonomous devices, the costs and time of litigation will increase tremendously.



Part VI

Comparison of the EU and US liability framework

6.1. Similarities

Both the EU and the US framework provide several pathways to invoke liability, categorized in a duality of malpractice and product defects. At first glance, both systems appear to be similar, but, as is often the case, the devil is in the details. In what follows, the similarities and differences will be further discussed, together with the accompanying difficulties in litigation for the patients of RAS.

6.1.1. The opposable parties

As stated above, both European and American patients can move against the surgeon, hospital, manufacturer, or all of them together. Much will depend on the cause of the harm to the patient. Malpractice by the surgeon will trigger the surgeon's or the hospital's liability, while a malfunction of the surgical robot will open the pathway for liability of the manufacturer. In addition, a patient could simultaneously be injured both by medical malpractice and a product defect. For example, if the patient was harmed by a defect of the robot for which the manufacturer did not warn the physician but should have been discovered had the surgeon had adequate training, both parties can be held liable. A careful analysis of the harmful cause is required to define the liable parties.

6.1.2. Medical liability

Regarding medical liability, both the European and American approaches set forth a similar set of prerequisites to establish the physician's liability (cause, harm, and causal link). For robotic surgery, the cause is most problematic. The "*bonus-medicus*"-doctrine and the standard of care play an equivalent role, establishing a particular benchmark for a physician to oblige: the level at which an ordinary, prudent professional with the same training and experience in good standing in an identical or similar community would practice under the same or similar circumstances.

Case law and development in the relevant field of work (i.e., surgery) shape this benchmark. Considering the nascent stage of robotic surgery, establishing whether the use of a surgical robot adheres to this benchmark is often ambiguous. When a physician with no or minimal robotic surgery training harms the patient, proving this breach of the benchmark is

straightforward. However, in most cases establishing this breach is trickier. For example, if a patient would deem that robotic surgery was more harmful than open surgery, his burden of proof increases. The patient will have to prove that open surgery was a better alternative and that another physician under the same circumstances would have chosen open surgery. This requires considerable expertise and data to demonstrate. Moreover, many scholars and researchers either promote or combat the presumed benefits of robotic surgery and hereby further complexify a clear answer to this conundrum.

6.1.3. Product liability

a. Strict liability

Although the US product liability framework differs significantly from the European product liability law, some similarities emerge. One of these parallels includes the strict liability approach. Therefore, the European Directive on Defective Products and the second restatement of torts consider the presence of a fault on behalf of the manufacturer irrelevant.[145] In light of the third restatement of torts, many states in the US have curbed this strict liability to manufacturing defects. Critics of the second restatement argued that strict liability for design defects and failure-to-warn is neither fair nor efficient.[146] This approach incentivizes manufacturers to reach optimal safety of their products while also promoting settling disputes out of court (with strict liability, only the damages are disputable, making it more susceptible to settlements).[147]

b. Consumer expectations test

The consumer expectations test constitutes another similarity between the European Directive and the manufacturing defects regime. As mentioned before, this test considers the public's legitimate expectations to determine the defectiveness of a product. Determination of the publics' expectations encompasses various challenges since the field of surgical robots is rapidly evolving.

[145] Article 4, Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, *OJ.L.*, 7 August 1985, no. 210: "*The injured person shall (only) be required to prove the damage, the defect and the causal relationship between defect and damage*".
[146] J. CASTILLO, "Products Liability in Europe and the United States", *Revista Chilena de Derecho*, 2012, vol. 39, no. 2, 292-293.
[147] *Ibid*., 291.

6.2. Differences

6.2.1. Medical liability

b. Trend towards no-fault systems

The differences in medical liability between European countries and the US do not primarily occur in the legal prerequisites but rather in the systems accompanying medical malpractice. The European trend to incorporate no-fault compensation systems for patients increases the chance of redress for patients. No such trend manifests in the US as of yet, despite the benefits. Firstly, the patient will not have to prove the physician's negligence, reducing the process's costs, length, and adversarial nature. Secondly, the compensation is moderate but just. This results in a reduction of lengthy malpractice cases in court, while patients have more options for redress.

Moreover, no-fault compensation might provide an ideal ground for redress in cases of RAS when it is unclear whether the adverse event is induced by the surgeon or the robot's malfunction. However, it remains uncertain if the no-fault systems would reduce the overall societal costs for malpractice, as minor malpractice claims might increase.[148] Furthermore, semi-no-fault systems, such as the one in Belgium, might surge defensive medicine (i.e., the physician's behavior of recommending a diagnostic test or medical treatment that is not necessarily the best option for the patient but to protect the physician against liability.[149] Avoiding high-risk patients forms another externalization of defensive medicine).[150]

b. Trial by jury

The trial by jury demonstrates another diverging system in the US.[151] European countries do not allow trial by jury for medical malpractice claims, but the judge decides on the issue at

[148] T. VANDERSTEEGEN, W. MARNEFFE and D. VANDIJCK, "Physician Specialists' Perception of the Medical Malpractice System in Belgium", European Journal of Health Law, 2015, vol. 22, no. 5, 489 and X., *Medical Liability: A World of Difference*, *American Medical News*, 2010, https://amednews.com/article/20100503/profession/305039938/4/.

[149] M. CATINO, "Why do Doctors Practice Defensive Medicine: The Side-Effects of Medical Litigation", *Safety Science Monitor*, 2011, vol. 15, no. 1, 1.

[150] M. CATINO, "Why do Doctors Practice Defensive Medicine: The Side-Effects of Medical Litigation", Safety Science Monitor, 2011, vol. 15, no. 1, 1 and T. VANDERSTEEGEN, W. MARNEFFE and D. VANDIJCK, "Physician Specialists' Perception of the Medical Malpractice System in Belgium", *European Journal of Health Law*, 2015, vol. 22, no. 5, 481-491, and T. VANDERSTEEGEN, W MARNEFFE, I. CLEEMPUT, D. VANDIJCK and L. VEREECK, "The determinants of defensive medicine practices in Belgium", *Health Economic, Policy and Law*, 2017, vol. 12, 363-386.

[151] J-M. GROSSEN and O. GUILLOD, "Medical Malpractice Law: American Influence in Europe?", *Boston College International and Comparative Law Review*, 1983, vol. 6, no. 1, 19. This study found eight reasons for the discrepancy between the American and European situations. Although some of the aspects are slightly outdated, the element of trial by jury is still applicable to the American system and absent in European case law.

hand. Scholars indicated that juries favor plaintiffs as they more often base their decision on emotional rather than rational grounds.[152] Medical malpractice forms a challenging matter to comprehend for laypeople. Furthermore, the intricacy of RAS complicates a sufficient understanding for a jury of non-specialists.

These differences result in more options for redress for European patients in cases of medical malpractice. The trend of no-fault compensation provides a pathway for European patients when it is unclear if RAS inflicted their injury, while American patients would remain empty-handed. Conversely, the US concept of trial by jury might be more beneficial than judges' decisions for the patients.

6.2.2. Product liability

Both the European and American approach to product liability find their roots in strict liability. However, the third restatement of torts has partially diverged from this path, reintroducing the negligence-based fault for both design defects and failures to warn. In contrast, European legislation has not created an opening for negligence-based claims in product liability. Consequently, both approaches differ considerably regarding design defects.

b. Risk-utility test

When a surgical robot's design would be flawed, courts of the European member states will have to apply the consumer expectations test, while US courts use the risk-utility test. Some scholars deem that the risk-utility test is more effective since "*consumers are generally unable to judge how an alternative design will affect the product's overall safety or how a complex product should function*".[153] Moreover, "*consumer expectations are subjective and courts often end up engaging in some form of risk utility balancing so that they may consider reasonable alternative designs*".[154,155] Next to that, the adoption of the consumer expectations test in the EU directive also impacts the definition of a defect. National courts of the member states had to interpret Article 6 and the concept of a defect in light of the consumer expectations test.[156]

[152] J-M. GROSSEN and O. GUILLOD, "Medical Malpractice Law: American Influence in Europe?", *Boston College International and Comparative Law Review*, 1983, vol. 6, no. 1, 20.
[153] L. STERRET, "Product Liability: Advancements In European Union Product Liability Law And A Comparison Between The EU And US Regime", *Michigan State International Law Review*, vol. 23, no. 3, 2015, 900.
[154] Some states in the US use a mix of the risk-utility test and consumer expectations test (e.g., Supreme Court of California, 16 January 1978, Barker v. Lull Engineering Co, Eng'g Co., 20 Cal. 3d 413.).
[155] L. STERRET, *op. cit.*, 900.
[156] See: Bundesgerichtshof (GER), 5 February 2013, nr. VI ZR 1/12 and High Court of Justice (UK), 26 March 2001, A v. National Blood Authority, 3 All E.R. 289.

Consequently, the US' third restatement offers a more comprehensive definition of what is considered a defect.

b. Distributing actors

The European directive also treats economic operators differently than the US regime. The directive defined a producer to include anyone, from the manufacturer of a finished product to individuals who import and distribute products.[157] This creates a cascade: if the producer cannot be identified, the supplier may be treated as the producer unless he informs the consumers of the producer's identity.[158] Although the third restatement also allows the injured party to sue the supplier, state law often shields the latter from strict liability.[159]

c. Punitive damages

Another significant difference between the EU and US systems arises from the types and amount of compensation available to the injured party. As mentioned before, in US product liability claims, courts allow for punitive damages.[160] In contrast, The majority in European jurisdictions consider punishment as reserved primarily for criminal law.[161] The caps introduced by the third restatement have partially mitigated this. However, US attorneys attempt to circumvent these restrictions by either focusing on less restricted compensatory damages, such as damages for pain and suffering or suing the plaintiff in a less regulated state.[162]

d. Exemptions

Finally, both systems allow manufacturers to exonerate themselves from liability under certain circumstances. The 'state of the art'-exemption, provided by the European directive, exonerates the manufacturer when the state of scientific and technical knowledge when he put the product into circulation was not such as to enable the existence of the defect to be discovered.[163] Although the American product liability framework also grants this defense, it is

[157] Article 3, Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, *OJ.L*., 7 August 1985, no. 210.
[158] *Ibid*.
[159] Restatement (Third) of Torts: Product Liability, §1, comment e.
[160] B.L. GUENDLING, "Product-Liability Risk Exposure in the US and Europe", *Michigan Bar Journal*, 2016, 20.
[161] *Ibid*.
[162] *Ibid*.
[163] Article 7, (e), Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, *OJ.L*., 7 August 1985, no. 210.

not considered absolute, but rather a relevant criterion[164] US law establishes many other exemptions for US manufacturers, of which the federal pre-emption is most common in medical device cases.[165] The exemption of tort law for PMA-approved medical devices features the most prevalent example.[166] As discussed before, this exemption offers a considerable benefit for the manufacturers of surgical robots, namely eliminating their risks for tort litigation.

To conclude, the European directive exhibits a more consumer-friendly approach, granting injured patients more accessible options for redress for injuries from defective products.

[164] Restatement (Third) of Torts: Product Liability, §2, comment d. and L. STERRET, "Product Liability: Advancements In European Union Product Liability Law And A Comparison Between The EU And US Regime", *Michigan State International Law Review*, vol. 23, no. 3, 2015, 906.
[165] Supreme Court of the United States, 20 February 2008, Riegel v. Medtronic, no. 451 F. 3d 104..
[166] 21 US Code § 360k.

Part VII

Conclusion

It stands to reason that both the EU and US frameworks for liability regarding surgical robots provide patients with several pathways to find compensation for their injuries. The emergence of surgical robots did not engender the necessity of entirely new routes for redress at present. Medical malpractice or defective product liability may be invoked depending on the cause of the injury (wrongful use or non-adversarial effect). This two-track system exhibits sufficient flexibility to encroach nascent developments such as robotic surgery and retains this pliability for as long as robots are considered mere tools. Nevertheless, one significant discrepancy appears regarding no-fault injuries in healthcare. In this scenario, the European patient can often find compensation via a fund. Such compensation mechanism is absent in the US, leaving the patient empty-handed.

Even so, providing these pathways does not guarantee redress, as each pathway has several prerequisites a patient has to prove. All of these imperatives were drafted in a time when surgical robots were merely a vague concept without considerable impact on society. Hence, applying these prerequisites to surgical robots calls for substantial flexibility and knowledge in the relevant matter. The discussion on the European and American framework underscored similar difficulties in all pathways.

Firstly, ascertaining the causal nexus between the breach of duty (medical malpractice) or defect (product liability) and the damage requires an in-depth analysis of the robot and its functioning. As mentioned before, surgical robots exhibit a complex interaction of multiple elements, all of which are susceptible to external influence. Hence, several jurisdictions in the EU (e.g., Belgium) allow the judge to infer a causal relationship between the damage and the defect, practically deviating from the standard established by the Directive on Defective Products.

Secondly, the notion of a defect under product liability may be problematic. The consumer expectations test has shown its merit for everyday products, but it falls short in technologically complex products. Determining the degree of safety consumers may expect from surgical robots will undoubtedly become a trigger for many disputes. In addition, establishing the defectiveness of a product in case of a design defect becomes even more burdensome, requiring a wide variety of skills the patient might not possess.

Lastly, the frameworks provide several exemptions exonerating the manufacturer from liability entirely. During litigation, patients may often encounter the PMA-preemption or the 'state of the art'-defense. These exemptions severely diminish their chances of redress, as a medical malpractice claim would require the physician's breach of the standard of duty.

All of this frustrates the idea of easily accessible redress for patients. The adherence to traditional tort law, which puts the burden of proof on the patient's shoulders, will complicate litigation regarding RAS to the point that it may dissuade the patient from filing a claim altogether. However, the new generation of robots displays higher degrees of autonomy, including the possibility to self-learn (e.g., Watson). In this case, the robot is no longer considered a tool but rather an agent with its own behavior, which will spark discussions on whether or not the manufacturer or physician can be held liable for this self-taught behavior. The time has come for legislators to reconsider the current framework to ascertain that sufficient and feasible mechanisms for compensation are available for patients.

Bibliography

1. Legislative works

1.1. European Union

Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, *OJ.L.*, 7 August 1985, no. 210.

Council Directive 90/385/EEC on Active Implantable Medical Devices, *OJ.L.*, 20 July 1990, no. 189.

Council Directive 93/42/EEC on Medical Devices, *OJ.L.*, 12 July 1993, no. 169.

Directive 98/79/EC of the European Parliament and of the Council on in vitro Diagnostic Medical Devices, *OJ.L.*, 7 December 1998, no. 331.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, *OJ.L.*, 5 May 2017, no. 117.

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, *OJ.L.*, 5 May 2017, no. 117.

1.2. United States

Code of Federal Regulations.

Restatement (Third) of Torts: Product Liability, 1998.

1.3. Belgium

Burgerlijk Wetboek of 21 March 1804, *BS* 3 September 1807.

Strafwetboek of 8 June 1867, *BS* 9 June 1867.

2. Case law

2.1. United States

Circuit Court of Cook County, 17 February 2012, Lenika Fernandez, etc. v. George Salti M.D., et al., no. 08 L 1117.

Supreme Court of California, 16 January 1978, Barker v. Lull Engineering Co, Eng'g Co., 20 Cal. 3d 413.

Supreme Court of the United States, 20 February 2008, Riegel v. Medtronic, no. 451 F. 3d 104.

2.2. Belgium

Cass. 7 December 1973, *Arr. Cass*. 1974.

Cass. 1 December 1994, *Arr. Cass*. 1994, no. 2, 1032.

Cass. 28 September 1995, *Arr. Cass*. 1995, 828.

Cass. 14 December 2001, *Arr.Cass*. 2001, no. 10, 2200, concl. J. DUJARDIN.

Cass. 28 February 2002, *T. Gez* 2002-03, no. 1, 12.

Cass. 20 March 2003, *Arr. Cass*. 2003, no. 3, 691, concl. DE RIEMAECKER.

Cass. 17 September 2003, *J.T*. 2003, 95.

Cass. 25 April 2005, *Arr. Cass*. 2005, no. 4, 928.

Cass. 12 May 2006, *Arr.Cass.* 2006, no. 5, 1084.

Cass. 11 January 2019, *T. Gez*. 2018-19, no. 5.

Rb. Brussel 12 mei 1997, *T.Gez*. 1999-00, 289.

2.3. Other

High Court of Justice (UK), 26 March 2001, A v. National Blood Authority, 3 All E.R. 289.

Bundesgerichtshof (GER), 5 February 2013, nr. VI ZR 1/12.

3. Literature

3.1. Books

BOCKEN, H. en BOONE, I., *Inleiding tot het schadevergoedingsrecht: buitencontractueel aansprakelijkheidsrecht en andere vergoedingsstelsels*, Brugge, Die Keure, 2011, 284 p.

BROWNSWORD, R., *Rights, Regulation and the Technological Revolution*, Oxford, Oxford University Press, 2008, 300 p.

DE BRUYNE, J. and TANGHE, J., "Software aan het stuur: Aansprakelijkheid voor schade veroorzaakt door autonome motorrijtuigen", in VANSWEEVELT, T. en WEYTS, B., *Nieuwe risico's in het aansprakelijkheids- en verzekeringsrecht*, Antwerpen, Intersentia, 2018, 1-75.

HILL, G. and HILL, K., *The People's Law Dictionary*, New York, MJF Books, 2002, 476 p.

JACQUEMENT, H. and HUBIN, J.B., "Aspects contractuels et de responsabilité civile en matière d'intelligence artificielle" in JACQUEMENT, H. and DE STREEL, A., *L'intelligence artificielle et le droit*, Brussels, Larcier, 2017, 73-141.

KURFESS, T.R., *Robotics and Automation Handbook*, Florida, CRC Press, 2018, 608 p.

MARCHANT, G., ALLENBY, B. and HECKERT, J. (eds.), *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem*, Dordrecht, Springer, 2011, 212 p.

RICHARD, N.M. and SMART, W.D. "How should the law think about robots?" in CALO, R., FROOMKIN, A.M. and KERR, I. (eds.), *Robot law*, Cheltenham, Edward Elgar Publishing, 2016, 3-22.

RUSSELL, H., MENCIASSI, A., FICHTINGER, G. and DARIO, P., "Medical Robotics and Computer-Integrated Surgery" in SICILIANO, B. and KHATIB, O., *Handbook of Robotics*, Dordrecht, Springer, 2008, 1627 p.

SCHWEIKARD, A. and ERNST, F., *Medical Robots*, Dordrecht, Springer, 2015, 424 p.

SIMPSON, J.A. and WEINER, E.S.C., *Oxford English Dictionary*, Oxford, Oxford University Press, 2020, 22.000 p.

VANDALL, F.J., *A History of Civil Litigation: Political and Economic Perspectives*, Oxford University Press, Oxford, 2011, 262 p.

VANDENBERGHE, H., "Medische aansprakelijkheid" in VANDENBERGHE, H. (ed.), *De professionele aansprakelijkheid*, Brugge, Die Keure, 2004, 286 p.

VANSWEEVELT, T., "De civielrechtelijke aansprakelijkheid van ziekenhuizen en ziekenhuisgeneesheren", in CLAASSENS, H., COUSY, H. en HERBOTS, J. (eds.), *De aansprakelijkheid in ziekenhuisverband*, Gent, Mys en Breesch, 1994, 150 p.

VANSWEEVELT, T., *De civielrechtelijke aansprakelijkheid van de geneesheer en het ziekenhuis*, Antwerp, Maklu, 1997, 938 p.

VANSWEEVELT, T. and WEYTS, B., *Handboek Buitencontractueel Aansprakelijkheidsrecht*, Antwerp, Intersentia, 2009, 935 p.

3.2. Articles

ALEMZADEH, H., IYER, R., KALBARCZYK, Z., LEVESON, N. and RAMAN, J., "Adverse Events in Robotic Surgery: A Retrospective Study of 14 years of FDA Data", *PLoS One*, 2015, vol. 11, no. 4, 30 p.

BAL, B.S., "An Introduction to Medical Malpractice in the United States", *Clin Orthop Relat Res.*, 2009, vol. 467, no. 2, 339-347.

BARFIELD, W., "Liability for Autonomous and Artificially Intelligent Robots" in *Paladyn, Journal of Behavioral Robotics*, 2018, vol. 9, no. 1, 193-203.

BRITTON, D., "Automating Surgery: The Law of Autonomous Surgical Robots", *Life Sciences Innovation: Law 321*, 2016, 34 p.

CALO, R., "Robotics in American Law", *University of Washington School of Law Legal Studies Research Paper Series*, 2016, no. 2016-04, 45 p.

CASTILLO, J., "Products Liability in Europe and the United States", *Revista Chilena de Derecho*, 2012, vol. 39, no. 2, 277-296.

CATINO, M., "Why do Doctors Practice Defensive Medicine: The Side-Effects of Medical Litigation", *Safety Science Monitor*, 2011, vol. 15, no. 1, 1-12.

FERRARESE, A. (et. al), “Malfunctions of robotic system in surgery: role and responsibility of surgeon in legal point of view”, *Open Med (Wars)*, 2016, vol. 11, no. 1, 286-291.

FOSCH VILLARONGA, E. and MILLARD, C., “Cloud Robotics Law and Regulation”, *Queen Mary School of Law Legal Studies Research Paper*, 2018, no. 295/2018, 32 p.

GEORGE, B.C., BOHNEN, J.D., WILLIAMS, R.G. (et al.), “Readiness of US General Surgery Residents for Independent Practice”, *Annals of Surgery*, 2018, vol. 267, no. 3, 582–594.

GLASS, B.D., “Counterfeit drugs and medical devices in developing countries”, *Research and Reports in Tropical Medicine,* 2014, vol. 5, 11-22.

GLENDE, S., CONRAD, I., KREZDORN, L., KLEMCKE, S. and KRÄTZEL, C., “Increasing the acceptance of assistive robots for older people through marketing strategies based on stakeholders needs” in *Int J Soc Robot*, 2016, vol. 8, 355–369.

GOELDNER, M. , HERSTATT, M. and TIETZE, C., “The emergence of care robotics—a patent and publication analysis” in *Technol Forecast Soc Change* , 2015, vol. 92, 115–131.

GROSSEN, J.M. and GUILLOD, O., “Medical Malpractice Law: American Influence in Europe?”, *Boston College International and Comparative Law Review*, 1983, vol. 6, no. 1, 1-27.

GUENDLING, B.L., “Product-Liability Risk Exposure in the US and Europe”, *Michigan Bar Journal*, 2016, 18-21.

HOLDER, C. (et al.), “Robotics and law: Key legal and regulatory implications of the robotics ages (part I of II)”, *Computer Law & Security Review*, 2016, vol. 32, no. 3, 383-402.

HONDIUS, E., “Comparative medical liability in Europe” in *Festschrift für Hans Stoll zum 75. Geburtstag*, Mohr Siebeck, Tübingen, 2001, 185-194.

JENA, A., SEABURY, S., LAKDAWALLA, D. and CHANDRA, A., “Malpractice Risk According to Physician Speciality”, *N Engl J Med*., 2011, vol. 365, no. 7, 629-636.

JOHANSSON-PAJALA, R.M., THOMMES, K. and HOPPE, J.A. (et al.), “Care Robot Orientation: What, Who and How? Potential Users’ Perceptions” in *Int J of Soc Robotics*, 2020, vol.12, 1103-1117.

LANFRANCO, A. (et al.), "Robotic Surgery A Current Perspective", *Annals of Surgery*, 2004, Vol. 239, No. 1, 14-21.

LEROUX, C. (et al.), "Suggestions for a green paper on legal issues in robotics", *euRobotics*, 2012, 78 p.

LINZER, N., "An ethical dilemma in home care" in *J Gerontol Soc Work, 2002*, vol.37, no. 2, 23–34.

LOUKIDES, M., "AI Adoption in the Enterprise 2021", *O'Reilly*, 2021, 26 p.

LUDVIGSEN, K. and NAGARAJA, S., "Dissecting liabilities in adversarial surgical robot failures: A national (Danish) and European law perspective", *ArXiv*, 2020, 38 p.

MAAK, T. and WYLIE, J., "Medical Device Regulation: A Comparison of the United States and the European Union", *Journal of the American Academy of Orthopaedic Surgeons*, 2016, vol. 24, no. 8, 537-543.

MCLEAN, T., "The complexity of litigation associated with roboticsurgery and cybersurgery", *Int J Med Robot*., 2007, vol. 3, no. 1, 23-29.

PANAGIOTOU, A., "Medical Liability in Europe at the Dawn of Cross-border Healthcare: Time to Reflect on the Possibility of Harmonising the Policies Regarding Medical Liability?", *European Journal of Health Law*, 2016, vol. 23, no. 4, 350-372.

PARASURAMAN, R., SHERIDAN, T.B. and WICKENS, C.D., "A model for types and levels of human interaction with automation", *IEEE Transactions on Systems, Man, and Cybernetics - Part A: Systems and Humans*, 2000, vol. 30, no. 3, p. 286-297.

ROBINSON, T.N. and STIEGMANN, G.V., "Minimally Invasive Surgery" in *Endoscopy*, Stuttgart, Thieme Medical Publishers, 2004, vol.36, no. 1, 48-51.

SAYBURN, A., "Will the machines take over surgery?", *Royal College of Surgeons of England*, 2017, vol. 99, no. 3, 88-90.

SHARKEY, A. and SHARKEY, N., "Granny and the robots: ethical issues in robot care for the elderly" in *Ethics Inf Technol*, 2012, vol.14, no. 1, 27-40.

STERRET, L., “Product Liability: Advancements In European Union Product Liability Law And A Comparison Between The EU And US Regime”, *Michigan State International Law Review*, vol. 23, no. 3, 2015, 885-925.

VANDERSTEEGEN, T., MARNEFFE, W. and VANDIJCK, D., “Physician Specialists’ Perceptions of the Medical Malpractice System in Belgium”, *European Journal of Health Law*, 2015, vol. 22, no. 5, 481-491.

VANDERSTEEGEN, T., MARNEFFE, W., CLEEMPUT, I., VANDIJCK, D. and VEREECK, L., “The determinants of defensive medicine practices in Belgium”, *Health Economic, Policy and Law*, 2017, vol. 12, 363-386.

VAN NORMAN, G., “Drugs and Devices: Comparison of European and U.S. Approval Processes”, *Journal of the American College of Cardiology: Basic to Translational Science*, 2016, vol. 1, no. 5, 399-412.

YANG, G.Z. (et. al), “Medical robotics – Regulatory, ethical, and legal considerations for increasing levels of autonomy”, *Science Robotics*, 2017, vol.2, no. 4, 3 p.

4. Institutional documents

4.1. European Union

European Commission, Proposal for a Regulation Of The European Parliament And Of The Council Laying Down Harmonised Rules On Artificial Intelligence (Artificial Intelligence Act) And Amending Certain Union Legislative Acts, COM(2021)206, 21 April 2021.

European Commission, Proposal for a Regulation Of The European Parliament And Of The Council On Machinery Products, COM(2021)202, 21 April 2021.

European Commission, “Europe fit for the Digital Age: Commission proposes new rules and actions for excellence and trust in Artificial Intelligence”, Press release, Brussels, 21 April 2021, https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1682.

Directorate-General For Internal Policies , *European Civil Law Rules in Robotics*, Study for the JURI Committee, 2016, 34 p.

Expert Group on Liability and New Technologies, "Liability for Artificial Intelligence and Other Emerging Digital Technologies", *Publications Office of the EU*, 2019, 70 p.

4.2. United States

US Food and Drug Administration Center for Devices and Radiological Health, *Progress in Achieving Our Vision of Patients First*, 2017, 8p., https://www.fda.gov/media/104262/download.

5. Internet sources

5.1. Articles

BUKOWSKI, M., *VISE affiliates to develop hand-held surgical robot for minimally invasive prostate surgery*, Vanderbilt University, 2 April 2019, https://www.vanderbilt.edu/vise/vise-affiliates-to-develop-hand-held-surgical-robot-for-minimally-invasive-prostate-surgery/.

DONOVAN, A., 15 Medical Robots That Are Changing the World, Interesting Engineering, 3 November 2020, https://interestingengineering.com/15-medical-robots-that-are-changing-the-world.

GAYLE D., TOPPING, A., SAMPLE, I., MARSH, S. and DODD, V., *NHS seeks to recover from global cyber-attack as security concerns resurface*, The Guardian, 13 May 2017, https://www.theguardian.com/society/2017/may/12/hospitals-across-england-hit-by-large-scale-cyber-attack.

JONES, U., *FDA Clears Robotic Surgical System*, 12 July 2000, https://www.meddeviceonline.com/doc/fda-clears-robotic-surgical-system-0001.

KOLATA, G., *The sad legacy of the Dalkon Shield*, New York Times, 6 December 1987, https://www.nytimes.com/1987/12/06/magazine/the-sad-legacy-of-the-dalkon-shield.html.

MARTENS, K., *Cyberdyne Bringing HAL Cyborg Exoskeleton to US Market*, Lexology, 2018, https://www.lexology.com/.

MILHIZER, P., *Family gets $7.5 million in death after spleen removal*, Chicago Daily Law Bulletin, 21 February 2012, https://www.personalinjurylawchicago.com/documents/Spleen.pdf.

MOORE, E.J., *Robotic surgery, medical technology*, Encyclopaedia Britannica, 18 November 2015, https://www.britannica.com/science/robotic-surgery.

X, *5 Medical Robots Making a Difference*, Case School of Engineering, 28 December 2017, https://online-engineering.case.edu/blog/medical-robots-making-a-difference.

X, *Medical Liability: A World of Difference*, American Medical News, 3 May 2010, https://amednews.com/article/20100503/profession/305039938/4/.

X, *Ransomware cyberattack : UK's health system recovered from hacking, interior minister says*, ABC News, 13 May 2017, https://www.abc.net.au/news/2017-05-13/ransomware-cyberattack:-technicians-work-to-restore-systems/8524170.

X, *The presence of tech giants in Europe is changing the dynamics of the region's talent pool*, State of European Tech Report, 2017, https://2017.stateofeuropeantech.com/chapter/talent/article/big-tech-giants-are-growing-presence/.

X, *How Exoskeletons Are Being Leveraged For More Than Healthcare*, Association for Advanced Automation, 1 June 2020, https://www.automate.org/blogs/how-exoskeletons-are-being-leveraged-for-more-than-healthcare.

X., *Attacks targeting healthcare organizations spike globally as COVID-19 cases rise again*, Check Point Blog, 5 January 2021, https://blog.checkpoint.com/2021/01/05/attacks-targeting-healthcare-organizations-spike-globally-as-covid-19-cases-rise-again/.

X, *FDA Authorizes First Robotically-Assisted Surgical Device for Performing Transvaginal Hysterectomy*, U.S. Food & Drug Administration, 1 March 2021, https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-robotically-assisted-surgical-device-performing-transvaginal-hysterectomy.

X, *Da Vinci Robot Lawsuit – Settlement Info*, Drug Dangers, https://www.drugdangers.com/da-vinci/robot-lawsuit/.

5.2. Other

https://www.orsi-online.com/nl.

https://www.oxfordreference.com/view/10.1093/oi/authority.20110803095426960.

www.aethon.com/tug/tughealthcare/.

https://ec.europa.eu/health/md_sector/overview_en..

https://www.technologyreview.com/2017/12/04/147323/europe-is-struggling-to-keep-local-talent-for-its-homegrown-tech-scene/.

https://www.ibm.com/watson-health.

https://www.ibm.com/watson.

https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k.

https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request.

https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls.

https://www.rosenbaumfirm.com/medical-malpractice-statistics.html.

https://www.millerandzois.com/malpractice-damage-caps.html.

https://centerjd.org/content/fact-sheet-caps-compensatory-damages-state-law-summary.

6. Other sources

LAVOUE, V., “Quel rationnel médico-économique de la chirurgie robot-assistée pour les pathologies bénignes ?”, *Société de Chirurgie Gynécologique et Pelvienne*, Webinar, 11 May 2021.

Robotgeassisteerde chirurgie: health technology assessment, KCE reports 104A, Federaal Kenniscentrum voor de Gezondheidszorg, 2009, 64.