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Malfunctions of robotic system in surgery: role and responsibility of surgeon in legal point of view

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Abstract: Robotic surgery (RS) technology has undergone rapid growth in the surgical field since its approval. In clinical practice, failure of robotic procedures mainly results from a surgeon's inability or to a device malfunction. We reviewed the literature to estimate the impact of this second circumstance in RS and its consequent legal implications. According to data from the literature, device malfunction is rare. We believe it is necessary to complement surgical training with a technical understanding of RS devices.

Keywords: Robotic surgery; Responsibility; Malfunction; surgery

Abbreviations
RS: Robotic Surgery
FDA: Food & Drugs Administration
RM: Robotic Malfunctions
LC: Learning Curve
MAUDE: Manufacturer and User Facility Device Experience

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Highlights

- In clinical practice, failure of robotic procedures mainly results from a surgeon's inability or to a device dysfunction.
- The likelihood of the a patient's being damaged not directly by the actions of the operator, but rather from the RS device, has always been a debated among robotic surgeons and legal medicine specialists.
- The learning curve involved in RS should consider both a purely technical part and a part to master the use of the device and resolution of technical problems

1 Introduction

Use of robotic technology in surgery has undergone rapid growth since its approval by the U.S. Food and Drug Administration (FDA). The possibility of 3D views and 360° instruments rotation allows for a considerable improvement in clinical practice. Many studies have confirmed the safety and feasibility of Robotic Surgery (RS) in all its applications [1]. Despite the device being initially meant for cardiac surgery, recent years have witnessed a rapid growth in its application to abdominal surgery by urologists, gynaecologists, and general surgeons. As has been mentioned in at least one study, this transition was not uncomplicated, because the device was designed to meet the demand of surgeries with small operative fields and specific instruments [2]. With its application in general surgery, new instruments had to be created; engineers are still researching new systems to assure an easier and safer articulation of robotic device arms.

In clinical practice, failure of robotic procedures is mainly due to a surgeon's inability or to a device dysfunction. This literature review estimates the impact of this second circumstance in RS and its consequent legal implications. The aim of this work is to evaluate the role

of the surgeon in this situation and the surgeon's level of responsibility.

2 Methods

A literature search, with the object of a review article, was performed for articles reporting device malfunctions in RS using the following keywords (and their intersections): malfunction, robotic surgery, robot, robotic complications, legal aspects, law. We examined Cochrane, PubMed, EMBASE, WebBased Knowledge, Scopus, and Google Scholar. The search was not narrowed by publication year, article type or language; all articles found were selected. We considered reviews, original articles, case reports, and works from the US database MAUDE (Manufacturer and User Facility Device Experience) on peri-operative robotic malfunctions.

3 Results

Regarding robotic system malfunctions in RS, we found 18 articles in the literature (Table 1) [3-21]. The oldest one is from 2005 by Eichel et al. [4]; the most recent is from 2014 by Buchs et al (Switzerland) [21]. In total, from 2005 to 2014, 386 malfunctions were described out of 14141 procedures, 20.9% of which was damage caused by malfunction of the RS arms and instruments. The total percentage of conversion in reported cases was about 2%. From a RS malfunction, 16 caused patient damage, of which 13 were mild and resolved without sequelae, and 3 were complex, including an external iliac vein lesion, ileal perforation, and urethral lesion. The latter were treated intra-operatively with direct iliac vein and ileal suture and reimplantation of the urethral lesion.

In 5 articles. no lesions in patients were detected; in the remaining studies this data is not made clear. There are no mortalities among the assessed cases. In two cases

Table 1: Description of robotic system malfunctions in literature

N°	Reference	Year	Author	TP	M (n°)	I	A	C	OS	S	%IM	%C (n°)	PI (n°)
1	4	2005	Eichel	200	5					5	0	(1)	
2	5	2006	Kozlowsky	130	6		1	2	1	2			
3	6	2007	Borden	350	9		2	3	2	2		0,86	nd
4	7	2007	Zorn	725	4				3	1		0,5	0
5	8	2007	Lavery	8240	34		14	4	14	2			
6	9	2008	Andonian		189						70		9
7	10	2009	Ham	26	1			1					
8	11	2009	Kim	1797	43	19	6	5	2	11	1.1	0,17 (3)	
9	12	2009	Nayyar	340	37						61	0,6	
10	13	2010	Park	> 150	1		1						
11	14	2010	Kaushik	260							21		
12	15	2010	Pereira	250									4
13	16	2011	Akbulut	70	2			1		1			
14	17	2011	Mues	454	12	12					100		3
15	18	2012	Agcaoglu	223	10								
16	19	2012	Tugcu		1		1						
17	20	2012	Chen	400	14		12		1	1			
18	21	2014	Buchs	526	18	9	4	3	2				

TP: Total Procedures
M: Malfunctions
I: Intstrument
A: Arms
C: Console
OS: Optical System & Camera
S: Software
%IM: % instrument malfunction
%C: % of conversion
PI: Patients Injuri

a robotic malfunction occurred during a urologic live-surgery session and a general surgery congress.

Studies from the US database MAUDE (Manufacturer and User Facility Device Experience) were considered. This is an anonymous database founded on voluntary reporting of adverse events that happened during robotic procedures. Lucas et al. (2011) studied the last updates of the database and compared two periods, before and after 2007 [22]. Lucas estimated a total of 205.000 robotic procedures and reported 1914 cases of malfunction, with patient damage between 0.5% and 5.4%. The incidence of robotic procedure conversions diminished from 21.3% to 9.9%. By contrast, the mortality rate increased from 0.0013% to 0.0061%.

We examined Makary's study about legal responsibilities related to RS malfunctions. No other work in the literature that we were able to find reported data on legal aspects, and there are no further hints on the surgeon's role and responsibility in these cases [23].

4 Discussion

The likelihood of a patient incurring damage not directly derived from operator decision but from a device has always been a debated issue among robotic surgeons and legal medicine specialists. The safety issue in RS therefore remains under discussion in international societies. There are two ways to make a robotic device malfunction known: publish a report, or make the FDA aware of the event through the MAUDE database [24]. The latter, as mentioned previously, is a voluntary database following no rules or guidelines. Authors who have examined and described this database are of the opinion that it underestimates failures, because the proportional relationship between this technology diffusion and number of reports on MAUDE is not realistic. According to the authors, even if the operator performance improves with the number of procedures performed, the device maintains the same manufacturing defect that is not possible to overcome. The number of malfunctions, in agreement among robotic engineers, will likely still increase, even if less dramatically, with the increasing use of RS for surgeries.

MAUDE estimates the incidence of 13 possible malfunctioning instruments per 10,000 procedures; this data also appears to be an underestimate. In actuality, data can't always consider all the aspects of different forms of malfunction. In the end, given that MAUDE is a union of single reports in form of reviews and case reports, data are difficult to verify by an information cross-check [24].

4.1 Robotic malfunctions

To define the implications for legal feedback, it is mandatory to evaluate malfunctioning types and possible implications for patients. The main types of robotic malfunctions (RMs) are: instrument alteration, mechanical arm alterations, console defects, optical system problems, or software issues. The incidence of defects depends mainly on the type of robotic device, on the manufacturer, and on the level of updating of various robot versions. As shown in Table 1, in the first years of robotic experience, authors described a greater frequency of RM due to the console or to the cart-like failures of the camera or optical system. With increasing experience, we assist in recent years to a decrease of cart-console problems, to the disadvantage of the increasing incidence of instruments and arms related RMs. Despite these data, some authors affirm that instrument-related problems, possibly due to an improper use, should be treated as a separate issue, and that we should consider only console problems. One of the main causes of instrument malfunction is the wear of the insulating membrane resulting from friction and also collision among instruments inside the abdomen, or during their insertion through trocars [25].

Surgical instruments have been regulated by the FDA since 1938, and all medical devices since 1976; the regulation demands carrying out controls at various stages of production and when instruments are in use on the field [26].

However, given the approximate 500% increase in robotic procedures. precautions had to be taken to help this system to maintain an adequate safety level. These precautions confirmed the need to cover instruments with a fireproof and insulating membrane and declared a maximum number of "lives" or procedures that an instrument can go through before being replaced.

The goal of this requirement is to limit the gap that could result in terms of inadequate protection. The data in Table 1 show that at the beginning of the RS experience, in case of a malfunction, conversion to laparoscopy or traditional surgery was considered a valid and safe option. Borden et al. report a conversion rate of 0.86% in their experience [6], whereas Kim et al (2009) state an incidence of 0.17% [11]. From 2010, no further indications appear about robotic procedure conversion, probably due to surgeons' increased ability to deal with malfunctions, and to the more frequent presence, in the operating room or through devices, of manufacturers' engineers who are able to solve software problems.

In contrast to decreases in conversion, it seems that patient damage by RM is relatively increased. Whereas

before 2009 only one casualty was described among 9 cases of patient damage in 189 adverse events [9], after 2010 Pereyra et al. [15] and Mues et al. [17] describe 4 and 3 RM related damages, respectively. The latter number only describes instrument failure related RMs, and all three damages were major complications (iliac vein lesions, ileal perforation, and urethral cauterization). No data on mortality are available in these articles. This fact appears to be in line with the very low incidence reported by MAUDE; our review seems to confirm the data.

Authors agree that surgery should be postponed should the RM emerge before anaesthesia induction, without starting the robotic procedure. However, if an RM occurs after the induction the surgeon must be able to deal with the problem, either directly or by calling in device specialists [16]. Maintenance suggestions are available from the manufacturers, including keeping the device's electric power under 3 kV or re-tightening the instrument's frame bolts after every use.

4.2 Legal implications

According to US societies, robotic surgery LC should consider both a purely technical part and a part in which the surgeon masters the ability in using the device and resolving technical problems. According to Buckley (2014), a surgeon's skills, although apparently increased after using the simulator, should be also refined in terms of technical problem resolution, again through a simulator [27]. Throughout the IC acquisition, in a surgery based on advanced technologies, informing the patient about eventualities such as robot malfunctioning and execution modalities becomes necessary [28]. Despite that the incidence of malfunctions is low, according to our literature review it would be good practice to inform patients of the possibility of the RS failure. Some authors declare that specific risk factors for a peri-operative damage exclusively caused by a device malfunction don't exist, and that the incidence of lesions is similar to traditional surgery. According to that statement, this eventuality could therefore be negligible [25].

Nothing In the literature clearly defines surgeons' legal responsibility in RMs: lesions due to these problems appear not to be the surgeon's responsibility, but imputable to the instrument and therefore to the manufacturer. The latter, however, isn't directly implicated if it has produced a robot following production standards that passes the FDA multi-step check. This eventuality is roughly attributable to the malfunction of a bipolar clamp in laparoscopic surgery, or of an electrosurgical knife in open surgery, or even the failure of a retractor; each surgical instrument, provided passing a quality check, has a potential malfunctioning risk not dependent on the operator. Responsibility falls on the surgeon if an incorrect use of the instrument is proven, but this is a very unusual eventuality. For every RM, it would be necessary to demonstrate that the RM risk would have been lower if the patient underwent the procedure with another surgeon or in another hospital: we know that this is hard to prove because, as mentioned previously, each instrument has a potential risk of rupture and malfunctioning due to its characteristics.

Dr. Martin Adel Makary, director of the General and Pancreatic Surgery division at The Johns Hopkins University School of Medicine has carried out various studies about malpractice and legal responsibilities in surgery [29,30]. One of these studies had the aim of reviewing FDA's RM mistakes database from the 1st of January 2000 to the 1st of August 2012. Makary and colleagues cross-checked LexisNexis' and PACER's database (public access to electronic "Records of Court") to detect inaccuracies in reporting errors resulting from an instrument deficit. We conducted this search to give patients a complete and realistic source of information about proposed robotic procedures. According to the report, when a device malfunction occurs, hospitals should report these accidents to the manufacturer, who should then contact the FDA.

Makary finds it essential to create a realistic database with transparent data that can be easily found, affirming that "currently doctors and patients are unable to correctly evaluate safety, because we have a random data collection system" [23]. In this transitional period, in fact, without regulatory indications, Makary claims that "it is too easy for a surgeon to state that there is no additional risk linked to robotic surgery, because the evidence at present is nowhere to be found." This lack of material in the literature is confirmed by our review. In accordance with Makary, we can simply affirm that information in RS is required to ensure a patient full information on potential risks.

5 Limits of the study

The revision conducted is a retrospective report's research. In the literature there is no adequate amount of data about legal implications in RM. There are no data related to the new models of robots put on the market in the last 2 years. Our conclusions result from the study of available

data, without the certainty of the feasibility of a global validation.

6 Conclusions

According to data collected from the literature, device malfunction is rare. A few years ago complications due to the breaking of an instrument frequently needed a surgical conversion and the prosecution by LS or open technique. At present, however, the operator's ability to repair the device during a procedure has increased. Basing on the US model of LC, we believe it is necessary to complement the surgical training with a technical part for knowledge of the device. Currently, it appears that a direct legal involvement for the operator doesn't exist in case of RS malfunction; nevertheless, we consider it good practice to inform patients of the possibility of the RS failure and its possible consequences.

Conflict of interest statement: Authors state no conflict of interest

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