Who is to blame? Autonomous surgical robots and liability issues

Are the current EU and national frameworks of France and Germany equipped to deal with healthcare liability in cases involving autonomous surgical robots?

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Chapter 1: Introduction

1.1 Background and problem statement

Artificial Intelligence (AI) and, more specifically, AI-driven robots are becoming increasingly embedded in our society. In the US, a test involving 1400 self-driving cars is currently being done on public roads, and algorithms are used to analyse and predict different aspects of human life, such as the spread of diseases.[1] In healthcare, approximately 86% of health care providers utilise some form of AI in their practices.[2] The use of AI has proven to be extremely helpful in diagnosing patients because AI can do this more accurately than physicians.[3] Furthermore, AI-driven non-autonomous robots are currently used to improve the abilities of doctors during surgeries, through increasing precision (by filtering out hand jitters done by a motion filter) and by giving the surgeon the ability to see smaller details than the human eye can (through a lens).[4] [5] Moreover, the use of AI-driven robots may protect the staff and the patient from infection.[6] Hence, many predict that the use of autonomous surgical robots will be the next step in making surgeries more efficient and, ultimately, safer.[7]

As of today, only non-autonomous surgical robots are being used. The Da Vinci surgical robot is an example of a non-autonomous robot: the surgeon controls its movements and the Da Vinci robot merely filters hand jitters and improves precision.[8] Unfortunately, these robots have not realised the expected and desired outcomes because their use has not made surgeries more efficient or cheaper, as was claimed when they were invented. The reason is that these tools still have to be controlled by the physician. Consequently, the physician has to carry out each task and control movement of the tool which causes the surgery to take longer than traditional

[1] Daniel Etherington, 'Over 1,400 self-driving vehicles are now in testing by 80+ companies across the US' (*Tech Crunch*, 11 June 2019) <https://techcrunch.com/2019/06/11/over-1400-self-driving-vehicles-are-now-in-testing-by-80-companies-across-the-u-s/> accessed 12-12-2020.
[2] Sarah Kamensky, 'Artificial Intellingence and Technology in Health Care: Overview and Possible Legal Implications' (2020) 21 DePaul Journal of Health Care Law <https://via.library.depaul.edu/jhcl/vol21/iss3/3> accessed 23 September 2020, 1.
[3] Thomas Davenport and Ravi Kalakota, 'The potential for artificial intelligence in healthcare' (2019) 6 Future Healthcare Journal 94, 95.
[4] Yoav Mintz and Ronit Brodie, 'Introduction to artificial intelligence in medicine' (2019) 28 Minimally Invasive Therapy & Allied Technologies 73, 73.
[5] Seong No Yoon and DonHee Lee, 'Artificial intelligence and robots in healthcare: What are the success factors for technology-based service encounters?' (2019) 12 International Journal of Healthcare Management 218, 220.
[6] Shane O'Sullivan, Nathalie Nevejans, Colin Allen, Andrew Blyth, Simon Leonard, Ugo Pagallo, Katharina Holzinger, Andreas Holzinger, Mohammed Imran Sajid, Hutan Ashrafian, 'Legal, regulatory, and ethical frameworks for development of standards in artificial intelligence (AI) and autonomous robotic surgery' (2018) 15 International Journal of Medical Robotics and Computer Assisted Surgery 1, 4.
[7] Mintz and Brodie (n4), 79.
[8] David Britton, 'Automating Surgery: The Law of Autonomous Surgical Robots' (2016) 321 Life Sciences Innovation: Law 2, 5.

surgery. Longer surgeries result in more working hours and fewer surgeries possible in a year, which is problematic (even though the surgery is more precise).[9] A solution to these problems could be the autonomous surgical robot, which is being developed by technical scientists.

Autonomous surgical robots are expected to make surgeries more precise, less time-costly and less expensive, precisely because of their autonomy.[10] The decision-making process and the actual carrying out of the surgery will be done by the robot, so the surgeon is relieved of these tasks. Consequently, this is expected to save time and make the surgery cheaper because the surgeon will not have to perform more tasks; in fact, the surgeon will have fewer tasks to perform. Moreover, the surgery may be argued to be safer because human failure is eliminated.[11] However, the use of this type of robot may create novel liability problems because the robots will make their "own" decisions without human intervention, in the sense that they can collect data and act on the conclusions drawn from these. Consequently, they might make the wrong decisions, due to mechanical or technical failure, and cause damage. Hence, it becomes unclear how medical liability frameworks would address the question of liability because there is no central human involvement in the chain of causation. The robot itself cannot be held liable because it has no legal personhood.[12] Consequently, the problem is that it becomes unclear who is responsible and liable if an autonomous robot injures a patient, more so because a variety of people is involved with the safety of the robot, such as the manufacturer, the hospital and the physician.

This thesis explores the use of autonomous surgical robot and the related liability issues that arise if a patient suffers injury due to this use. *Liability* is defined as "the responsibility of one party for harm or damage caused to another party, which may be a cause for compensation, financially or otherwise, by the former to the latter."[13] To research the liability issues and possible solutions, the national laws of France and Germany and European Union (EU) law are discussed. These national laws regulate healthcare liability within the traditional situation of a surgery performed by a surgeon, who can be held liable, whereas EU law focuses on the damage caused by the product/robot itself.[14] Focus is on Germany and France because they often have

[9] Britton (n8), 3.
[10] Ibidem, 4.
[11] Mohamed Attia, Mohammed Hossny, Saeid Nahavandi, Mohsen Dalvand and Hamed Asadi, 'Towards Trusted Autonomous Surgical Robots' (2018) IEEE International Conference on Systems, Man and Cybernetics 4083, 4085.
[12] Woodrow Barfield, 'Liability for Autonomous and Artificially Intelligent Robots' (2018) 9 Journal of Behavioral Robotics 193, 194.
[13] European Commission, 'Staff working document: Liability for emerging digital technologies' COM (2018) 237 final, 2.
[14] Ewoud Hondius, 'Comparative medical liability in Europe' (2001), 188.

interesting differences in liability law, which are discussed later on in this chapter.[15] Furthermore, the liability law systems of these two countries give an overview of two main legal traditions across Europe because both countries influenced a considerable number of other legal systems in the European Union.[16]

In the case of 'traditional' surgery performed by a physician, the basic aspects of liability include that an injured patient can sue the physician in case the latter was negligent (which means that they did not act with reasonable care, more extensively discussed in Chapter 3).[17] [18] On the other hand, when the robot causes damage, there are three possible liable parties: the doctor could be held liable because they supervise the surgery and the robot; the manufacturer of the robot could be held liable because they designed the robot and the code and do the maintenance (this would constitute product liability); or perhaps the hospital that chose to buy and deploy the robot or did not sufficiently educate the surgeons on how to use it can be held liable. This last option would be vicarious liability, which is a form of liability that holds an employer liable for the employee's conduct under certain circumstances. Accordingly, if the hospital did not adequately instruct the surgeon how to supervise and operate the robot, the hospital would be responsible for the negligence of the surgeon if they act within the scope of their employment.[19] A different actor that could be held liable is the technician or operator of the robot. However, this thesis focuses on medical liability and the relationship between physician and patient, so the liability of the technician or operator is not addressed in this thesis. It is presumed that the physician has been educated to program the robot (and also actually programs it) and that the manufacturer does the maintenance of the robot.

The difference in the implementation of traditional medical liability (which regulates the liability of the doctor and of the hospital) versus product liability is fundamental; it changes different aspects within liability law, such as the role of negligence and the required proof. Moreover, product liability is governed quite extensively by the EU, whereas traditional medical liability law is mostly left to the Member States.[20] To hold a manufacturer liable according to product liability, the product has to be defective regarding some aspect; negligence does not play a role. Article 6 of the European Directive on Liability for defective products

[15] Hondius (n14), 188-190.
[16] Cees van Dam, *European Tort Law* (Oxford University Press 2013), 9.
[17] Ibidem, 188.
[18] Joseph Raz, 'Responsibility and the Negligence Standard' (2010) 30 Oxford Journal of Legal Studies 1, 6. The notion of negligence is more extensively discussed in Chapter 3.
[19] Kamensky (n2), 10.
[20] 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 [1985] OJ 2 210/29.

(hereafter: Product Liability Directive or PLD) states that a defect means the product "does not provide the safety which a person is entitled to expect, taking all circumstances into account."[21] [22] In sum, it is not certain what type of liability should be applied in case a patient is injured by an autonomous surgical robot.

Due to the questions and uncertainties surrounding liability and autonomous surgical robots, it is important to investigate the liability issues that may arise from the use of autonomous surgical robots and analyse whether the current EU and national healthcare liability frameworks of France and Germany are equipped to deal with these issues. If these situations are not sufficiently regulated, a regulatory gap will develop. This has a number of consequences. Firstly, patients who suffer injury due to the malfunctioning of the robot will have no means for redress, which would constitute a significant legal problem. Secondly, a regulatory gap will result in legal uncertainty not only for patients, but also for manufacturers, physicians and hospitals. This could result in surgeons and hospitals being unwilling to use autonomous surgical robots and manufacturers unwilling to make them because the deployers and developers of the robot are not sure whether they will be held liable when something goes wrong. This so-called chilling effect would be particularly problematic in the context of attempting to maximize the efficiency and safety of healthcare, because failure to do so can have consequences on people's health and subsequently lives. Therefore, the regulation of autonomous surgical robots is essential for an efficient and equipped legal environment.

1.2 Research question

The main research question that is addressed in this thesis is: "To what extent are the current EU product liability framework in healthcare and the laws on medical liability of France and Germany equipped to deal with the liability issues that arise from the use of autonomous surgical robots?"

To answer the main research question, the following sub-questions need to be answered:

- What is the current state-of-the-art of surgical robots in healthcare and how is this likely to develop?
- When is a liability framework sufficiently equipped to deal with liability issues?
- What do the current EU liability framework in healthcare and healthcare liability laws of France and Germany entail with regards to injury suffered during surgery?

[21] Van Dam (n16), 301.
[22] Directive on liability for defective products (n20), art. 6.

- What are the liability issues that the use of autonomous surgical robots might cause and how are these addressed by the discussed frameworks?

1.3 Focus

Certain choices have been made regarding the focus of this thesis. Firstly, focus is on autonomous surgical robots, because the use of this type of robot creates different liability problems than the technologies that are only used to enhance the doctor's senses or abilities (which are non-autonomous). The autonomy is a crucial new feature that sets this technology apart from the normal tools used by surgeons because they can act on their own and, consequently, cause damage. With regards to *autonomy* in the context of medical robotics, it is useful to differentiate between six levels, where level 0 means no autonomy at all, and level 5 means full autonomy, in the sense that no human is needed.[23] In this thesis, an autonomous surgical robot means a level 5 medical robot. This is a robot that is defined by Britton as following the 'sense – think – act paradigm', which entails that the robot can see or recognise what type of tissue it is cutting, for example by "feeling" if the tissue is firmer and needs more pressure to move or not. Subsequently, it can autonomously process information, draw conclusions from the processed information, and act upon these.[24] No human intervention is needed. This particular definition is used because it concurs with Calo's discussion of robotics (the sense – think - act paradigm), which is a widely used and cited theory.[25] A surgical robot is defined as "any electro-mechanical device which carries out surgical functions..."[26]

The focus on autonomous surgical robots is linked to a second choice made: focus is on the liability issues that arise from the use of the autonomous surgical robot, and not from any mistakes of the physician who prepped the robot for the surgery or prepared the patient. In case the physician does not act according to a certain standard, the physician can be held liable; that is a traditional scenario, which is called fault liability. The liability of physicians is nothing new, which is why this part is not addressed in this thesis. Instead, a question that is answered is whether the physician can be held liable for the mistakes that the robot makes completely on its own.

Thirdly, as touched upon in the first section of this chapter, focus is on both the EU

[23] Guang-Zhong Yang, James Cambias, Kevin Cleary, Eric Daimler, James Drake, Pierre E. Dupont, Nobuhiko Hata, Peter Kazanzides, Sylvain Martel, Rajni V. Patel, Veronica J. Santos and Russell H. Taylor, 'Medical robotics—Regulatory, ethical, and legal considerations for increasing levels of autonomy' (2017) 2 *Science Robotics* eaam8638, 1.
[24] Britton (n8), 4.
[25] Ryan Calo, 'Robotics and the Lessons of Cyberlaw' (2015) 103 California Law Review 513.
[26] O'Sullivan et al. (n6), 8.

legislation and national liability laws of Germany and France because the main research question cannot be answered by looking solely at either the national or supra-national framework. The choice for this combination has been justified in the problem statement. The national legislation of Germany and France are going to be compared, but the main goal is to give a complete overview of medical liability in Europe. This information will help answering the main research question.

On another note, for anyone who has basic knowledge of the different liability law systems in Europe, it is indisputable that the UK as a common law country is interesting to highlight because it has an opposite policy approach to tort law in comparison to the French-influenced part of Europe, which can be seen in the focus on the defendant and correction of his behaviour in English liability law, whereas French liability law focuses on compensation for the victim and distributive justice.[27] However, since the UK has left the EU, the combination of EU and national law, which it is essential for this thesis, is no longer present.

Lastly, this thesis focuses on liability issues, more specifically, tortious liability. Tortious liability means liability outside the context of a contract.[28] Depending on the country, medical liability is governed by either tortious or contractual liability. Due to the limited space, discussion of both types of liability is not possible. The focus is on tortious liability because this is in line with product liability. Product liability is defined as "a form of statutory extracontractual liability referring to the civil liability of manufacturers."[29] Discussing national medical liability only with regards to tortious liability is, therefore, the most logical choice for this thesis.

1.4 Literature review

A gap exists in literature regarding the adequacy of existing liability rules in the EU with regards to autonomous surgical robots. A great number of articles mention that new liability issues will arise from the use of surgical robots, the reason for which is often greater autonomy. However, none discuss whether the current legal framework in the EU is equipped to deal with these liability issues, while they do acknowledge that legal frameworks are vulnerable to these changes. These articles can help identify the different liability problems relevant for this thesis.

One noteworthy discussion in literature is the debate around the (lack of) foreseeability of the conduct of autonomous robots and the consequences for liability thereof. Unforeseeable

[27] Van Dam (n16), 9.
[28] European Commission (n13), 6.
[29] Ibidem, 6.

conduct is caused by algorithms making decisions without showing how it came to these.[30] Some authors, such as Barfield, argue that the difficulty to determine what damage autonomous robots can cause, results in an impossibility to hold a person morally or legally liable because no human could have ever foreseen all possible conduct of which an algorithm can think.[31] Arguably, no human can be identified as a causative factor in the chain of events leading to injury. Consequently, causation, which is a requirement to establish liability, cannot be proven.[32] [33] What exactly causation entails, is further discussed in Chapter 3. However, this view on the inability to prove causation is contested by authors who argue that there is indeed unpredictability for most users of the robot, but not for the designers of the code, whereas others argue that even the designer cannot always predict how the robot will act in a real world setting.[34] Another argument is that in case even the designer cannot predict certain behaviour of a robot, the robot has a defect. This might open up the possibility to sue according to product liability. Hence, the designers can still be held liable, even if the robot caused damage in a way that they could not have foreseen.[35] I agree with the side of the debate that wants to hold designers liable, even more so because holding no one responsible is not an option when a patient suffered injury or damages. However, it is an interesting debate to keep in mind during this thesis because it shows the uncertainty regarding liability and autonomous robots.

One aspect of liability that the literature does agree on is that the robot itself cannot be held liable as of today.[36] The most important reason is that they have no legal personhood, and so they have no civil liberties or duties. A different debate is the desirability of giving robots legal personhood (which the EU considered).[37] However, this debate goes beyond the scope of this thesis, since the solution for the problem described is attempted to be found in the existing liability frameworks. Therefore, focus in this thesis will be on the involved natural or legal persons who may be held liable.

As can be concluded from this literature review, many authors worry about certain aspects of the autonomous surgical robot and try to come up with a solution, often in the context of liability. However, as of today, no research has focused on the existing healthcare liability

[30] Kamensky (n2), 7.
[31] Barfield (n12), 193.
[32] Ibidem, 194.
[33] Edoardo Datteri, 'Predicting the Long-Term Effects of Human-Robot Interaction: A Reflection on Responsibility in Medical Robotics' (2013) 19 Science and Engineering Ethics 139, 155.
[34] Kamensky (n2), 13.
[35] O'Sullivan et al. (n6), 6.
[36] Barfield (n12), 194.
[37] O'Sullivan et al. (n6), 7.

framework in and of the EU to see whether these are adequate to address the concerns. This is where the research question of this thesis comes in: to fill this literature gap.

1.5 Methodology and methods

The chosen methodology for this thesis is dogmatic legal research with prominent features of comparative legal research. The main research question is an evaluative question because it evaluates the adequacy of certain laws to address the discussed liability issues. The primary methodology is dogmatic legal research because different legal frameworks are discussed and evaluated. The research revolves around the laws and how these react (or do not react, or not adequately) to certain liability issues caused by autonomous surgical robots. This is the most important information needed to answer the main research question. When discussing the different tort law regimes of France and Germany, one cannot escape a comparison. However, the main goal is to give a complete overview of medical liability in Europe, as has been discussed in the problem statement.

One of the methods used to answer the main research question are a discussion of different pieces of legislation that exist on EU level on product liability and medical devices, combined with the national healthcare liability laws of France and Germany. The former are the Product Liability Directive[38] and the Regulation on Medical Devices.[39] Moreover, the national laws of Germany and France on medical liability are analysed to be able to conclude whether these are equipped to regulate the liability issues. The second method is a literature review that is conducted to research the use of the autonomous surgical robot and to know when a legal framework is equipped to deal with a certain issue. In sum, the methods used for this research are literature review and review of legislation. These two combined will supply the information needed to analyse the current state of the discussed problem and answer the main research question.

1.6 Structure

The structure of this thesis is as follows:

In Chapter two, it is explained what type of surgical robot is currently being deployed, with focus on the advantages and disadvantages of this type. Additionally, the type of robot that is expected to be used in the future is analysed. This second type will have more autonomous functions, which is interesting with regard to the liability issues that can arise (these will be

[38] Directive on liability for defective products (n20).
[39] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [2017] OJ 2 117/1.

discussed in Chapter five). This research is useful to give an answer to the first sub question.

Chapter three is more theoretical, since it focuses on how it can be determined whether a liability framework is equipped to deal with liability situations. Focus is on how specifically a healthcare framework fits into this discussion. This question is answered by conducting a literature review.

In Chapter four, the national laws that revolve around medical liability and the EU product liability laws are discussed. The medical liability laws of France and Germany are researched, so in what ways physicians or hospitals can be held liable. The EU regulation that is relevant in this chapter are the Regulation on Medical Devices[40] and the Product Liability Directive.[41] Focus is on the general and fundamental rules of these frameworks.

Chapter five will combine Chapters two and four, to be able to conclude what kind of liability issues will arise from the future use of surgical robots and how the liability frameworks will 'react' to this use. It is discussed whether patients can sue the hospital, doctor or manufacturer.

Chapter six is the conclusion of this thesis, in which the answer to the main research question is given. Moreover, recommendations for future research are noted and the limitations of the research are evaluated.

1.7 Conclusion

To conclude, in the way that is explained in this first chapter, an answer can be given to the question whether the healthcare liability laws of the EU, France and Germany are equipped to address the liability problems that may be caused by deployment of autonomous surgical robots. The first step is to look into the type of surgical robots currently used and the type that will be used in the future, which are discussed in Chapter two.

[40] Regulation on Medical Devices (n39).
[41] Directive on liability for defective products (n20).

Chapter 2: (Non-)Autonomous Surgical Robots

2.1 Introduction

In this chapter, an overview is provided of the development of the field of surgical robotics. This overview helps clarify what type of robot is relevant for the research in this thesis. This clarification is important to determine because it has implications for the liability issues that are discussed later on in this thesis. The first step in this overview is a short history of robots in surgery, followed by a description of the type of surgical robot that is currently being used, with a focus on the DaVinci surgical robot, since this specific robot is used most often in surgeries. This type of robot is non-autonomous. Subsequently, a number of advantages and disadvantages, in terms of surgery outcomes, of the type of robot currently being used is discussed. The final substantial section is an explanation of the type of surgical robot that is being developed and is expected to be used in the future, which is fully autonomous. The chapter is ended with a conclusion.

2.2 History of robots in surgery and non-autonomous robots

Whereas the history of robotics in general goes back almost a century,[42] the relevance of robots in the medical field is relatively new. Robotic technology was used in a surgery for the first time in 1985, when a needle was guided into a person's brain, for a biopsy, by a robot.[43] In the 1980s, the application of robotics in surgery became more widespread because the use of this technology made it possible to perform a surgery with a significantly smaller incision.[44] [45] This was possible because the robot gives the physician more precise control over very small movements.

The deployment of surgical robots has been accepted to the greatest extent in the area of telerobotic surgery. This area revolves around robots that have a virtual reality display and robotic arms that can be operated by a physician from a remote console.[46] An example of this type of robot, which was introduced in the early 2000s, is the DaVinci surgical robot. This robot is the most recognised one worldwide.[47] It offers the surgeon an arm that replicates exactly what a human arm can do, but also more with regards to angles and endurance. There have been a

[42] Christine G. Gourin and David J. Terris, 'History of Robotic Surgery' in Russell A. Faust (ed), *Robotics in Surgery, History, Current and Future Applications* (Nova Science Publishers, Inc. 2007), 3.
[43] Ibidem, 7.
[44] Jay Shah, Arpita Vyas, Dinesh Vyas, 'The History of Robotics in Surgical Specialties' (2015) 1 American Journal on Robot Surgeries 12, 12.
[45] Youri P. A. Tan, Philippe Liverneaux and Jason K. F. Wong, 'Current limitations of surgical robotics in reconstructive plastic microsurgery' (2018) 5 Frontiers in Surgery 1, 1.
[46] Ibidem, 7.
[47] Shah et al (n44), 13.

few versions, but the newest version has three operating arms, one camera holder, increased range of motion of the arms and a second surgeon's console, so less experienced surgeons can be trained.[48] The surgeon is seated at a remote console from which he can control the robot's arms. Furthermore, surgeons can see their hands in the console, which enhances hand-eye coordination and gives the illusion that the patient is directly in front of the surgeon.[49] The vision system is 3D and the image can be magnified. Moreover, the robot follows the movement of the surgeon's hands, but gross movements can be translated to much finer movements at the patient's side, and this motion scaling improves surgical precision.[50] The DaVinci surgical robot is used in all kinds of minimally invasive surgeries, for example in coronary artery bypasss surgery.[51]

In summary, the robotic systems currently used are predominantly non-autonomous and function at the will of the surgeon who controls it. This means essentially that the surgeon performs the surgery; the robots can merely enhance the view and the precision of the movements of the physician.

2.3 Advantages and disadvantages of non-autonomous surgical robots

Non-autonomous surgical robots have a number of advantages and disadvantages. The first and greatest advantage is the manipulation of the movement of the surgeon by the computer of the non-autonomous surgical robot. In current surgical robotic systems, there are four major components, which are the surgical interface device, the computer controller, the robotic arms and the visualisation system. The movements of the physician are digitized by a computer controller, and this information is passed on to the arms.[52] The information can be manipulated by the computer through tremor filtering and motion scaling, which enhances precision. The filtering of the tremor is increased when the instruments are longer.[53] Moreover, the motion scaling changes large movements at the surgical interface device into microsurgical movements at the patient's side of the robot.[54] Consequently, the technology integrated in the robot helps to increase the precision of the surgery, which decreases the risk of injuring a patient by accidentally cutting in tissue or a vein that should be left intact.

Another advantage is the position of the surgeon during the surgery. In traditional

[48] Shah et al (n44), 13.
[49] Gourin and Terris (n42), 9-10.
[50] Ibidem, 10.
[51] Ibid., 10-11.
[52] Michael D. Diodato, Sunil M. Prosad, Mary E. Klingensmith, Ralph J. Damiano Jr., 'Robotics in surgery' (2004) 41 Current Problems in Surgery 752, 756.
[53] Ibidem, 757.
[54] Ibid., 760.

surgery, physicians bend over the patient, which can cause neck and back stiffness. This problem is eliminated by the robotic system because the surgeon is seated at the console in an upright position. This increases their concentration and focus, which in turn improves their performance during the surgery.[55] Moreover, the robot itself cannot become tired or stiff, so its performance is not influenced by these human weaknesses and is, therefore, more consistent.[56] In sum, these characteristics improves surgery outcomes.

Besides these advantages, there is also a number of disadvantages connected to the use of non-autonomous surgical robots. One disadvantage of the use of robot arms is the loss of direct human contact with the tissue.[57] There is no haptic feedback, which is necessary in delicate procedures to realise surgical goals; the amount of pressure that is applied has to be controlled because otherwise the risk exists that the surgeon slips and injures the patient. At present, the amount of pressure applied can only be based on visual cues.[58] Models are being developed to give the surgeon haptic feedback, so a type of forceful sensation can be felt when more pressure is applied.[59] Another option is for strain sensors to be incorporated in the robot and provide a scaled amount of feedback; a vibration becomes more intense when a surgeon applies more pressure.[60] Currently, however, this is a disadvantage of non-autonomous surgical robots.

As was briefly touched upon at the end of the previous section, one of the most fundamental aspects of non-autonomous surgical robots is their dependency on human control, which means that the robot is a tool that is used by the surgeon according to the slave/master paradigm.[61] This type of robot can be categorised as a level 0 surgical robot.[62] The robot can increase the precision of the movements of the surgeon, but is dependent on the surgeon to actually be able to move. This can be regarded as an advantage, because the robot cannot "make" mistakes. It is always the surgeon who controls what the robot does and can, consequently, be held responsible. However, the risk that the surgeon makes a mistake remains because the technology is completely dependent on the decision of the surgeon. A mistake could be caused by the lack of haptic feedback or simply because the surgeon made a wrong decision.

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[55] Diodato et al (n52), 763.
[56] Sandip Panesar, Yvonne Cagle, Divya Chander, Jose Morey, Juan Fernandez-Miranda and Michel Kliot, 'Artificial Intelligence and the Future of Surgical Robotics' (2019) 270 Annals of Surgery 223, 223.
[57] Diodato et al (n52), 763.
[58] Anton Simorov, R. Stephen Otte, Courtni M. Kopietz and Dmitry Oleynikov, 'Review of surgical robotics user interface: what is the best way to control robotic surgery?' (2012) 26 Surg Endosc 2117, 2118.
[59] Diodato et al (n52), 763.
[60] Simorov et al (n58), 2124.
[61] Panesar et al (n56), 223.
[62] Yang et al (n23), 1.

This risk is eliminated when using a different type of surgical robot: autonomous surgical robots. This type of robot is discussed in the next section.

2.4 Current developments

As said above, the type of robot that is being developed and is expected to be used in the future is the autonomous surgical robot.[63] Autonomous surgical robots would be able to combine the advantages of non-autonomous surgical robots (insusceptibility to fatigue, tremor filter, scalable motion) with the removal of potential for human error because the need for a surgeon directly performing the surgery is eliminated.[64] [65] The robot's acts are controlled by an algorithm, and the robot directly performs what the algorithm calculates. This type of robot is categorized as a level 5 surgical robot.[66] As said in Chapter 1, this type of robot follows the sense-think-act paradigm.[67] The robot is no longer the assistant but the primary operator, whereas the surgeon is demoted to assistant; they observe, but can overrule the robot.[68] However, a big challenge for developers of medical robotics is that the number of different tasks, environments and risks is practically infinite.[69]

In 2014, the Smart Tissue Autonomous Robot (STAR) outperformed human surgeons in a number of surgical tasks.[70] In fact, an experiment proved STAR to be four times more consistent than human physicians, five times faster than surgeons using non-autonomous surgical robots and nine times faster than physicians performing the surgery themselves.[71] Normally, human error can be caused by numerous physical, technical and mental variables. Consequently, a perfectly capable physician can make mistakes, for example, because their hand becomes stiff after holding a medical knife for hours, because they programmed or used one of the surgical machines wrong, or simply because they misjudged a situation. Therefore, a big advantage of an autonomous surgical robot is that it does not suffer from these human aspects (or better: weaknesses) and can, therefore, improve surgical consistency and surgical

[63] Panesar et al (n56), 223.
[64] Ibidem, 223.
[65] Attia et al (n11), 4085.
[66] Yang et al (n23), 1.
[67] Britton (n8), 4.
[68] Qingchuan Ma, Etsuko Kobayashi, Hideyuki Suenaga, Kazuaki Hara, Junchen Wang, Keiichi Nakagawa, Ichiro Sakuma and Ken Masamune, 'Autonomous Surgical Robot With Camera-Based Markerless Navigation for Oral and Maxillofacial Surgery' (2020) 25 IEEE/ASME Transactions on Mechatronics 1083, 1085.
[69] Yang et al (n23), 2.
[70] Panesar et al. (n56), 223.
[71] Simon Leonard, Kyle L. Wu, Yonjae Kim, Axel Krieger and Peter C.W. Kim, 'Smart Tissue Anastromosis Robot (STAR): A Vision-Guided Robotics System for Laparoscopic Suturing' (2014) 61 IEEE Transactions on Biomedical Engineering 1305, 1305.

outcomes.[72] [73]

A second advantage is that the algorithm, which makes the robot's decisions, may be able to sense information that a human would not percept (such as the specific measurement of pressure that is applied to the tissue of the patient when using a non-autonomous surgical robot). Consequently, the algorithm can predict or detect adverse events more accurately and timely than a physician.[74] This advantage is the result of the fact that the algorithm can make an estimate of the environmental state by mapping the inputs in the sensors and then estimate outputs (so, how to proceed with the surgery). Moreover, the algorithm can provide real time feedback, which means that the robot can react to a changing environment.[75] The ability to change their behaviour in accordance with changing conditions is what makes this type of robot autonomous, besides the lack of human involvement.[76]

However, a challenge that the scientists developing this type of robot are facing is the fact that the robot has to be pre-programmed to perform a certain goal and, at the same time, be able to respond to the changing surgical environment.[77] Consequently, the robot has to 'learn' how to perform the surgery and how to react when something goes differently. A combination of teaching the robot by directly programming, letting the robot observe a surgeon or video and providing a database with knowledge on how to react in certain situations to safely perform the surgery and achieve the goal of the surgery are fundamental parts in teaching the robot.[78] However, it would be unrealistic to expect the autonomous surgical robot to always make the right decision at the right time. Therefore, the next paragraph focuses on the situation where an autonomous surgical robot has caused damage or injury to a patient.

The potential damage that can be done in the context of the surgery is often very serious, which makes potential failure of the technology a big risk and, consequently, it is essential that someone is held liable for the failure. However, first it has to be explained how the autonomous surgical robots can cause damage. There are two types of failures in this context: technical and human. Technical failures include *inter alia* system errors (software malfunctions), unintended operation of the instrument, and electrical arcing, sparking or charring of the instrument (both of which are mechanical malfunctions).[79] The complexity of the changing circumstances that

[72] Panesar et al (n56), 223.
[73] Attia et al (n11), 4083.
[74] Ma et al (n69), 1085.
[75] Panesar et al (n56), 224.
[76] Attia et al (n11), 4083.
[77] Panesar et al (n56), 224.
[78] Ibidem, 224-225.
[79] Attia et al (n11), 4083.

can occur during a surgery make it difficult for an algorithm to consistently make the right decision. Namely, a situation might occur that the algorithm did not learn or that it was programmed to react in a way that can cause damage.[80] This is also a failure of the technology, more specifically a software malfunction. Human failure can be caused by wrongly planning the surgery, which means that the robot is pre-programmed using wrong or incomplete data.[81] Essentially, humans are responsible for human failure. However, it is unclear who is responsible for damage caused by the failure of the algorithm.

This is where the use of autonomous surgical robots can become problematic. Normally, it is logical to hold the surgeon responsible when a patient is injured in the course of a surgery. When a technical failure causes an autonomous robot to harm a patient, this may become an issue because an algorithm made the decisions. Therefore, the risk is that no one may be held accountable because no human can be seen as having caused the damage. This is problematic because the patient has to be compensated, but there is no straightforward answer who should compensate. This opaqueness is caused by the fact that the algorithm works autonomously. The physician and technician who program the robot did not tell the robot to cause injury; the robot determined that on its own. Focus of this thesis is on the failure of the algorithm; the assumption is that the physician pre-programmed the robot currently (according to the right data, such as the type of surgery and the characteristics of the patient, among other things), but the robot caused damage because the algorithm made a wrong decision due to an intrinsic error in the software.

In conclusion, autonomous surgical robots are expected to be the safest options for patients during a surgery. However, in case injury is caused by the failure of the algorithm, the uncertainty regarding liability will be an additional problem for the injured party. This obscurity should be solved. Moreover, while there have been promising developments of partially autonomous surgical robots, the realization of a truly autonomous surgical robot still lies in the future.[82]

2.5 Conclusion

To conclude, non-autonomous surgical robots have evolved over the last 40 years, and they have become essential in minimally invasive surgeries. This is the current state-of-the-art type of surgical robot. The disadvantages of these master/slave robots, which are the lack of haptic feedback and the possibility for human error, can be solved by using algorithm/AI-driven

[80] Panesar et al (n56), 223.
[81] Attia et al (n11), 4085.
[82] Panesar et al (n56), 223.

autonomous surgical robots. The algorithm can sense the pressure applied to a tissue and the haptic feedback thereof and can make decisions of its own. Human intervention is not needed, so human error is prevented. However, this type of robot is not yet completely developed. Moreover, a possible consequence of using this type of surgical robot is that it could become more and more difficult to hold the surgeon liable when the robot causes damage due to software malfunction. The risk if no one can be held accountable for a medical decision is that the victim cannot be compensated. To be able to evaluate how complex it is to hold a party accountable and whether existing legal frameworks can solve these liability issues, it first has to be researched when a tortious liability framework is equipped to deal with liability situations and issues. This is discussed in the next chapter.

Chapter 3: Tortious Liability Framework

3.1 Introduction

To be able to give an answer to the liability questions arising from the use of autonomous surgical robots, it first needs to be researched when a tort law framework is equipped to deal with the issues that arise when a victim is injured. This is done by first explaining the basics of tort law in Europe, so on what grounds liability can be established and what the consequences are thereof. This is done by explaining fault liability and strict liability, with a focus on the Product Liability Directive in the latter section. The focus is on Europe in this case because this is in line with the thesis in general. After that, medical tort law is discussed by highlighting the differences with regards to general tort law. The Medical Device Regulation is discussed in this section with regards to EU tort law. The chapter is concluded with a summary of the criteria which have to be fulfilled for a tort law framework to be equipped to deal with tort law issues, which is also the answer to the second sub question.

3.2 Tort law

Giving one universal explanation of tort law is impossible; even the tort law systems in Europe differ in many aspects.[83] These are pointed out, where relevant, in this section. However, there are some general rules and principles that are present in each of them, which are the subject of this section. Moreover, there has been an effort to harmonise aspects of tort law in the Principles of European Tort Law (PETL). These Principles are not actual legislation, but an academic attempt to unify the tortious liability laws of the European countries.[84] Where relevant, these guidelines are also noted.

The definition of a "tort" is a "wrongful act other than a breach of contract which relief may be obtained in the form of damages or an injunction."[85] Hence, tort law focuses on a wrongful act that is not governed by a contract and on damages that the injured party possibly can obtain. This wrongful act may be intentional or unintentional.[86] Furthermore, the damage has to be deemed a loss that is compensable, which means that it relates to a "legally protected interest."[87] In this thesis, the focus is on unintentional interferences with a person's health or life. Unintentional because the assumption is that the physician or manufacturer did not

[83] Van Dam (n16), 9.
[84] European Group on Tort Law, 'Principles of European Tort Law' (2005)
[85] Merriam-Webster Dictionary, 'Tort' <www.merriam-webster.com/dictionary/tort> accessed 14 January 2021.
[86] Basil S. Markesinis, 'Tort' (*Encyclopaedia Britannica,* 19 September 2019) <www.britannica.com/topic/tort> accessed 14 January 2021.
[87] European Group on Tort Law (n84), Art. 2:101.

intentionally injure the patient or instruct a robot to injure a patient. The assumption is that the physician did successfully program the robot for surgery on a patient, but that the injury was caused by failure of the algorithm. In the context of this thesis, the protected interests are life and bodily integrity, which are universally recognised and deserve the highest degree of protection.[88] [89]

3.2.1 Fault liability

One of the ways to establish liability is to prove the conduct that resulted in personal injury of another person was a 'fault'. Logically, this type of liability is called fault liability. A fault requires negligent or intentional conduct, injury and causation between the two.[90] Whether conduct is negligent can be determined by looking at the objective criteria of standard of care.[91] The defendant must behave as the *bonus pater familias*, or the reasonable person in the particular circumstances.[92] The reasonable person is a "person with an ordinary degree of reason, prudence, care, foresight, or intelligence…"[93] If the defendant did not behave according to that standard, the conduct was careless/negligent. This standard includes inaction, which can lead to liability of someone who should have prevented the injury under the circumstances, but did not. To be liable for inaction, that person has to be subject to an affirmative duty, such as a physician is towards its patient when the former is giving information about a surgery, and not act according to the duty.[94]

The second requirement, injury, is not difficult to prove in the context of medical treatment because complications and surgery outcomes are well-documented. Naturally, medically necessary injuries are not compensable injuries, since the patient agreed to undergo the surgery.

The third and final requirement that the conduct must lead to harm is called causation, which can be determined based on different tests, such as the foreseeability test in the UK, the "scope of the rule" test in Germany and the "certain and direct" rule in France.[95] These two latter rules are more broadly discussed in the next chapter. However, the requirement that is at

[88] Bernhard A. Koch, 'The "Principles of European Tort Law"' (2007) 8 ERA Forum 107, 112.
[89] European Group on Tort Law (n84), Art. 2:102.
[90] Van Dam (n16), 141.
[91] Ibidem, 57.
[92] European Group on Tort Law (n84), Art. 4:102.
[93] Merriam-Webster Dictionary, 'reasonable person' <www.merriam-webster.com/legal/reasonable%20person> accessed 6 February 2021.
[94] Van Dam (n16), 250.
[95] Ibidem, 314, 318 & 319.

the basis of all of these is the *conditio sine qua non* requirement.[96] [97] This requirement entails that conduct is the cause for the damage "if, in the absence of the activity, the damage would not have occurred."[98] However, fulfilling this requirement is often not sufficient without other contributing factors, such as foreseeability or the nature of the damage.[99] These factors are added to the *conditio sine qua non* requirement, which makes the establishment of causation more difficult, but also fairer. Namely, the *conditio sine qua non* can establish many different factors as 'necessary' without each of them actually being the cause. Moreover, this is why the different tort law systems in Europe have their own rules, to add to the *conditio sine qua non* requirement in a way they find sufficient. Causation works a bit differently in case of liability for inaction. In that case, the defendant has to prove that there is no causation between the inaction and the harm. Therefore, the person who owed the claimant a duty of information (for example) has to prove that the claimant would have made the same decision even with the information.[100] However, fault liability is just one way to hold a person liable.

3.2.2 Strict liability

Liability can also be established when there is no fault, under certain circumstances. This means that a person can be held liable for conduct or harm that they did not do themselves, but for which they are responsible in some way, or for conduct which they did do themselves, but not negligently. This is called strict liability. There are a number of different types of strict liability, one of which is vicarious liability, which was briefly explained in the introduction chapter. In the case of vicarious liability, the employer is deemed liable for the wrongful conduct done by an employee in the exercise of their employment. However, this is not the case in every country; in Germany, this rule has been implemented in a different way. There, the employer is only liable if he to blame for either wrongly selecting/supervising the employee or for failing to supply his employee with necessary and adequate equipment.[101] Consequently, it becomes more difficult to hold the employer responsible for conduct of its employees in Germany.

Another form of strict liability is responsibility for damage that is done by things that that person has control over, such as vehicles or animals.[102] A robot that is being controlled by

[96] Koch (n88), 112.
[97] European Group on Tort Law (n84), Art. 3:101.
[98] Ibidem, Art. 3:101.
[99] Koch (n88), 112.
[100] Van Dam (n16), 325.
[101] Markesinis (n86), section on Liability without fault'<www.britannica.com/topic/tort/Liability-without-fault> accessed 14 January 2021.
[102] Ibidem.

a surgeon, such as the DaVinci surgical robot, might fall under this category. However, when the surgical robot is autonomous, the control of the surgeon is practically eliminated, as was discussed in Chapter 2. Therefore, this type of liability may not be useful for the issue at hand.

A related but distinct form of strict liability is product liability. In Europe, this type of liability is primarily regulated by the Product Liability Directive, which is further discussed in Chapter 4. The concept of product liability entails that a manufacturer can be held liable because the product they produced has a defect and caused damage or injury.[103] A 'product' is a movable (something that is capable of being moved), even if it is incorporated into an immovable or another movable.[104] A product is defective when it "does not provide the safety which a person is entitled to expect, taking all circumstances into account."[105] This standard is further unpacked in Chapter 4.

3.2.3 Compensation

The largest consequence for the victim, and the wrongdoer, when the latter is found liable for a certain wrongful act is that the victim has a right to be compensated for the harm suffered as a result of the defendant's negligent conduct or as a consequence of harm suffered by a person or thing for which the defendant is responsible.[106] For liability rules to be effective, they need to provide a remedy because the focus is on compensation of the harm suffered by the victim and prevention of harmful conduct.[107] Without a remedy, both these goals are not reached. There is often a possibility to be compensated for pecuniary and non-pecuniary losses. Moreover, in case a person dies, the relatives can claim damages.[108] However, the rules and principles of fault liability discussed change when the wrongdoer is not an average person, but a surgeon. This is discussed in the next section on medical tort law.

3.3 Medical tort law

The majority of the aspects discussed in the previous section also applies to medical tort law, but there are a few differences.

3.3.1 Fault liability

A difference that should be noted falls under fault liability. The reasonable man standard in fault liability is normally assessed according to an average, well-thinking citizen. However,

[103] Directive on liability for defective products (n20), Art. 1.
[104] Ibidem, Art. 2.
[105] Ibid., Art. 6.
[106] Van Dam (n16), 346.
[107] Ibidem, 347.
[108] Ibid., 347.

surgeons are not ordinary people in their field; they have studied years to be able and certified to do their work. Therefore, most countries in Europe agree that they should be held to a different standard, that of the reasonable medical practitioner.[109] This standard is higher than the reasonable man standard, so the surgeon can be held liable more easily when he injures a patient in the course of a surgery. Naturally, an average person would never be held liable for not being able to perform a surgery correctly, whereas a surgeon can be held liable in that case. Certain circumstances are taken into account when determining whether a surgeon acted negligently, such as the urgency of the situation, the impossibility of transportation to a hospital or a lack of drugs.[110] These can be seen as mitigating factors, which can exempt the surgeon from liability. For example, if a patient suffered injury, because they did not receive the treatment or surgery that they needed, they can sue the physician. However, if the physician can prove that they did everything they could and was expected of them, except that they did not have the required drugs to be able to perform a medically necessary surgery, the surgeon can subsequently be exempted from liability. Moreover, the standard of care includes the duty of the doctor to inform the patients of any risks relating to the surgery, so this is an affirmative duty they have to fulfil.[111] Thus, the higher standard of care for surgeons is an important difference when looking at healthcare and liability, instead of general tort law.

3.3.2 Strict liability

The hospital can be held liable under certain circumstances through the doctrine of vicarious liability. This is a possibility when one of their employees acts negligently and injures a patient.[112] Next to that, hospitals might be held liable "for failing to exercise due care in hiring, training, or supervising employees, or for failing to maintain adequate facilities and equipment."[113]

Besides vicarious liability, there is also the possibility to hold the manufacturer of medical devices liable, which is not that different from normal product liability. The malfunctioning of medical devices falls under the general product liability regime.[114] The safety standard that manufacturers of medical devices have to comply with are governed by the Medical Device Regulation.[115] However, the liability itself is governed by the Product Liability

[109] Peter De Cruz, *Comparative Healthcare Law* (Cavendish Publishing Limited 2001), 532.
[110] Ibidem, 532.
[111] Hondius (n14), 186.
[112] Hannah R. Sullivan and Scott J. Schweikart, 'Are current tort liability doctrines adequate for addressing injury caused by AI?' (2019) 21 AMA Journal of Ethics 160, 162.
[113] Ibidem, 162.
[114] Directive on liability for defective products (n20).
[115] Regulation on medical devices (n39).

Directive.[116] The safety that a person is entitled to expect under the PLD may be determined by using the standards set out in the Medical Device Regulation, which are additional to the standards of the PLD. This is further discussed in Chapter 4 and not here because this chapter focuses on (medical) tort law in a more general context, whereas Chapter 4 focuses on the specific laws regarding medical/product liability.

In essence, the fact that the patient was injured in the context of receiving healthcare does not change the concepts of vicarious and product liability. The only large difference in the context of healthcare is the higher standard of care that is expected of physicians and the higher standards to which medical devices have to adhere.

3.4 Conclusion

To summarise, fault liability can be established by fulfilling three requirements: negligent or intentional conduct, injury and causation. However, conduct of a surgeon is more easily defined as negligent because they are expected to act based on adequate knowledge. Moreover, the producer of medical products/devices can be held liable through strict product liability, the requirement for which is that the product has a defect. Lastly, the hospital can be held liable for the conduct of its employees under vicarious liability.

To conclude, a tort law framework is equipped to deal with liability issues when a person can be held responsible according to effective and specific rules and requirements, and the victim (or relatives of the victim) can be compensated for the losses they suffered. The injured party needs sufficient means for redress; the framework has to be able to hold someone accountable when that person is responsible for the damages (directly through fault liability or indirectly through strict liability). The rules on liability have to specifically address who has to pay damages under what circumstances. Moreover, for the rules to be effective and specific, a liability framework should hold different actors to different standards where appropriate. Firstly, a surgeon should be more careful and skilled than an average citizen. Secondly, a manufacturer should ensure that his product fulfils the relevant safety requirements. Thirdly, a hospital should employ capable employees. Therefore, a tort law framework should differentiate between average citizens and actors with special responsibilities. Only then can the victim always be rightly compensated, and is the liability framework equipped. Thus, the overarching question arising from this chapter is: are the liability rules in the context of healthcare in France, Germany and the EU specific enough to hold someone accountable for damages done by an autonomous robot? This question in answered in the next two chapters.

[116] Directive on liability for defective products (n20).

Moreover, in the course of this chapter, a number of differences were noted between different tort law systems, which are relevant for the next chapter. In Chapter 4, the healthcare liability frameworks of France and Germany and the product liability framework of the EU are discussed.

Chapter 4: Healthcare Liability Frameworks of France, Germany and the EU

4.1 Introduction

In this chapter, the tortious healthcare liability frameworks of France and Germany, and the product liability framework of the EU in the context of healthcare are discussed. In the sections on the national healthcare liability frameworks, focus is on the different ways liability of health professionals or hospitals can be established in the context of surgery. Additionally, the purpose of these sections is to highlight a number of "special" rules governing specific healthcare situations in either France or Germany. Subsequently, the EU section focuses on the Product Liability Directive and Regulation on Medical Devices. These two pieces of legislation determine liability of the manufacturer instead of the health care provider in the context of healthcare. The chapter is concluded in the last section.

4.2 France

4.2.1 Fault liability

The healthcare liability regime in France is based on the division of the public and private sector. The public sector includes the public hospitals, and the private sector consists of private practitioners or institutions.[117] One of the consequences of this division is that disputes involving public hospitals have to be brought before administrative courts, and disputes involving private parties should be brought before civil courts.[118] However, because of the Kouchner Act, this distinction is often irrelevant for the way liability can be established, even though the court procedures might differ.[119]

The Kouchner Act, also called the Patients' Rights Law, was introduced in 2002. Before the introduction, general liability law governed cases of medical liability.[120] The Patients' Rights Law unified the liability rules of medical malpractice regardless of the public or private nature of the case and included general principles of responsibility of health professionals and hospitals/clinics which are not regulated by the Code of Public Health (CSP).[121] The Act also

[117] Florence G'Sell-Macrez, 'Medical Malpractice and Compensation in France, Part I: The French Rules of Medical Liability since the Patients' Rights Law of March 4, 2002' (2011) 86 Chicago-Kent Law Review 1093, 1093.
[118] Ibidem, 1095.
[119] Dominique Thouvenin, 'French Medical Malpractice Compensation since the Act of March 4, 2002: Liability Rules combined with Indemnification Rules and correlated with several kinds of Proceedings' (2011) 4 Drexel Law Review 165, 170.
[120] Ibidem, 170.
[121] G'Sell-Macrez (n117), 1095.

organises compensation for victims of injuries that cannot be attributed to any wrongful behaviour and gives an alternative for courts: Conciliation Commissions, which can review cases of both public and private nature, and decide on compensation for the victim.[122] [123] These commissions include representatives from patient associations, medical facilities, medical experts and a magistrate.[124] The rationale was to combine medical and legal expertise.[125] Using the service of the Commission does not preclude suing for damage in a normal court.[126] Thus, the Patients' Right Law gives victims more possibilities to claim compensation. However, the Act did not change the way fault liability can be established in the context of healthcare. This type of liability is governed by the CSP.

As was discussed in Chapter 3, fault liability can be established when three requirements are fulfilled: negligent/intentional conduct, injury and causation.[127] Since the *Mercier* case of 1936, negligent conduct has to be proven because it was no longer sufficient that the expected result of the treatment was not reached. However, French courts are not reluctant to deem behaviour negligent. A simple or clumsy mistake may be deemed negligent; the threshold is low.[128] An example of this is a case where the surgeon forgot a compress in a patient's body and this was deemed negligent.[129] Naturally, such a mistake can have severe consequences for patients, which is why this is deemed negligent. However, it is a much smaller mistake than, for example, cutting an artery. Another reason the threshold for negligence is low is the high duty of care physicians have to adhere to. Article 1111-5 para. 1 of the CSP states that "[A]ny person, given his health and the emergency response that it requires, is entitled to receive the most appropriate care and to receive treatment whose effectiveness is recognised and which guarantees the best safety in light of established medical knowledge. Acts of prevention, investigation, or treatment should not, in the state of medical knowledge, make him take risks that are disproportionate to the expected benefits."[130] If the medical practitioner does not act according to this standard, his behaviour is deemed negligent, so this is relatively simple for the injured party to prove. Moreover, this is an objective test; the personal capacities of the relevant physician are not relevant. Therefore, the physician cannot claim that he did not know how to proceed after a complication (for example), this cannot be used as a defence; he should have

[122] G'Sell-Macrez (n117), 1096.
[123] Thouvenin (n119), 176 & 186.
[124] Ibidem, 176.
[125] Ibid., 176.
[126] Ibid., 178.
[127] G'Sell-Macrez (n117), 1097.
[128] Ibidem, 1099.
[129] Council d'Etat, Jan. 9, 1957, Rec. Lebon 22.
[130] Code of Public Health (CSP), art. 1111-5 para. 1.

known.[131]

Besides the duty of the physician to provide good care, they also have a duty of disclosure. Article 1111-2 CSP states that the practitioner has to disclose the risks related to treatment or surgery. However, only frequent risks or serious but normally predictable ones should be noted. Exceptional risks do not have to be noted.[132] To clarify, a patient should be informed about the risk of infection, but not of the hospital going up in flames. The burden of proof is on the doctor in this case, so they have to convince the judge that they did inform the patient to the extent required.[133]

The last aspect of fault liability discussed in this section is causation. As was touched upon in Chapter 3, the *conditio sine qua non* theory is relevant, but in France, it is often supplemented by the adequate causation theory.[134] This second theory focuses on whether the defendant's act has played a particular role in causing the damage or injury in the normal run of things.[135] This is often difficult to establish in a concrete case because in a surgery, the normal run of things does not mean everything always goes perfectly (for example, complications happen), which is why the courts sometimes use the concept of loss of chance to compensate the victim when a causal link is uncertain.[136] For example, when a patient was not informed of the risks of treatment, it is uncertain what the patient would have chosen (surgery or no surgery) if they did know all the risks. Therefore, the actual loss that the patient suffered is the loss of a chance because the patient has lost the opportunity to avoid the treatment.[137]

Thus, to summarise the last paragraphs: negligence, injury and causation are the relevant requirements to establish fault liability. For both negligence and causation, French courts are not reluctant to accept these relatively easily. However, there is also the option to establish vicarious liability and product liability in some cases.

4.2.2 Strict liability

Under French law, it is possible to hold the physician vicariously liable for the medical team that they have chosen, and it is possible to hold the clinic or hospital liable for the conduct of its employees.[138] Here, the difference between the public and private sector is relevant because private clinics are only responsible for the practitioners that are employed. Self-employed

[131] Van Dam (n16), 265.
[132] G'Sell-Macrez (n117), 1101.
[133] Ibidem, 1102.
[134] Ibid., 1110.
[135] Ibid., 1111.
[136] Ibid., 1114.
[137] Ibid., 1103.
[138] Ibid., 1103.

physicians are responsible and liable for their own acts. Physicians working in a public hospital are always employed by the hospital. Vicarious liability means that surgeons are not personally liable for negligent conduct that happened in the course of a mission assigned to them by the employer or in the course of the function for which they were employed.[139] [140] This means that the employer cannot be held liable for the conduct of the employee where the latter acted outside the functions for which he was employed, did so without authorisation or for purposes outside the ones related to his tasks.[141] However, it may be the case that the medical team did not act wrongly, but that the products they used were defective and caused damage.

Liability situations caused by defective products, such as health products or medical devices, are governed in two different ways in France. The first possibility is to hold the health professional or hospital strictly liable for the use of a defective product because they owe their patients an obligation of safety for all products used for treatment or surgery.[142] However, a different way to establish liability in the context of defective products is product liability.[143] The Product Liability Directive (PLD) of the European Union has been implemented in law 98-389 in France. This implementation may threaten the rules on strict liability of the health professional or hospital, since the Directive states that manufacturers are liable for the defective products that they make, and not medical practitioners when they use the products. Moreover, this general product liability regime excludes the specific national healthcare liability regime in this case, so defective health products might no longer be governed by the CSP.[144] Product liability is extensively discussed in section 4.4 on the European Union.

In sum, patients who suffered injury as a result of a surgery have sufficient options for redress; establishing negligence of the treating physician is not difficult in France, the hospital can often be sued for conduct of its employees, and the requirements for causation are not stringent. In the next section, an overview is given of the healthcare liability framework in Germany.

4.3 Germany

Whereas in France, the distinction between private and public health institutions was pointed out, in Germany, a noteworthy distinction is between federal law and *länder* law. The state has provided the underlying statutory framework of the healthcare liability regime, and the *länder*

[139] G'Sell-Macrez (n117), 1104.
[140] Code Civil, art. 1284 al. 5.
[141] Van Dam (n16), 507.
[142] G'Sell-Macrez (n117), 1105-1106.
[143] Thouvenin (n119), 174.
[144] G'Sell-Macrez (n117), 1107.

can govern the aspects that are not regulated by this centralised regime. These aspects mostly include the detailed ordering and running of the healthcare system.[145] Therefore, the underlying federal framework is the subject of this section.

4.3.1 Fault liability

A patient who suffered injury has several choices to make with regards to acquiring compensation. Most compensation claims are made within the context of a private law case, which is also the focus of this section. In Germany, an action can be brought under contract or under tort law, which do not differ in terms of results because in the German Civil Code (BGB), the rules are essentially the same for both types of action. [146] For example, the standard of care to which the physician has to adhere is the same for an action brought under contract and tort.[147] Hence, the patient can choose, but in this section, focus is on tortious liability as stated in 823(1) BGB.[148] Moreover, the patient may choose to sue the doctor and/or the hospital.[149] Doctors can be sued for their direct, negligent behaviour (discussed below), and the hospital because it can be vicariously liable for the doctors' conduct.[150]

Within private law cases, there is a distinction between treatment malpractice and disclosure malpractice. A treatment malpractice case follows the familiar paradigm of fault liability. Negligence is determined through the standard of reasonable care. Within the context of healthcare, this is not the normal standard of a reasonable man, but that of "a respectable and conscientious medical professional of average expertise in the relevant field."[151] This is an objective standard, which means that it does not matter what the individual doctor actually knows and can do, but what is expected of an average doctor.[152] This standard is determined by the court, perhaps with the advice of professionals. The standard works in the same way as in France. Therefore, the doctors cannot defend themselves by claiming that they did not know how to handle a certain situation; they often should have known. Another consequence of this objective approach is that the hospital cannot plead lack of resources because a hospital should

[145] Marc S. Stauch, 'Medical Malpractice and Compensation in Germany' (2011) 86 Chicago-Kent Law Review 1139, 1140.
[146] S. A. Sommer, R. Geissler, U. Stampfl, M.B. Wolf, B. A. Radeleff, G. M. Richter, H. U. Kauczor, P. L. Pereira, C. M. Sommer, 'Medical Liability and Patient Law in Germany: Main Features with Particular Focus on Treatments in the Field of Interventional Radiology.' (2015) 188 Fortschr Röntgenstr 353, 354.
[147] Stauch (n145), 1144.
[148] Ibidem, 1143.
[149] Ibid., 1145.
[150] Marc S. Stauch, *The Law of Medical Negligence in England and Germany: A Comparative Analysis* (Hart Publishing 2008), 12.
[151] Bundesgerichtshof [BGH] [Federal Court of Justice], Jun. 13, 1960, NEUE JURISTISCHE WOCHENSCHRIFT [NJW] 600, 1961.
[152] Stauch (n145), 1149.

have the necessary resources (naturally, there are certain exceptions, for example in crisis situations).[153]

A different type of claim is the disclosure malpractice claim, which entails that the doctor did not inform the patient of all the risks of the treatment surgery and possible alternative treatment. Even quite negligible risks should be noted, so the patient can give valid consent to undergo treatment.[154] It seems that France might be more lenient in this duty than Germany. However, France and Germany are alike in placing the burden of proof on the physician in cases of disclosure malpractice.[155]

However, in cases of treatment malpractice, the burden of proof is on the patient, which means that the patient has to show that the injury arose from the breach of standard of care and not from, for example, an underlying medical condition. Thus, the patient has to prove causation. The basis for causation is, again, *conditio sine qua non*. However, in the context of healthcare in Germany, this theory is supplemented by the standard of "judicial conviction", which is a strict standard.[156] Essentially, this standard entails that the victim has to ensure the court is convinced to a high degree of the negligence of the health professional. However, there are situations where this standard is lightened.[157] However, when looking at the standard of causation, Germany seems to be more stringent than France.

Besides disclosure malpractice claims, there are cases that require the hospital or doctor to prove that they are not liable for a certain breach. One such case is called the 'fully masterable risk'. This entails the situation where a certain risk in the treatment environment results in harm to the patient.[158] The treatment environment includes technical apparatus.[159] The risk falls under the subsidiary obligations of the treatment contract, which means that this obligation is construed strictly: the occurrence of the risk is enough to qualify as a breach of contract, so the victim does not need to prove this.[160] The relevant aspect of the treatment environment has to fall under the full control of the doctor; they are responsible for ensuring a safe environment for the patient. The burden of proof is reversed in this particular case.[161] However, this is a breach of contract, so not a tort. Contractual liability falls outside the scope of this thesis, but

[153] Stauch (n145), 1150.
[154] Ibidem, 1156-1157.
[155] Ibid., 1157.
[156] Ibid., 1153.
[157] Edward I. Hyslop, 'European Causation in Tort Law: a Comparative Study with emphasis on Medical Law in the United Kingdom, Germany and France and Luxembourg' (PhD thesis, University of Luxembourg 2015), 173.
[158] Stauch (n145), 1151.
[159] Hyslop (n157), 189.
[160] Stauch (n145), 1151.
[161] Hyslop (n157), 189.

the fully masterable risk might be relevant for the technology discussed in this thesis, which is why it is included here.

4.3.2 Strict liability

Vicarious liability of the hospital works in a similar way as in France. The rule is that "anyone who has employed another person for a task (…) is liable for the injury unlawfully caused by that other person in accomplishing the task."[162] [163] However, there are also some important differences in comparison with France with regards to the exemption of liability of the employer: the hospital cannot be held liable if it exercised reasonable care in selecting the employee, in the procurement of tools and in the supervision of the employee. The employer has to prove that they exercised reasonable care. Moreover, the hospital is not liable in case the injury would have happened even if they had exercised this level of reasonable care.[164] These defences are not available to hospital in France. However, even though German hospitals can exempt themselves from liability by proving the defences discussed before, the high level of care required is close to a strict liability rule because it may not matter how high the level of care was; it might still not be enough.[165]

Injury caused by the use of non-pharmaceutical medical products is governed by the Products Liability Act, which implemented the EU Directive on product liability.[166] This Directive is covered in the next section.

4.3.3 Social compensation

Patients who cannot recover the damages through the private law compensation or strict liability schemes can fall back on the general system of social security. This system compensates further remedial treatment and costs of ongoing nursing care. Collective social protection can be used by any injured person, irrespective of the source of injury.[167]

To summarise, the standard of care that health professionals and hospitals have to ensure is quite high, and the objectivity thereof makes it easier for a victim to prove negligence, which is positive for the victim's chances of receiving compensation. However, causation might be more difficult to prove than in France. Moreover, the "fully masterable risk" might be relevant for liability issues regarding autonomous surgical robots, discussed in Chapter 5. Both this and

[162] Van Dam (n16), 502.
[163] BGB, art. 831.
[164] Van Dam (n16), 502.
[165] Ibidem, 503.
[166] Stauch (n145), 1146.
[167] Ibidem, 1147.

the previous section talked about the EU Product Liability Directive, which is discussed hereafter.

4.4 The European Union

The European Union governs product liability in a supranational manner. The fundament of the EU framework of product liability is Directive 85/374/CEE of 25 July 1985 concerning liability for defective products.[168] This Directive requires maximum harmonization, which means that few national derogations are allowed.[169] Consequently, it creates an almost uniform liability regime for product liability across the Member States. For an injured to party to be able to enjoy the protection of the EU framework, they have to base their claim on the national laws that implement the Directive.[170] The goal of the Directive is to give consumers the possibility to sue a manufacturer for a defective product without having to establish fault, which means the liability is strict and negligence is not required. The need for this possibility came from the increasing technicality of our society and the need for a fair divide of the inherent risks. However, the "powers" of the consumer are limited by the exoneration grounds that a producer may invoke and by time limits after which a victim can no longer bring a claim against a manufacturer.[171] In the upcoming paragraphs, the regime of the EU is explained, starting with a number of definitions.

Article 1 of the Directive states that "the producer shall be liable for the damage caused by a defect in his product."[172] Thus, the key notions are *producer*, *product* and *defect*. *Producer* is defined broadly, since it can mean the manufacturer of the finished product, but also the manufacturer of a component part.[173] Moreover, even an importer or supplier can be seen as a producer under the Directive.[174] A *product* means a movable, even if its incorporated into another movable or an immovable.[175] The definition of a *defect* is given in article 6(1): a defective product "…does not provide the safety which a person is entitled to expect, taking all circumstances into account…"[176] These circumstances include the presentation of the product, the expected use and the time when the product was manufactured.[177] Firstly, the presentation

[168] Directive on liability for defective products (n20).
[169] Van Dam (n16), 29.
[170] K. Alheit, 'The applicability of the EU Product Liability Directive to software' (2001) 34 *The Comparative and International Law Journal of Southern Africa* 188, 192.
[171] Annabelle Bruyndonckx, Vladimir Murovec and Michael Bulckaert, 'Product Liability: Compliance and Safety Issues' in Jelena Madir (ed), *Healthtech: Law and Regulation* (Edward Elgar Publishing 2020), 116.
[172] Directive on liability for defective products (n20), Art. 1.
[173] Ibidem, Art. 3(1).
[174] Ibid., Art. 3(2) and 3(3).
[175] Ibid., Art. 2.
[176] Ibid., Art. 6(1).
[177] Ibid., Art. 6(1).

of the product includes the information that has to be given with regards to the risks of the product. Secondly, the expected use has to be considered in combination with the behaviour of the victim. The manufacturer has to anticipate the use and possible inattention of the user. Thirdly, the time when the product was put into circulation means that manufacturers cannot be not punished solely because a better product was put into circulation at a later time; the fact that technologies improve does not mean that the earlier products are defective.[178]

The roles that the victim and the manufacturer play are quite typical: the victim proves the wrong of the wrongdoer, and the wrongdoer can defend themselves with certain arguments. The burden of proof is on the victim, who needs to prove three things: a defect in the product, the damage suffered and a causal relationship between the two.[179] Therefore, it is irrelevant whether the manufacturer was negligent; proof of a defect that caused damage is enough for the victim to fulfil its burden. However, only damage caused by death, personal injury and damage to private property may be compensated.[180] This does not amount to a problem in healthcare cases.

Moreover, the manufacturer is protected by time limitations and exoneration grounds. With regards to time limitations, the Directive provides a short-term and a long-term limitation period. The short-term begins when the victim knows or should have known that there was a defect and damage, and after that moment, they have three years to bring a claim. The long-term period is ten years, and it starts on the day the defective product was put into circulation.[181] Once one of these periods have passed, the injured party can no longer bring a claim. Moreover, article 7 lists six exoneration grounds, two of which are relevant in the context of healthcare liability. The first is developments risks. This ground refers to the situation where the scientific and technical knowledge that was available at the time the product was put into circulation was not sufficient to discover the defect.[182] Therefore, the manufacturer is not liable for these defects. The second exoneration ground is only usable for producers of component parts or raw materials because they can be exonerated if they prove that "the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product."[183]

To give a full overview of the Product Liability framework of the EU, it has to be noted

[178] Directive on liability for defective products (n20), Art. 6(2).
[179] Ibidem, Art. 9.
[180] Alheit (n170), 205.
[181] Directive on liability for defective products (n20), Art. 10 & 11.
[182] Ibidem, Art. 7(e).
[183] Ibid., Art. 7(f).

that this framework is linked to the safety requirements with which a healthcare product has to comply before it can be put into circulation in the EU.[184] These safety requirements give additional meaning to the safety that a person is entitled to expect, so to the meaning of a *defect*.[185] Relevant for the topic of this thesis is Regulation (EU) 2017/745 on medical devices.[186] A *medical device* is "…any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability…"[187]

Moreover, this Regulation governs whether medical devices are safe enough to be put on the EU market.[188] The general principles with regards to safety of medical devices are that the device must not be a danger to the safety of the patient; the benefits of the device must outweigh the risks; the risks must be eliminated or minimised according to the state of the art; and the performance of the device must be according to the manufacturer's intentions.[189] Furthermore, Annex I, section 17 focuses on "[E]lectronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves"[190], which lists certain requirements that the manufacturer has to comply with, such as the requirement to develop and manufacture the software in accordance with the state of the art.[191] Furthermore, manufacturers have to ensure the reliability, repeatability and performance in line with the intended use of the software.[192] The adherence of manufacturers to these rules can help them defend themselves against claims for compensation when someone is injured by their product because the manufacturer can claim that the device offered the safety that a person is entitled to expect.

To summarise, the product liability framework that the EU established regulates the

[184] Bruyndonckx et al. (n171), 126.
[185] Ibidem, 136.
[186] Regulation on medical devices (n39).
[187] Ibidem, Art. 2.
[188] European Medicines Agency, 'Medical devices legislation' <www.ema.europa.eu/en/human-regulatory/overview/medical-devices#medical-devices-legislation-section> accessed 10 February 2021.
[189] Bruyndonckx et al. (n171), 136-137.
[190] Regulation on medical devices (n39), Annex I (17).
[191] Ibidem, Annex I (17.2)
[192] Ibid., Annex I (17.1).

cases of damage caused by defective devices, and in combination with the safety rules for medical devices, the standards of the PLD can be interpreted and used in medical situations. The PLD makes it easier for injured parties to establish liability because they need not prove that the manufacturer acted negligently. However, the manufacturer can invoke exoneration grounds and time limits. Furthermore, the applicability of the Product Liability Directive to software is discussed more extensively in Chapter 5. However, the inclusion in the Regulation on Medical Devices sets the stage for the requirements that a manufacturer should adhere to.

4.5 Conclusion

To conclude, the national healthcare liability frameworks of France and Germany give injured patients the possibility to get compensation by having different types of liability in place. Both countries provide for dual responsibility of health professionals: they have to act with a certain level of care and are required to inform patients of risks and alternatives. In France, the hospital can be held vicariously liable for its employees and the physician can be held liable for his medical team. In Germany, the injured party can also sue the hospital when the physician caused injury. In this regard, in Germany, courts seem to be more lenient for the injured party and hold the hospital liable more easily than in France. Moreover, Germany has a special regime in place for when the environment of the patient (the operation room) causes damage to a patient, and in France, the hospital or physician is strictly liable for the medical devices used. These rules might partly overlap with the legislation of the EU because the Union has prescribed the way Member States shall regulate product liability. Therefore, the environment of a patient, with regards to medical devices, can simultaneously fall under the relevant rules of France and Germany and under product liability. EU law has primacy in this situation. The EU uses a combination of safety rules that manufacturers have to adhere to before placing a product on the market and product liability rules for when a product is defective and causes damage. The Product Liability Directive covers many different technologies because it is technology-neutral in defining *product*. Moreover, it was concluded by the commission in a report to the European Parliament that the PLD seems to have stood the test of time and is flexible enough to regulate many new technologies.[193] However, this is no guarantee that all future technology will be sufficiently regulated by this legislation. If not, it has to be seen whether injured patients can be compensated by holding the health professional or the hospital liable under national rules.

[193] European Commission, 'Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the application of the council directive on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products (85/374/EEC)' COM (2018) 246 final, at 2.

Whether the frameworks explained in this chapter are equipped to deal with the liability issues arising from the use of autonomous surgical robots is discussed in the next chapter.

Chapter 5: Autonomous Surgical Robots and Liability

5.1 Introduction

In this chapter, it is analysed what liability issues will arise due to the use of autonomous surgical robots and how the discussed healthcare tort law systems will respond to these issues. Firstly, focus is on the liability issues that will arise from the use of autonomous surgical robots. Secondly, it is discussed how the healthcare liability frameworks of Germany and France and the product liability framework of the EU respond to these issues. Thirdly, a number of publications of the EU is discussed, in which the EU pronounces the need for new/amended legislation around AI. In the conclusion, the question is answered whether these solutions are enough, which is also the answer to the main research question.

5.2 Failures and liability issues

As was discussed in Chapter 2, autonomous surgical robots can independently cause damage and harm a patient. Consequently, this gives rise to a number of questions about liability. In this section, a quick recap is given of information on the different ways in which autonomous surgical robots can harm a patient. Afterwards, two liability questions with regards to these robots are discussed. These questions result in liability issues for the injured party because it is unclear whether and how a victim can establish liability in these cases.

As discussed in Chapter 2, failures in autonomous robots can be of a technical or human nature. Human failures are caused by the wrong use of the robot by humans. The physician who used the robot in a wrong way (for example, by using the robot for a surgery for which he was not programmed) may be held liable according to fault liability in France and Germany because it may be clear that the physician is the direct cause of the damage. Without their incorrect behaviour, the damage would not have occurred, and with regards to the professional expertise, they should adhere to a high standard of care. Therefore, in the case of human failures, the question of liability may often not be difficult to answer. However, focus of this thesis is on technical failures, so the assumption is that human failure is not a link in the chain of causation. Technical failures should be seen as built into the robot; it revolves around software and physical parts of the robot. Technical failures can be divided into software malfunctions and mechanical malfunctions according to Attia et al.[194] Software malfunctions are caused by a defect in the software and include the resulting movements of the robot. Mechanical malfunctions are caused by a defect in the physical aspects of the robot and the way it was built,

[194] Attia et al (n11), 4083.

such as weird movements or faulty parts that cause damage when used.[195] Focus in this chapter is on software malfunctions because this is the part of the autonomous surgical robot that makes the wrong decision and causes damage. Therefore, this type of malfunctions raises more questions with regards to liability. Essentially, software malfunctions are caused by the person who wrote the code. The question is whether the manufacturer of the code/robot (might be the same person, might not be) can be held liable.

The liability issues that arise from software malfunctions are twofold. Firstly, an aspect of autonomous surgical robots that results in lack of clarity and, consequently, liability issues is the fact that the robots make their own decisions and can cause damage. This has consequences for establishing fault liability (with regards to physicians) because the required causal link between negligent human behaviour and damage might be a hurdle for establishing this type of liability. The causation issue is discussed in the next section. However, product liability might be a solution for these issues.

A second issue is related to product liability, and the difference between the mechanical part and the software part. The mechanical aspect of the robot logically falls under the Product Liability Directive because it is a movable and, therefore, a product.[196] Software might not fall under the Directive. Firstly, a relevant question is whether software can be regarded as a product in the meaning of article 2 of the Directive. The answer to this can be derived from literature and the Directive and is discussed later on in this chapter. Secondly, if the answer to the first question is positive, it might be unclear when the software is defective (in other words, when does software not provide the safety a person is entitled to expect). Namely, it is extremely difficult or even impossible for the producer of the code to predict how the robot will react in all circumstances.[197] Some argue that this means that the robot is defective, which might make it possible to hold the designer liable under product liability.[198] However, this view is not uncontested. In section 5.4, both issues are discussed.

In this section, a number of technical failures and resulting liability issues have been pointed out. In the upcoming section, it is analysed whether the national healthcare liability framework of Germany and France are equipped to solve the first issue.

[195] Attia et al (n11), 4083.
[196] Directive on liability for defective products (n20), Art. 2.
[197] Barfield (n12), 193.
[198] O'Sullivan et al. (n6), 6.

5.3 Germany and France

In this paragraph, it is first discussed whether fault liability of the physician can be established in the context of damage caused by an autonomous surgical robot. Given that France and Germany have the same requirements to establish fault liability, they are discussed together. Hereafter, a few special medical situations are discussed where other rules apply that might be useful to establish liability in the context of autonomous surgical robots. The section ends with a discussion of social compensation laws.

Firstly, fault liability requires negligence, which in France entails not acting according to the duty of care of physicians to give the most appropriate care and weigh the expected risks and benefits.[199] In Germany, physicians have to act according to the standard of a good medical professional.[200] When using an autonomous surgical robot, physicians are not likely to act negligently because they may still adhere to these standards. A correctly programmed robot would be safer than a human surgeon. Moreover, the physician is probably not aware of a bug in the software, and since the physician is not a technical expert, the physician cannot always be expected to know there is a bug. Thus, it might be hard to prove negligence in such cases because the physician acted according to the standard required (or, so we assume).

Secondly, injury is not difficult to prove because this will be well documented and the right to bodily integrity gets a high degree of protection.[201]

Thirdly, causation. Both France and Germany first analyse causation using the *conditio sine qua non* test. This test revolves around the question whether the injury would also have occurred in the absence of the act of the physician. Here, it is essential what is regarded as the *act* of the physician. The deployment of the robot can be seen as an act, since the physician decides whether the robot is deployed in a particular surgery or not. However, there are also acts such as setting the right parameters, ensuring the environment is safe, and monitoring and intervening when necessary. These can be seen as affirmative duties, so acts that the physician should do and can cause omissions when he fails to do these. The patient has to prove that the injury would not have occurred if the physician had acted according to the duty. This could very well be a successful claim, since the injury would not have occurred if the physician had acted. However, focus in this thesis is on the 'active' act of the physician, so the actual decision to deploy the robot, since the scenario would otherwise be too complex. These omissions should

[199] Code of Public Health (CSP), Art. 1111-5 para. 1.
[200] Bundesgerichtshof [BGH] [Federal Court of Justice], Jun. 13, 1960, NEUE JURISTISCHE WOCHENSCHRIFT [NJW] 600, 1961.
[201] Van Dam (n16), 171.

be researched further in the future.

Thus, besides deploying the robot, the other acts of the physician are left aside. In this particular scenario, it can be said that the act of the physician caused the damage indirectly because the physician decided to deploy the robot. However, this decision cannot be said to be negligent.

Consequently, the hospital cannot be held vicariously liable, since this requires the negligence of the employee. Liability based on fault appears not be an option for victims. However, medical liability governs a number of special situations with might be useful, such as the fully masterable risk.

The fully masterable risk, as was explained in the section on Germany in Chapter 4, only applies to the equipment in the operation room over which the physician has full control.[202] This cannot be said about a physician deploying an autonomous robot. However, the robot might still be subject to a certain degree of control, through appropriate technical measures for example. Therefore, victims might be able to base their claim on this special liability rule. However, as previously noted, because this rule falls under contractual liability and the discussion whether an autonomous robot is controllable goes beyond the scope of this thesis, it will suffice here to conclude that this rule might be helpful for victims.

Moreover, in France, there is a regime of strict liability for the physicians or hospitals with regards to medical devices used. The physician and hospital owe their patients an obligation of safety regarding these devices.[203] However, these rules are no longer relevant because the Product Liability Directive of the EU has primacy in these cases.[204] Therefore, victims should base their claim on the national rules that implemented the PLD, which focus on the liability of the manufacturer.

A last resort could be the social compensation laws, such as regulated under the Patients' Rights Law in France.[205] A victim can get compensated for injury that cannot be attributed to wrongful behaviour. Moreover, in Germany, patients can fall back on the general social security system. However, this system does not give full compensation for the damages.[206] Therefore, this cannot be seen as giving victims full compensation.

To conclude, the national healthcare liability frameworks of France and Germany do not give sufficient options to hold the physician or hospital liable for injury caused by an

[202] Hyslop (n157), 189.
[203] G'Sell-Macrez (n117), 1105-1106.
[204] Ibidem, 1107.
[205] Ibid., 1096.
[206] Stauch (n145), 1147.

autonomous surgical robot. The social compensation or social security laws might give some compensation, but victims will probably try to get full compensation. In that case, the product liability framework of the EU might be better suited to help them.

5.4 The European Union

Since the adoption of the Product Liability Directive in 1985, healthcare has undergone a great number of developments, many related to new technologies.[207] The EU concluded in a report that the Directive is flexible enough to tackle these liability problems.[208] However, this might not be the case for all future technologies. Whether the Directive also governs the cases regarding autonomous surgical robots depends on two questions: 'Who are regarded as *producers*?', and 'Is software regarded as a *product* under the Product Liability Directive?'. The focus of the latter question is on software because the physical aspect of the robot is a movable, and therefore a product.[209]

With regards to the first question, a *producer* is defined as the manufacturer of the finished product or the manufacturer of a component part.[210] Article 1 states that "[T]he producer is liable for damage caused by a defect in his product."[211] Consequently, the producer of the final product is responsible for the complete product, even if there are third party components embedded into it.[212] Moreover, the third party manufacturer can be held liable for its component part because this manufacturer is also seen as a producer under the Directive.[213] Therefore, the manufacturer of the finished product can be held liable for mechanical and software malfunctions, whereas the manufacturer of the software can only be held liable for software malfunctions. However, according to article 7(f) of the PLD, the manufacturer of a component is not liable in case "the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product."[214] Consequently, if the manufacturer of the software cannot prove this, they are liable for their own components. If they can prove this, only the manufacturer of the finished product can be held liable. However, this analysis relies on the assumption that software is a product.

This assumption might not be correct when looking at the law and literature revolving around the nature of software. This might create legal uncertainty, but in this paragraph it is

[207] Bruyndonckx et al. (n171), 124.
[208] European Commission (n193), at 2.
[209] Directive on liability for defective products (n20), Art. 2.
[210] Ibidem, Art. 3(1).
[211] Ibid., art. 1.
[212] European Commission (n13), 10.
[213] Directive on liability for defective products (n20), Art. 3(1).
[214] Ibidem, Art. 7(f).

made clear that the answer is quite simple. Some argue that software should not be regarded as a product under the PLD. For example, Calo argues that a mistake in code should not be regulated by product liability in the same way that a book with wrong information is not covered by product liability.[215] Software might also be regarded as a service, and liability in the context of services is governed by national laws.[216] [217]

The main difficulty with software is its intangibility. Even though intangible products are not explicitly excluded from the PLD, the inclusion of electricity seems to point to the exclusion of other intangible products.[218] Including one intangible product implies that that that is the exception to the general rule. Nevertheless, when the software is embedded into a robot, the software does function and directly dictates movements, since it decides how the robot moves. Therefore, the software can cause damage directly: there is material output.[219]

Furthermore, regarding software as a product complies with the objectives behind the Directive because the manufacturer is in the best position to detect and prevent defects. Moreover, the manufacturer can absorb and spread the risk (and related costs) of the damage.[220]

Yet a different argument is that tools used in healthcare that are controlled by algorithms and software qualify as medical devices under the Medical Devices Regulation, which makes them products.[221] This link between the Medical Devices Regulation and Product Liability Directive is useful because these pieces of legislation complement each other: The safety requirements of the MDR fill in the defective requirement of the PLD. To summarise all the arguments, software is a product and, therefore, governed by the PLD.

To establish product liability under the Directive, the injured party has to prove a defect, damage and a causal relationship between the two.[222] The defectiveness of the product is viewed with regards to three factors. One of these is the use to which the software (and robot) is expected to be put. This criterium is more stringent when human lives may be endangered by the application of the software.[223] Consequently, it would become easier to prove the software was defective. With regards to the robot, human lives are most certainly endangered by its application because there is an inherent risk to surgeries and mistakes might have tragic consequences. Furthermore, the causality between a defect in the software and the damage is

[215] Calo (n25).
[216] Alheit (n170), 199.
[217] European Commission (n13), 4.
[218] Alheit (n170), 200.
[219] Ibidem, 201.
[220] Ibid., 206.
[221] Bruyndonckx et al (n171), 115 & 118.
[222] Directive on liability for defective products (n20), Art. 9.
[223] Alheit (n170), 203.

direct because the software is incorporated into the robot, sets it in motion and causes injury.[224] Therefore, causation is not difficult for the victim to prove.

However, it is important to keep in mind that software is never bug-free, which means that producers can sometimes invoke the development-risk defence. Consequently, bugs in the software are excusable if the state-of-the-art in software technology could not detect the defect.[225] [226] Not knowing how the robot is going to react to certain circumstances might be regarded as a defect, but if a specific reaction could not be detected by the state-of-the-art, then the manufacturer can defend themselves using this argument. However, the safety standards for software discussed in the MDR should always be adhered to.

The Product Liability Directive is not binding on the Member States. As said in Chapter 4, it is a maximum harmonization Directive, and small derogations are possible. This is relevant here because in France, software that is embedded into hardware is considered to be a product under the national product liability regime (which incorporates the Directive in the national legal system). However, in Germany, it is questionable whether software is a product under the Product Liability Act.[227] This can have consequences for the victim in a concrete case. The injured party might be able to sue the manufacturer of the robot for mechanical malfunctions of the robot, but if the cause of the damage was the software, then it might be more difficult, since this does not fall under the German implementation of the PLD.

To conclude, the autonomous surgical robot and its software fall under the regime of the Product Liability Directive. The victim can hold the producer of the final product liable for damage caused by a defect in its product, and the victim can hold the producer of the software liable for software malfunctions. Therefore, the injured party has enough options for redress under the European framework. However, this is not the case in every Member State because it is a Product Liability *Directive*. Injured parties in France enjoy better protection than in Germany in this context. Fortunately, the EU is still improving the liability framework around AI and robotics.

5.5 Efforts of the EU

In this section, three efforts are discussed through which the EU wants to ensure that its legal framework is and remains equipped to deal with rapidly evolving technologies that use AI.

Firstly, the EU Commission published a communication regarding general regulation of

[224] Alheit (n170), 205.
[225] Ibidem, 204.
[226] Directive on liability for defective products (n20), Art. 7(e).
[227] Bruyndonckx et al (n171), 119.

AI.[228] The aim of the Commission is to ensure that the development of AI is surrounded by an adequate ethical and legal framework. The values that this framework should be based on are the ones set out in the Treaty of the European Union and the EU Charter of Fundamental Rights.[229] Moreover, this framework should include guidance on existing product liability rules.[230] This communication is quite general and creates the opportunity for more concrete policy changes.

Secondly, the EU parliament adopted a resolution in which they recommend that the Commission creates a civil liability regime for AI.[231] This regulation should lay down "rules for the civil liability claims of natural and legal persons against operators of AI-systems."[232] The resolution proposes to put liability on the operator of the AI-system and not on the manufacturer.[233] However, it remains unclear whether this means that the manufacturer is exempt from liability where an AI-system causes damage. Moreover, with regards to what type of liability (fault or strict) is applicable to the operator, a distinction is made between high-risk AI-systems and other AI-systems.[234] An exhaustive list should set out which specific systems are considered high-risk, and systems not included are not high-risk.[235] With regards to high-risk AI-systems, the operator is strictly liable for damage caused by the system, which means they cannot exempt themselves by claiming that they acted with due care.[236] Furthermore, the long-term time limitation period stated in art. 11 of the Product Liability Directive would be adapted for claims based on injury to life, health or limb caused by high-risk AI-systems. This limitation period would not be 10 years, but 30 years from the date on which the injury occurred.[237] This special time limitation period would not apply for claims based on damage caused by an AI-system that does not constitute a high-risk. Moreover, claims against operators of other AI-systems should be based on fault liability.[238] Consequently, negligence has to be proven for liability to be established, and acting with due care can be used as a defence. To conclude, this resolution is quite detailed and concrete. It clearly notes the risk of certain AI-

[228] European Commission, 'Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions: Artificial Intelligence for Europe' COM (2018) 237 final.
[229] Ibidem, 14-15.
[230] Ibid., 4.
[231] European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL)).
[232] Ibidem, 2.
[233] Ibid., 2.
[234] Ibid., 2.
[235] Ibid., 3.
[236] Ibid., 2.
[237] Ibid., 3.
[238] Ibid., 3.

systems and the need to hold the responsible person accountable. This is why the resolution focuses on the operator, and not (only) on the producer. Moreover, in the resolution, it is stated that the PLD should be revised, because it has to be ensured that it will remain effective with regards to new technologies.[239]

Thirdly, the Commission has drafted a staff working document on liability for emerging technologies.[240] In this working document, several questions relating to aspects of liability in the context of new technologies are noted. For example, a question that is also central in this thesis: who is liable when technology acts autonomously and the damage cannot be linked directly to a defect or a human wrongdoing?[241] Moreover, it is suggested that guardians of robots might be held liable in the same way as guardians of animals. This liability would be based on the lack of predictability of animal behaviour.[242] Furthermore, the document expresses the need to analyse the development risk defence included in the Product Liability Directive.[243] This seems logical because the development risk defence could be used often by manufacturers of new technology, but it should not become an easy excuse for dangerous technology. This could be relevant for the manufacturers of autonomous surgical robots. One of the goals of clearing these points of discussion up is to create a stable legal framework, which stimulates investment. Moreover, for consumers to trust the technologies, sufficient remedies are necessary.[244] The Commission will analyse the questions and conclude whether new or amended legislation is needed.[245]

5.6 Conclusion

In this chapter, it is concluded that the national liability rules in the context of autonomous surgical robots in healthcare would not be useful for victims to acquire compensation. The behaviour of the programmer of the robot and the physician cannot be defined as negligent under the frameworks of France and Germany. Furthermore, the special French rule according to which the physician is strictly liable for the tools that he uses is also not useful in the situation of damage caused by an autonomous surgical robot because of the Product Liability Directive. Additionally, the German rule of the fully masterable risk might be useful for victims, but it goes beyond the scope of this thesis to address this more extensively.

[239] European Parliament (n231), 2.
[240] European Commission (n13).
[241] European Commission (n13), 10.
[242] Ibidem, 19.
[243] Ibid., 19.
[244] Ibid., 2.
[245] Ibid., 21.

Furthermore, it is concluded that the Product Liability Directive of the EU could generally be used by victims to sue the manufacturer of autonomous surgical robots. However, whereas in France both the physical aspect and the software are regarded as products, in Germany, software might not be regarded as product, and patients might not enjoy the protection the PLD provides in France. Moreover, unforeseeable behaviour of the robot can be regarded as a defect, unless the manufacturer can successfully invoke the state-of-the-art defence. This seems to strike the right balance between the interest of the victim and that of the manufacturer because the latter cannot be held liable for a defect that could not have been detected at the moment that they built and programmed the robot. With regards to software, this situation might be quite realistic, but also dangerous because manufacturers should do everything reasonably possible to detect and prevent any defects and should not be less motivated to do this because they have a defence to fall back on.

Even though the EU framework seems to give patients sufficient options for redress, a look in the future promises an even better framework for liability with regards to AI and new technologies. New legislation will hopefully be introduced that compiles the rights of the victims, so they have a clear overview of how to claim compensation. Furthermore, new legislation should eliminate the differences between Member States, so that injured parties in all EU states enjoy equal protection under the EU Framework.

In the next chapter, this thesis is concluded and summarised. Moreover, the limitations of this thesis are discussed and a reflection is given on some conclusions.

Chapter 6: Conclusion

6.1 Introduction

In this final chapter, the thesis is concluded. Firstly, a recap is given of the literature gap and problem surrounding the topic of this thesis, and it is discussed how this gap was attempted to be filled. Secondly, the main research question is answered and the importance of the findings is explained. Thirdly, the limitations of the research and findings are discussed. Lastly, the chapter is concluded in the final section.

6.2 Literature gap and problem

In this thesis, the problem that was addressed was the uncertainty from the point of view of the injured party that arose from certain liability questions/issues in the context of the use of autonomous surgical robots. Moreover, an essential part of the problem was the uncertainty whether these liability issues could be adequately addressed by the liability frameworks of France, Germany and the EU. This specific issue had not yet been addressed in literature, which means there was a literature gap. The gap was filled by researching what liability issues arise from the use of autonomous surgical robots, what it means for a tort law framework to be equipped to solve liability issues, and explaining the tort law frameworks of France, Germany and the EU. Moreover, all this information was combined in Chapter 5, where the question was answered how the frameworks would respond to these liability issues. The main focus of the research was on the legislation of Germany, France and the EU. With regards to France and Germany, the analysis focused on national tort law in the context of healthcare. With regards to the EU, focus was on the Product Liability Directive and the Medical Devices Regulation, which added to the necessary information to answer the main research question. This answer is given in the next section.

6.3 Main research question

The main research question that has to be answered in this thesis is: “To what extent are the current EU product liability framework in healthcare and the laws on medical liability of France and Germany equipped to deal with the liability issues that arise from the use of autonomous surgical robots?” As was discussed in Chapter 3, this question essentially tries to figure out what options of redress victims have when they are injured by an autonomous surgical robots and whether these options are sufficient to claim compensation. Focus is on damage that is caused by the software of the robot, which has a bug caused by the producer of the code. The answer to the main research question is: injured parties that bring a claim in France (for example

because they received treatment in France) have sufficient means for redress because of the national implementation of the Product Liability Directive, but in Germany, injured parties do not enjoy this level of protection. In France, the injured party can invoke the national rules that implement the Product Liability Directive and software is regarded as a product under French law. Therefore, they can hold the manufacturer of the robot or the manufacturer of the software liable for damage caused by a defect in the product. Unpredictable behaviour may be regarded as a defect, unless the manufacturer can prove that the defect could not be detected by state-of-the-art technology. The combination between technology-neutral EU law and French law, which does include software as a product, is a good environment for the injured party. Moreover, for producers of technology that includes software, it becomes clearer when they are liable and what kind of claims they can expect, which is positive for the development of new technologies.

In Germany, the injured party is in a more difficult position. There, software is not regarded as a product and does, therefore, not fall under the national rules that implement the Product Liability Directive. Therefore, injured parties cannot invoke these rules to claim compensation for software malfunctions. Mechanical malfunctions do fall under the PLD, and can be compensated.

Moreover, as discussed in Chapter 5, the national rules on fault liability are not suitable for victims to base their claims on. The conduct of the physician cannot be defined as negligent under the healthcare liability frameworks of France and Germany. However, injured parties in Germany can try to claim compensation under the social security laws. Furthermore, the German tortious liability framework might be able to learn from the contractual liability rule of the fully masterable risk, since it might be possible to hold the physician liable for using an autonomous surgical robot.

In my opinion, holding the manufacturer strictly liable has two positive sides. Firstly, a strict liability regime acknowledges that damages caused by technology cannot be avoided in its entirety, but it ensures that the victim can hold the manufacturer liable without having to prove wrongdoing, which makes it easier for the injured party. Secondly, I agree that the manufacturer should be held liable because they have the biggest influence on the way the software and robot are built, so they can avoid this. Moreover, they often have the financial capacity to compensate the victim, and they have the financial benefits of selling the robot and should, therefore, also bear the costs of any damage caused by the product they manufactured. The approach that the Commission is suggesting, which focuses on the liability of the operator, could not be favourable for the field of surgical robotics in my opinion because this will perhaps

be a reason for the physician to choose not to deploy the autonomous robot because the physician knows that the liability will fall upon him or her. Consequently, the development of the field will stagnate in Europe because there would not be any demand in Europe. This does not happen when the manufacturer is held liable because they can invoke the development risks defence and more often have the means to cover the financial consequences of damage caused by a defect product.

The importance of these findings is that the research revealed the efficiency of the discussed tort law frameworks with regards to this new technology. Autonomous surgical robots are expected to be used often in the future, which means that sufficient options for redress are necessary for injured parties. Moreover, by concluding that Germany does not give sufficient options, this research can help as an impulse to try and change the framework for either the national legislator or the supranational legislator.

6.4 Implications

The implications of the findings are, firstly, that they could help improve the healthcare liability frameworks with regards to new technologies. Even though this thesis focuses on autonomous surgical robots, the way the research is conducted can be used for many different types of technologies. Improving the healthcare liability framework is important for injured parties, but also for the parties producing or deploying the robots. Manufacturers should know that they can expect claims in case their robots cause damage. However, the physician might be able to deploy the robot without fear of prosecution (unless he acts negligently, or does not inform the patient of all the associated risks). The legal certainty helps with the development of the technology.

Secondly, new questions arise such as: What is the answer to the question when one focuses on different liability frameworks? Victims should have sufficient means for redress, but at what point does the chilling effect set it? In other words: how far can we go in holding parties liable? Or is there a better alternative than changing the law, such as soft law options?

Thirdly, even though victims can often invoke certain rules to base their claim for compensation on, the European Union is trying to improve the liability framework with regards to new technologies. However, what is important for the EU to take away from this research is that it should not matter whether an injured party is situated in one Member State or another: patients all over Europe should enjoy the same level of protection and have the same options to hold the manufacturer of an autonomous surgical robot liable. Therefore, the EU should govern these issues by way of a Product Liability Regulation, instead of a Directive. That way, it will

not matter whether Germany accepts software as a product; the injured party can rely on a Regulation. The resolution adopted by the European Parliament is a step in the right direction.

6.5 Limitations

One of the limitations of the research is the near lack of discussion of case law. Focus is on legislation because with new technologies it is important that these automatically fall under a sufficient framework and rules. Injured parties should not have to wait for case law to know how far the protection of the law reaches and whether their specific case falls under the tort law rules. Moreover, this is just as important for the producer of the technology. However, as the use of the robots increases and more cases are ruled, the body of case law should be researched to see what additions there are with regards to the legislation. Moreover, the discussion of French and German laws relied on literature, which caused a dependency on the bias and analysis of the authors. This limitation was attempted to be limited by including a variety of articles.

A second limitation is the exclusion of contractual liability. This thesis focuses on tortious liability because it is logical when discussing national and supranational legislation together in this context. However, there will often be a contract between the physician and patient. Therefore, contract law might give patients different means of redress than tortious liability, and these means might also work for damage caused by autonomous surgical robots. This should be researched further.

A third limitation is the assumption that the physician did not act negligently, but that the robot caused the damage on its own because there was a bug in the software. This assumption was necessary to be able to conclude how the legal frameworks would react to this specific type of situation. However, it might be the case that more often than not the physician did do something wrong. Therefore, it should not be a general assumption that the physician is perfect, but it was useful for this thesis to pretend like they are.

6.6 Conclusion

Trust is immensely important with regards to new technologies. However, we cannot expect technologies to never cause any damage and always work perfectly. Therefore, trust can be increased by ensuring a suitable legal framework, so people who undergo the treatment know that even if something goes wrong, they can hold someone accountable. Moreover, it is important that people in different Member States enjoy the same level of protection. Thus, let’s ensure that we keep trying to make the world safer by improving technologies, and have an equipped legal framework for the times technologies fail.

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