SAFETY IMPLICATIONS OF ROBOTIC SURGERY: A STUDY OF 13 YEARS OF FDA DATA ON DA VINCI SURGICAL SYSTEMS

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13. ABSTRACT *(Maximum 200 words)*

Robotic surgical systems are intended to enable surgeons to perform minimally invasive operations with increased vision, precision, dexterity, and control, and to reduce the rate of injuries, blood loss, length of hospital stay, and post-operative complications. Recently, concerns regarding the safety and effectiveness of robot-assisted surgeries have heightened as an increased number of adverse events associated with the surgical robots have been reported to the U.S. Food and Drug Administration (FDA). Our study focuses on the analysis of the adverse events and recalls of da Vinci surgical systems, collected by the FDA over a period of 13 years from 2000 to 2012. We use the data on deaths, injuries, and robot malfunctions, combined with the technical problems and corresponding recovery actions taken by the company (provided by the recalls), together with systematic accident analysis using a tool called CAST. Using an automated natural language parsing tool trained with domain-specific dictionaries and part-of-speech and negation taggers, we extracted valuable information on the potential causes of robotic accidents in order to understand the effectiveness of using robotic devices for different minimally invasive procedures. We found that despite the increasing number of procedures being done with the da Vinci surgical system, a significant number of malfunctions and system downtimes with potentially adverse impacts on patients are being experienced. We provide insights on the use of existing state-of-the-art technologies for enhancing safety in future robotic surgical systems.

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Safety Implications of Robotic Surgery:
A Study of 13 Years of FDA Data on da Vinci Surgical Systems

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Context: Robotic surgical systems are intended to enable surgeons to perform minimally invasive operations with increased vision, precision, dexterity, and control, and to reduce the rate of injuries, blood loss, length of hospital stay, and post-operative complications. However, an increasing number of adverse events, in which injuries and deaths occurred during or after robotic procedures, have been reported.

Objectives: To assess the safety and effectiveness of existing robotic systems in performing different types of minimally invasive procedures by studying the robotic surgery incidents that led to prolonged procedures, patient complications, injuries, and deaths.

Data Sources: Recalls and adverse events reported to the U.S. Food and Drug Administration (FDA) between January 2000 and December 2012, collected from two public FDA databases: the Medical and Radiation Emitting Device Recalls ("recalls") database and the Manufacturer and User Facility Device Experience ("MAUDE") database.

Analysis Methodology: Using an automated natural language processing tool, trained with domain-specific dictionaries of relevant keywords and part-of-speech and negation taggers, we analyzed the *Event Type, Patient Outcome, Event Description* and *Manufacturer Narrative* fields of the adverse event reports as well as the technical problems and corresponding recovery actions taken by the company, provided by the recalls. We extracted the rates and patient outcomes of the adverse events, most common types and number of device and instrument malfunctions, and the number of procedures converted to traditional techniques or rescheduled to be done at a later time, across different classes of surgery. CAST, a sophisticated accident analysis tool was employed to systematically analyze example injury and death reports to identify the system hazards and potentially violated safety constraints that led to adverse events.

Results: During the study period, a total of 4,798 adverse events (involving 86 deaths, 410 patient injuries, and 3405 device malfunctions) and 19 recalls issued by the company (involving 109,709 devices and instruments) were reported to the FDA. The rate of adverse event reports on average is declining, but an overall increasing trend in the rate of injury and death reports can be observed since 2004, going from 13 reports per 100,000 procedures in 2004 to about 50 in 2012. In 4,382 cases (91.3%), a device or instrument malfunction occurred, such as parts of the device or burnt/broken pieces of instruments falling into the patient, electrical arcing of instruments, system errors or video/imaging problems, and unintended operation of instruments. In 275 (5.7%) of the adverse events, the system was restarted to troubleshoot the problems; in about 640 (13.3%) cases, the procedure was completed non-robotically through conversion to traditional techniques such as open or laparoscopic; and in 236 cases (4.9%) it was rescheduled to a later time. Causal Analysis using System Theory (CAST) helped us to determine that the likely causes for many of the accidents include inadequacy of safety controls, absence of comprehensive warnings to the surgeon, limited safety and training practices, lack of user certification, and limited surgical experience.

Conclusions: Despite the increasing number of procedures being done with the da Vinci surgical system, a significant number of malfunctions and system downtimes with potentially adverse impacts on patients are being experienced. Better dissemination of this information may allow a more measured evaluation of the role of da Vinci robotic systems especially in performing complex procedures. Adoption and use of state-of-the-art safety engineering techniques for accident analysis and design with existing robotic technology may reduce the adverse event rates in future safety-critical systems for robotic surgery.

I. INTRODUCTION

Recently, concerns regarding the safety and effectiveness of robot-assisted surgeries have heightened because of the increased number of adverse events associated with the surgical robots, as reported to the U.S. Food and Drug Administration (FDA) [1][2][3]. In part, this rise is due to the exponential increase in the number of robotic procedures over the last decade: In 2012, around 450,000 robotic procedures were performed in hospitals worldwide with an installed base of 2,585 robotic systems [4][5][6].

This study focuses on the analysis of adverse events and recalls of da Vinci surgical systems, the only existing FDA-approved robotic system for minimally invasive surgery. Our study spans all the reports collected by the FDA over a period of 13 years from 2000 to 2012 [7]. We studied patient outcomes and causes of adverse events reported for different classes and types of surgeries as well as the recalls issued by the manufacturing company. While previous work has reported on subsets of the adverse events data and the experiences of different institutions with the robot, this is the only large-scale study of adverse events, including 4,798 reports, and all the recalls of robotic surgical systems, which in total affected nearly 3,741 devices and 105,968 instruments on the market.

In our study, we followed the FDA guidelines on using the MAUDE data[1] [8], and augmented the adverse events data with the recalls data, as well as knowledge of the system and discussions with expert surgeons who have extensively used the robotic system in general, urologic, and cardiothoracic surgical procedures. Specifically, we used the factual data on deaths, injuries, and robot malfunctions, combined with the technical problems and corresponding recovery actions taken by the company (provided by the recalls), together with systematic accident analysis using a tool called CAST. We extracted valuable information on the potential causes of robotic accidents in order to understand the effectiveness of using robotic devices for different minimally invasive procedures. We provide insights on the use of existing state-of-the-art technologies for enhancing safety controls in future robotic surgical systems.

The main contributions of the paper are as follows:

- Studying the device malfunctions and recalls of the robotic systems, including system errors and broken pieces of instruments that caused interruption of procedures or conversion/rescheduling
- Studying the effectiveness of robotic systems across different classes of surgery in terms of rate of injuries, deaths, device malfunctions, conversions, and rescheduling, as well as a comparison to laparoscopic and open surgery.
- Identifying examples of inadequate safety mechanisms in the system by analysis of example injury and death reports using CAST, a sophisticated accident analysis tool for safety-critical systems.

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[1] According to the FDA and several studies in the literature [9][10][11], the MAUDE database may not provide an accurate representation of true rates and severity of adverse events due to underreporting, and incomplete, inconsistent, and duplicate reports submitted by volunteer reporters. But the reported malfunctions, injuries, and deaths are valuable data if treated as a sample of real adverse events that occurred during robotic procedures and affected the safety of patients.

- • Providing examples of the state-of-the-art techniques for modeling, accident analysis, and safety-based design, which, if combined with existing robotic technology, will improve the safety of future surgical systems.

In the next section we present the data analysis methodology and the results.

II. DATA ANALYSIS

The data from the FDA MAUDE and recalls databases [7] were analyzed using MedSafe, a framework for automated extraction and analysis of medical device safety reports, based on the flow presented in [12]. MedSafe first uses several filters to remove non-essential terms and phrases as well as redundant records from the extracted reports. Then it employs a natural language processing engine that uses several domain-specific dictionaries (e.g. keywords related to surgical instruments, malfunction types, and surgery classes) as well as parts-of-speech, negation, and temporal taggers to extract semantic and timing information from the reports. The results from MedSafe were continually tested for accuracy and validity both from the systems and the medical perspectives. Figure A1 (Appendix) shows the overall MedSafe analysis flow. The specifics of analysis performed at each step are given in the following sections.

1) Frequency of Adverse Events and Their Patient Impact: Using MedSafe we first extracted all the reports related to "da vinci" and "intuitive surgical" by searching for the related terms in the *Device Name* and *Manufacturer Name* fields of over 2.5 million adverse events reported to the FDA from January 1, 2000 to December 31, 2012. That led us to an initial list of 4,930 adverse event reports, from which we filtered out those with duplicate database keys (reporting the same adverse event for multiple devices) and those that were reported before 2013, but were received by the FDA in 2013. The final list contained 4,798 reports including both reports on the da Vinci system itself and on its accessories manufactured by either Intuitive Surgical, Inc. (98.9%) or other companies (0.6%). Via a detailed review of the *Event Type*, *Event Description* and *Manufacturer Narrative* fields of these reports, we extracted four types of adverse events reported to the FDA: *device malfunctions*, *injuries*, *deaths*, and *other*:

Device Malfunctions: Over 3400 of the reported adverse events (71%) involved device malfunctions, such as broken or burnt pieces of instruments, system error codes, arcing of instruments, and unintended instrument movements. Those malfunctions often required the surgical staff to spend additional time on troubleshooting the errors, retrieving the broken pieces from the patient's body, or, in extreme cases, converting the procedure to a non-robotic (laparoscopic or open) surgery. To varying degrees, all these actions prolonged the procedures, as discussed in more detail in the next section.

Injuries and Deaths: About 500 of the reports (10.3%) indicated significant negative patient impacts including injuries (410 cases) and deaths (86 cases). About 103 (2.3%) of the adverse events that were reported as *Malfunction* or *Other* were indeed injuries. MedSafe identified these reports by searching the

Event Description and *Manufacturer Narrative* fields using keywords related to different types of patient complications. Some example keywords in our dictionary include "injury," "bleeding," "burns," "cuts," "puncture," or "damage of organ". In addition, we found three events reported as an *Injury*, that their description explicitly mentioned no injuries occurred, and one *Injury* that later led to patient *Death*.

Other: For the rest of the adverse events (897 cases), information on the type of event either was not available or was indicated by the reporters as *Other*. Using MedSafe we found that a major part of these events (721 reports) were related to system errors that interrupted the procedure, broken instruments that fell into the patient's body, or video/imaging problems at the surgeon's console (See Table I).
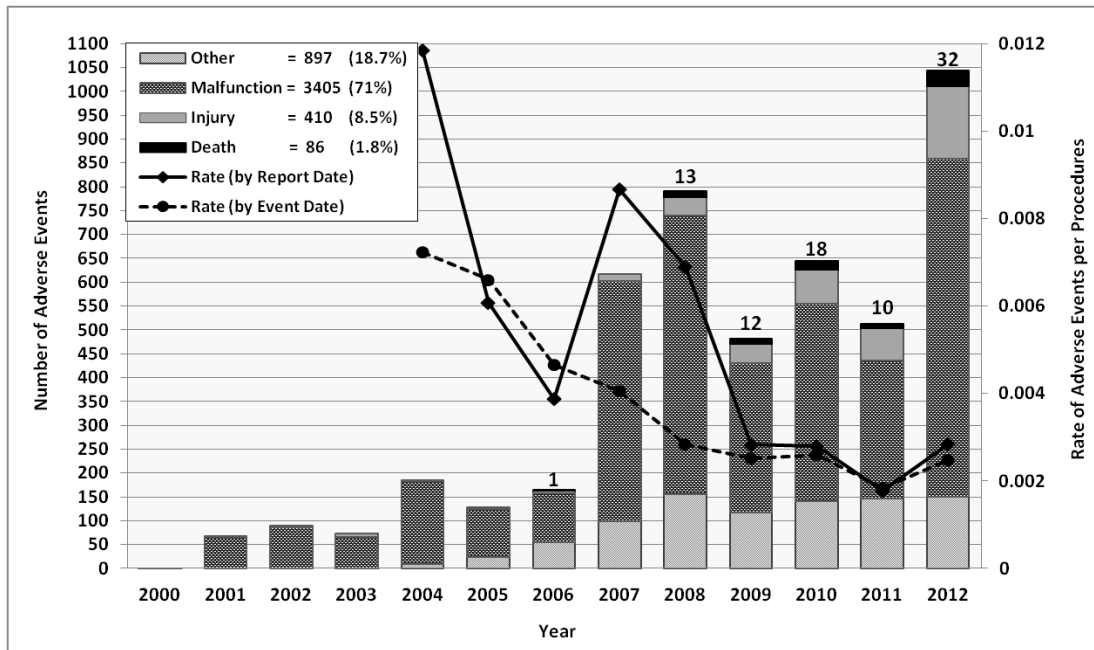

Figure 1 – Number of da Vinci Adverse Event Reports and Average Rate of Reports per Procedure: X axis corresponds to the year the report was received by the FDA. Numbers on the bars indicate number of deaths reported per year. The secondary Y axis shows the rates of adverse events per procedure.

Rate of Adverse Events: Figure 1 (primary vertical axis) plots the frequency of adverse events versus time based on the year that reports were received by the FDA. We see that the total number of adverse events reported for the da Vinci system and its instruments has linearly increased, going from 67 reports in 2001 to 1043 in 2012. This observation can be partly explained by the exponentially increasing use of da Vinci surgical systems in the US and worldwide.

We calculated the rate of adverse events reported per procedure for each year, by dividing the number of adverse events by an estimated[2] number of annual procedures performed in the U.S., extracted from the company investor presentations [5]. The trend lines in Figure 1 (secondary vertical axis) show the rate of

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[2] We estimated the number of annual procedures performed in the U.S., by measuring the bars displayed on the graphs in the investor presentations (from 2009 to 2013). Whenever the estimated numbers from two different presentations didn't match, we assumed the maximum number of procedures for that year.

adverse events per procedure based on both the year the events occurred and the year they were received by the FDA. We observe that the trend in overall rate of adverse events is decreasing (going from about 0.0118 in 2004 to 0.0028 in 2012). Similar decreasing trends for the rate of adverse events are shown in recent statements made by Intuitive Surgical, Inc. for the period of 2010–2013 [13]. However, our longer-term analysis of the reports over the 8-year period of 2004–2012 (Figure 2) shows that the trend of injuries and deaths on average is increasing, with a fivefold increase from 0.00013 reports per procedure in 2004 to 0.00050 in 2012. These increasing trends cannot be observed in the manufacturer's statements because of their inadequate scaling of figures and the fact that the analysis was limited to a short period of three years.
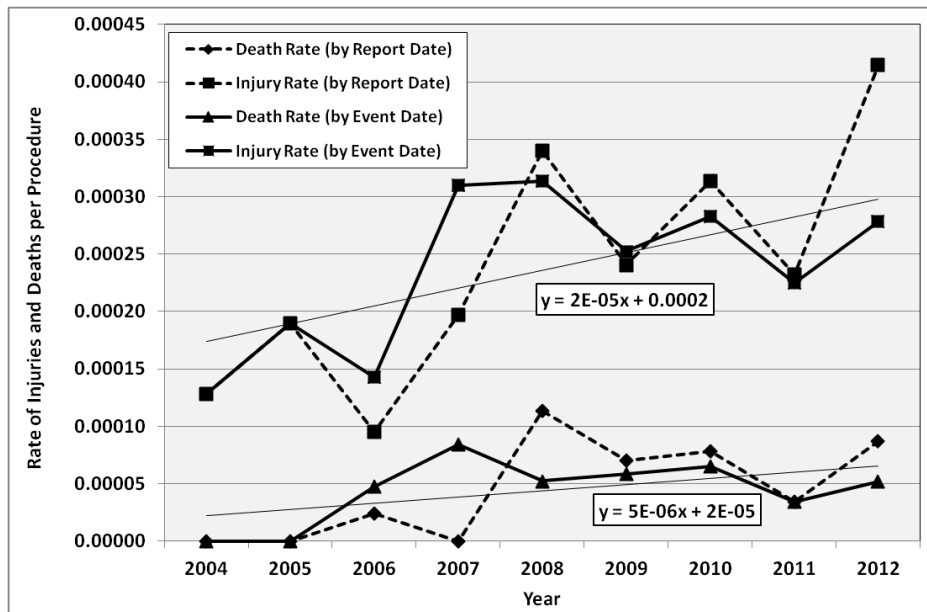

Figure 2 - Average Number of Injuries and Deaths Reported per Procedure, by the dates of event and report received by FDA

Intuitive Surgical, Inc. claims that the recent rise (from 2011 to 2012) in the number of adverse event reports is due to a change in their medical device reporting (MDR) practice that happened in September 2012, and the majority of recent reports are related to the robot accessories (e.g. cable breaks) and not the core system itself [14]. But a closer look at the long-term trends shows that sudden changes in failure frequencies have also occurred in the past (from 2006 to 2007). Further, if the surgical system is considered as both the control system and its instruments then any failures of the instruments and accessories also affects the system operation. Additionally, we believe that state-of-the-art sensing technology allows both the detection of instrument failures and their proactive reporting to the surgical team in a timely fashion. Logging and reporting of such conditions by the system allow early diagnosis, repair, and replacements.

We can make two important observations based on these results: First, despite a relatively high number of adverse events reports, the vast majority of procedures were successful and did not involve any problems,

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which can be seen by calculating the rate of adverse events per procedure, shown in Figures 1 and 2. That finding is also confirmed by many surgeons who routinely use the robot in general, urologic, and gynecologic surgeries. Nevertheless, an important question is whether robotic surgery is substantially better than laparoscopy, especially for complex types of procedures in cardiothoracic and head and neck. The evidence to answer this question is discussed further in subsection 4, where we show a comparison of outcomes between robotic versus traditional laparoscopic and open surgery found in the literature. In the next subsection, we present a more detailed discussion of the device malfunctions and their impact.

2) Impact of Device and Instrument Malfunctions: In order to understand the impact of device and instrument malfunctions in terms of procedure time and patient complications, we performed a detailed analysis of the *Event Description* and *Manufacturer Narrative* fields of the reports, including those that *were not indicated by the reporters as a device malfunction*.

Table I - Major Categories of Malfunctions Reported (Event Types: Malfunction (M), Injury (IN), Death (D), and Other (O))

Malfunction Category	Description	No. of Reports (% of all)	Malfunction Impact (% of cat.)			Event Type			
			System Reset	Surgery Converted	Surgery Rescheduled	M	IN	D	O
System Errors	- System error codes and faults - System transferred into a recoverable or non-recoverable safety state	473 (9.9%)	194 (41.0%)	305 (64.5%)	121 (25.6%)	28	16	0	429
Broken Instruments, Fell-Into Cases	- Burnt/Broken parts and components - Fell into the surgical field or body cavity - Required additional procedure time to be found/ removed from the patient.	1,940 (40.4%)	13 (0.7%)	82 (4.2%)	15 (0.8%)	1,783	55	0	102
Burns/Holes in Tip Covers, Elec. Arcing	- Tears, burns, splits, or holes on tip cover - Electrical arcing, sparking, charring	917 (19.1%)	1 (0.1%)	16 (1.7%)	0 (0.0%)	760	130	0	27
Unintended Instrument Operation	- Unintended or unstoppable movements started without the surgeon's command - Instruments not working, open/closed - Instruments not recognized by the system	424 (8.8%)	24 (5.7%)	66 (15.6%)	17 (4.0%)	316	36	2	70
Video/Imaging Problems	- Loss of video - Display of blurry images at the surgeon's console or assistant's touchscreen	200 (4.2%)	44 (22.0%)	111 (55.5%)	74 (37.0%)	14	4	0	182
Other	- Electrosurgical unit malfunctions, etc. - Other events reported as Malfunction	813 (16.9%)	8 (1.0%)	14 (1.7%)	0 (0.0%)	790	23	0	0
Total Malfunctions	- All the malfunctions found by MedSafe	4,382 (91.3%)	247 (5.1%)	526 (11.0%)	204 (4.3%)	3,405	254	2	721
Total Reports	- All the adverse events reported	4,798 (100%)	275 (5.7%)	640 (13.3%)	236 (4.9%)	3,405	410	86	897

MedSafe was trained by domain-specific dictionaries to search for different malfunction categories. Parts-of-speech and negation taggers were used to infer semantics from the sentences and filter out the cases where the keywords were not used in the intended pattern and context. Table A1 (Appendix) shows examples of malfunctions reported in different cardiothoracic surgeries and their effect on patients (minor injuries or burns), extracted using a dictionary of keywords built based on the online Instrument Accessories catalog of Intuitive Surgical [15]. Table I shows five major categories of malfunctions

identified by MedSafe, along with their descriptions, number of reports in each category, the impact on procedure, and the event types as reported to the FDA. Note that the failure categories are not mutually exclusive and in many cases two or three different malfunctions were reported in one event. Figures A4 and A5 (Appendix) use Venn diagrams to depict the intersection between different malfunction categories and impacts. The *Other* category includes other kinds of malfunctions that couldn't be classified in any of the classes. Table A2 (Appendix) lists all the system error codes that we extracted from the reports, along with their description by the company and the number of adverse events that involved each type of error. The following are our major findings based on these results (refer to Table I):

- System errors and video/imaging problems constituted 659 (13.7%) of the adverse events and were the major contributors to the system resets (231 cases, 84% of all system resets), conversion of the procedures to a non-robotic approach (409 cases, 63.9% of all conversions), and rescheduling of the procedures (191 cases, 80.9% of all cases). About 91% of these events were reported as *Other*.

- A major part (40.4%) of the adverse events (about 52% of all malfunction reports) were related to breakage or burning of a component or part of an instrument during the procedure and/or falling of the broken/burnt pieces or the whole instrument itself into the patient's body. In almost all those cases the procedure was interrupted, and the surgical team spent some time retrieving the pieces from the body; in 55 cases, a patient injury was reported.

- About 917 reports (19.1% of the adverse events) were related to burns and holes that developed in the tip cover accessories and electrical arcing, sparking, or charring of instruments, which led to nearly 130 injuries, such as burning of the tissue under surgery.

- Unintended operation of instruments, such as uncontrolled movements and powering on/off by themselves, happened in 424 of the adverse events (8.8%), including 36 injuries and 2 deaths.

In total, we found 4,382 reports on problems that occurred during surgery, including 721 cases that were reported as the "*Other*" type of event but were actually related to system errors, video/imaging problems, broken parts, and unintended operation of instruments. About 275 (5.7%) of the adverse events involved system resets; in about 640 (13.3%) cases, the procedure was completed non-robotically through conversion to traditional techniques such as open or laparoscopic surgery; and in 236 (4.9%) cases the procedure was rescheduled to a later time. That means that in 912 cases (19% of all the adverse events), the procedure was interrupted and time was spent on troubleshooting the errors, identifying whether the error was actually recoverable or non-recoverable through resetting of the system, or converting the procedure to a traditional technique. If we assume that in each case a minimum of 15 minutes was needed to restart the procedure[3], this translates to about 228 hours of downtime and unavailability of the system.

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[3] For example in the MAUDE report shown in Table A5 (Appendix), half-an-hour was spent only for troubleshooting a system error code, and then the surgeon decided to convert the procedure.

3) Reasons for Recalls and Recovery Actions: We extracted 19 recalls of the da Vinci surgical system and instruments reported to the FDA from January 2000 to December 2012 [7]. While only a small number of recalls were issued by the company over the years[4], they impacted a large number of devices (109,709 devices and instruments) on the market. Moreover, important insights into the safety issues of the robot can be extracted from the recalls, because the data include the actual technical problems confirmed by the manufacturing company that may present potential harm to patients, as well as the recovery actions taken by the company to address the failures.

Table II and Table A3 (Appendix) list all the recalls of the da Vinci (S) Endoscopic Instrument Control System and accessories; we further classified the recalls, based on their reasons, into four categories of *software*, *electrical*, *computer control*, and *mechanical* problems. The following are our findings:

- Of all the recalls, 10 were reported for the robot's control system, affecting about 3,741 systems on the market, while the rest (9 out of 19) were related to accessories and instruments used with the robot, affecting about 105,968 devices.
- The majority (7 out of 10) of control system recalls (Table II) were due to computer- and electrical-related malfunctions (affecting 1568 devices), but the recalls due to mechanical malfunctions (3 out of 10) affected a larger number of devices (2173) on the market.
- The problems with the robot control system were often handled at a very high cost to both the manufacturer and the hospitals:
  - Software and mechanical issues were addressed by sending field system engineers to all the locations to update or repair the systems (in about 1,500 devices).
  - Hospitals were advised to have backup equipment and instrumentation available and to be prepared to convert to alternative surgical techniques (mentioned in [16] and in the system's user manual, according to [17]), costing about $2 million per back-up device and instruments.

The manufacturer's recommendations that providers continue using the device until the corrective system updates or service visits are made (e.g. for recall numbers Z-2204-2008 and Z-2930-2011) and that they use the backup systems in the case of failures, do not reflect advisable practices. Many of the reported failures might be repeatable and in the time until the service visit, there is potential for system downtime, prolonged procedures, or patient injuries in all devices that are affected by the same defect (259 devices in these two examples). Additionally, some of the problems such as a software defect that can lock up the system cannot be resolved even by having redundant backup devices. It is well-understood in software engineering that two versions of the same software may well experience the same technical problems [18].

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[4] After the concerns raised by the FDA and the public about recent increase in the number of adverse event reports, the manufacturer issued 13 new recalls in the 8-month period of April-November 2013 alone.

Table II - Recalls of da Vinci (S) Endoscopic Instrument Control System (Years 2000-2012)

Recall Record Numbers	Device Name (Model Number)	Date	Malfunction Type	Reason for Recall	Company Recovery Action	Num. of Devices
Z-1244-2007	da Vinci S A4.3 SW (Model IS1200)	Sep 26 2007	Computer Software	Under certain conditions, the product's software may crash and require a manual override or restart before functioning again.	Service Visit + Software Upgrade	405
Z-0079-2008	da Vinci S (Model IS2000)	Feb 21 2008		System lock-up: Software anomalies could cause product failure during use; or on start-up. System transitions to a safe "soft-lock" state.	Software Upgrade	159
Z-2204-2008	da Vinci S (Model IS2000)	Sep 16 2008		Defective software chip may cause the system to fail and lock up.	Urgent Letter + Replace Chip	112
Z-1245-2007	da Vinci S (Model IS2000) (Auxiliary power board (APB))	Feb 22 2008	Electrical	Product may malfunction and fail to start up on AC power.	Service Visit	38
Z-0151-2008 Z-0152-2008	da Vinci S (Model IS2000) (Vision Cart Model VS2000)	Feb 22 2008		Under-rated fuses may be installed which will result in fuse failure and a loss of power to the vision cart and any ancillary equipment connected to it.	Notification Letter + Correction	63
Z-1180-2008	da Vinci S (Model IS2000) (Revision A51_P5)	June 12 2008	Computer Control	Delay in responding: In certain circumstances, the device may not respond immediately to a user's command, such as master clutch or camera control.	Notification Letter + Correction	9
Z-1161-2010	da Vinci S (Model IS2000) (Revision A51_P7)	Apr 05 2010		Gripper or scissor jaws may close inadvertently, and will not open on command, and various other reported modes of failure. Control by surgeon may fail, and this failure may be difficult to detect.	Notification Letter + Service Engineer Visit	782
Z-0670-2007	da Vinci S 4 Arm (Model IS2000)	Mar 29 2007	Mechanical	Spinal pin could limit mechanical motion of the arm and make system unavailable for surgery.	Rework as Part of Routine Service Visit	24
Z-2930-2011	da Vinci Si (Model IS3000)	Aug 03 2011		Potential failure of the retention component of the Master Tool Manipulator (MTM) could cause uncontrolled movement.	Urgent Correction Letter + Component Retrofit	183
Z-1202-2012	da Vinci S, da Vinci Si, da Vinci Si-e	Mar 13 2012		The holding brake may allow passive uncontrolled motion due to gravity during specific power-off conditions.	Urgent Correction Letter + Instructions	1966

Notwithstanding the fact that existing da Vinci robotic systems already have built-in safety and recovery mechanisms, the reported failures are identifiable single points of failures that could be prevented or recovered from at much lower costs and in a more timely fashion. The software lockups can be resolved by using a technique called rollback recovery (or *check-pointing*), a standard technique that have been shown to be effective in tolerating 70–90% of hardware and software faults [19][20]. Other examples include the use of redundant components in the system design, real-time error detection and reconfiguration strategies for automatic replacement of defective system components, and timely software updates.

4) Adverse Events across Different Classes of Robotic Surgery: We extracted the class and type of surgeries involving adverse events by training the MedSafe parsing engine with a dictionary of keywords related to different surgical procedures that was built based on information provided on the website of the company [21]. Table I shows the number of adverse events that happened in each class of surgery and their patient impacts. For the most common types of procedures in each class (highlighted in column 6 of Table I), we provide a comparison of the mortality, morbidity, and complication rates to those of laparoscopic and open surgery, based on previous studies found in the literature. Figures A2 and A3 (Appendix) show for each class of surgery, the number of adverse events per year, and the percentage of cases in which the procedure was converted or rescheduled. From those results, we observe that:

- Of all the adverse event reports, only 2,259 (47.1%) indicated the type of surgery involved; among those, the majority were related to gynecologic (23.1%), urologic (16.8%), and cardiothoracic (3.1%) surgeries, such as hysterectomy, prostatectomy, and mitral valve repair respectively. The higher percentage of adverse events (39.9%) in gynecologic and urologic surgeries could be explained by the higher number of these procedures performed. According to the company, in 2012 over 400,000 gynecology and urology procedures were performed worldwide, while the number of other surgeries altogether was less than 80,000 [5].

- Cardiothoracic and head and neck surgeries involved a higher chance of deaths per adverse event report (11.6% and 17.6%, respectively) compared to gynecology and urology (2.4%). In 12 (out of 15) deaths reported for head and neck surgeries, the patient expired after experiencing peri-operative bleeding or infection. However, because of inconsistent and incomplete information provided in the reports, it is not easy to identify the causes of the deaths.

- A major percentage of adverse events reported for general (58.8%), gynecologic (49.5%), and colorectal (44.1%) surgeries were attributed to broken/fallen-into cases.

- The highest conversion rate were for head and neck (35.3%), colorectal (26.5%) and cardiovascular (25.2%) procedures and the highest rates of rescheduling were for urologic (15.7%), head and neck (5.9%), and cardiothoracic (4.8%) surgeries.

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Table III - Number of Adverse Events Reports in Different Surgery Classes and Comparison to Laparoscopy Surgeries
(In the last column, OPN, LAP, and ROB, respectively, stand for open, laparoscopic and robotic types of surgery)

Surgery Class	Num of Adverse Events	Num of Deaths	Num of Injuries	Num of Malfunctions	Common Types of Surgery (Number of Adverse Events)	Ref.	Comparison to Other Types of Surgery
Gynecologic	1106 (23.1%)	26 (2.4%)	191 (17.3%)	714 (64.6%)	-Hysterectomy (873) -Myomectomy (142) -Sacrocolpopexy (42) -Ovarian Cystectomy (6)	[22]	Mortality: ROB: 0.1% LAP: 0.2%
						[23]	Complications: ROB: 5.5% LAP: 5.3%
Urologic	807 (16.8%)	19 (2.4%)	65 (8.1%)	413 (51.2%)	-Prostatectomy (709) -Nephrectomy (70) -Pyeloplasty (15)	[24]	Mortality: ROB: 0.8% OPN: 0.5%
						[25]	Complications: ROB: 2.5-26% LAP: 0-25%
Cardiothoracic	147 (3.1%)	17 (11.6%)	32 (21.8%)	52 (35.4%)	-Mitral valve repair (32) -Lobectomy (31) -Coronary arteries bypass (20)	[26]	Complications: ROB: 3.2-3.8% OPN: 3.2%
						[27]	Morbidity/ Mortality: ROB: 36.8%
Head and Neck	85 (1.8%)	15 (17.6%)	16 (18.8%)	22 (25.9%)	-TransOral robotic (Tors) (63) -Thyroidectomy (13) -Tongue base resection (6)	[28]	Complications: ROB: 11.5% Mortality: ROB: 1.5%
						[29]	Complications: ROB: 10.1% Mortality: ROB: 0.3%
General	80 (1.7%)	2 (2.5%)	15 (18.8%)	54 (67.5%)	-Cholecystectomy (23) -Nissen fundoplication (16) -Cystectomy (16) -Gastric Bypass (12)	[30]	Complications: ROB: 2% LAP: 2%
Colorectal	34 (0.7%)	3 (8.8%)	7 (20.6%)	15 (44.1%)	-Colectomy (18) -Colon Resection (4) -Proctectomy (4) -Rectopexy (3)	[31]	Complications: ROB:5/17=29.4% LAP:2/15=13.3%
						[32]	Complications: ROB: 14% LAP: 17%
N/A	2539 (52.9%)	4 (0.2%)	84 (3.3%)	2135 (84.1%)			

Previous studies on the effectiveness of robotic surgery show contradictory results. Most of the studies especially in the classes of gynecology and urology, for which the robot is extensively used, show better outcomes compared to laparoscopy and open surgery in terms of rates of complications and deaths. But comparisons of outcomes for cardiothoracic, head and neck, and colorectal surgeries have rarely been done, and the existing studies often show that the robot is no more effective, or even worse, than laparoscopy. The best that we can assess from the available data is that the higher percentage of deaths

and conversions in cardiovascular, head and neck, and colorectal surgeries could be indirectly explained by higher complexity of the procedures, less frequent use of robotic devices, less robotic expertise in these fields, and complications related to patient histories, to varying degrees that are unknown. In the next section, we discuss some of the possible causes of deaths that were identified by detailed review of the reports.

III. ACCIDENT ANALYSIS

We performed a detailed review of adverse events involving injuries and deaths to find the actual number of reports that explicitly indicated that a device malfunction or robotic technical issue caused the harm to patients. Through discussions with expert surgeons as well as careful review of adverse event reports, we classified the things that contributed to patient injuries or deaths into three main categories: inherent complications of the surgery, technical issues with the robot, or mistakes made by the surgeon or staff.

For the majority of the death reports, the cause was attributed to surgeon/staff mistake (6 out of 86), the patient's history (10 out of 86), or inherent risks involved with the surgery (such as infection (6), sepsis (4), and bleeding (9)). Of all the reported deaths in different classes of surgery, we found that at least 75.3% (64 of 86) happened after the procedure and at least 17.4% (15 of 86) during the procedure. Of the deaths that occurred during the procedures, five were due to inadvertent cuts or punctures of organs and the others were related to complications such as uncontrolled bleeding, pulmonary embolism, and cardiac arrest. We identified 17 cases of deaths that happened after the surgery because the patients were diagnosed with an infection and sepsis (10) or uncontrollable and heavy bleeding (7).

Recall that of 410 injury reports, 254 involved device or instrument malfunctions (as shown in Table I). Of the rest (i.e., 156), in 29 cases, the manufacturer attributed the injury to user or surgeon error; in 17 cases, improper positioning of the patient for a long time during the procedure led to post-operation complications (such as nerve damage or neuropathy); in 9 cases, burning near the port incision was reported; in 16 cases, the inherent risks of the surgery or the patient's history were indicated as the cause of the event; in 6 cases, the manufacturer investigations concluded that the burning of patient tissue may have been caused by electrosurgical unit currents passing through the instruments to the patient, if the patient was not properly grounded; and in 2 cases, the surgeon felt some shocking at the surgeon's side console. We believe that the events other than user errors could potentially be prevented by improved safety controls in the design of systems.

The rest of the events, including 77 injury and 27 death reports, could not be classified in any of the categories. These reports provided little or no detailed information about the possible causes that led to the events or insights on how such catastrophic events could be prevented in the future. Table A4

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(Appendix) shows a few representative example death events reported in recent years to the FDA, along with summaries of their descriptions, types of surgery, and the potential causes of the death that can be identified from the descriptions provided in the reports.

We employed a sophisticated accident analysis tool for safety-critical systems, called Causal Analysis using System Theory (CAST) [33], for more detailed review and analysis of example accidents. While such an external review cannot determine exactly what was involved in the actual incidents that occurred, it can provide insight on the potential hazards and their causes involved in such robotic surgeries and potential factors to explore in examining specific incidents.

We first identified the main entities involved in a robotic-assisted surgical system, including the human operators (surgeons, surgical staff, and technical support engineers), the automated controllers and components of the robot, and the patient. Then using the semantics of STAMP (Systems-Theoretic Accident Model and Processes) [33], we modeled the hierarchical control structure of a typical robotic surgical system, composed of the main controllers (human operators and automated robot control), the controlled processes (robotic arms and the patient), and the control loops (See Figure 3.a). In this structure, the interactions between the controllers and controlled processes are modeled by control loops composed of the commands (e.g., hand and foot movements) that a controller (e.g., main surgeon) sends to a controlled process (e.g., robot control) and the response or feedback (e.g., 3D images on the surgeon's console) received from the controlled process.

Using CAST, the characteristics and responsibilities of each of the controllers, the interactions among them, and the context in which they make decisions and take actions were analyzed to uncover potential safety hazards and violated safety constraints and to identify safety controls that should be added to the design of system. Note that our analysis is limited to the incomplete information provided in the *Event Description* and *Manufacturer Narrative* fields of MAUDE reports. Careful analysis of accidents based on the investigations made by the company and hospitals is necessary to completely determine the causes for the events.

Figure 3.b shows the list of possible system hazards, along with examples of potentially flawed control actions and inadequate feedback that could lead to violation of safety constraints, which in turn could lead to accidents that caused serious injury or death. In each case, the related control loop number (from Figure 3.a) is highlighted in parentheses and an example MAUDE report is listed in the last column. Control loop 0 refers to higher levels in the control structure, related to the decisions taken and procedures performed by the company in the design, manufacturing, and testing process. Tables A5 and A6 (Appendix) show a specific example of CAST analysis for an adverse event reported in 2008 (MAUDE report no. 2240665).
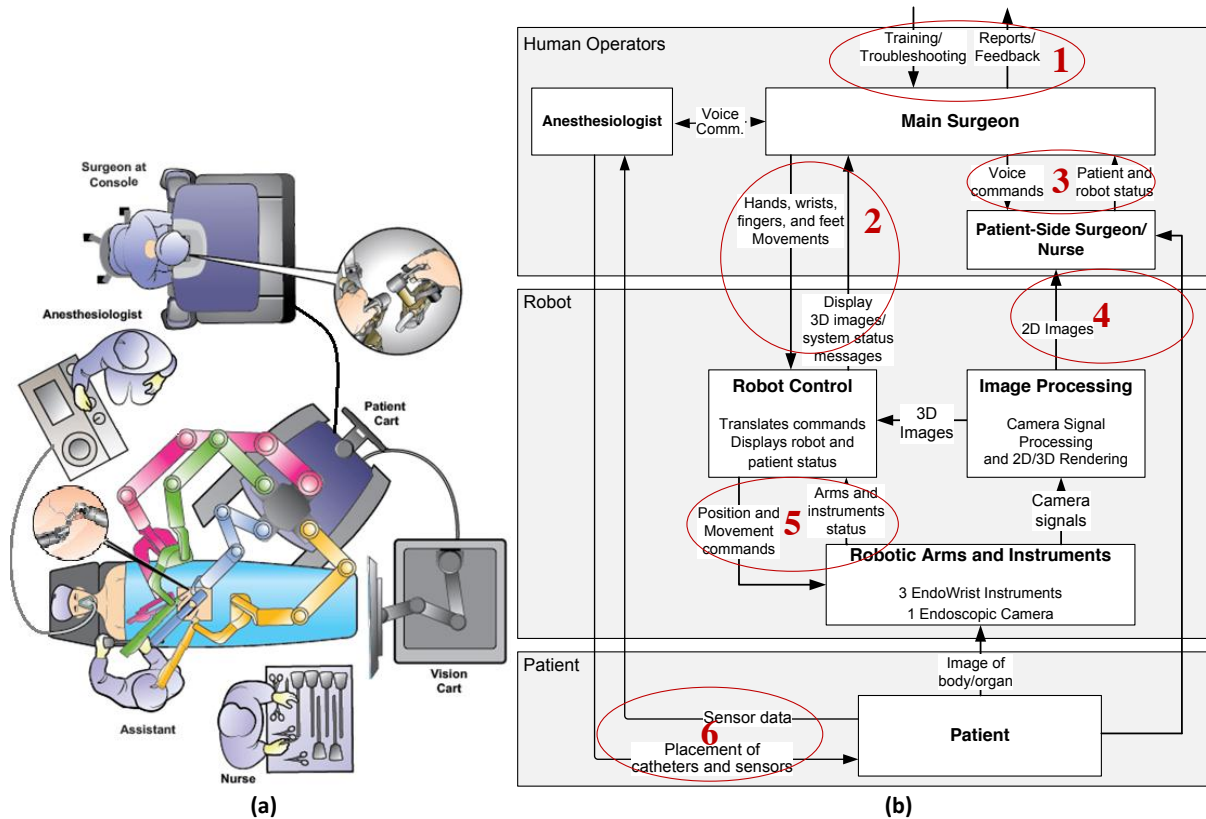
System Hazards	Example Flawed Control Actions and Inadequate Feedback (Related Control Loop)	MAUDE Report No.
The robot instruments/arms move or cut or apply energy to an unintended position on the patient's body.	- Inadequate training of the main surgeon or surgical staff (1) - Inaccurate hand movements by the main surgeon (2) - Inaccuracy or loss of vision on the surgeon's console (2) - Inadequate communication between the surgeon and staff (3) - Incorrect commands from the robot control to arms (5)	1692421 2563461 1891889 2567858 1077464
Procedure continues for a prolonged time.	- Inadequate information displayed on surgeon's console (2) - Inadequate support and troubleshooting from the company (1) - Decisions made by the main surgeon (e.g. use of 2D imaging, manual manipulation of arms, not converting) (2)	2240665 2494890 1760256 1515425
The robotic console or instruments/arms cause shock, burning, or fire for the surgical staff.	- Inadequate safety instructions provided by the company (1) - Inadequate safety testing/procedures by the company (0)	1622530 1735914 1633732

Figure 3 - Causal Analysis using System Theory (CAST) for Example Accidents:
(a) da Vinci System, Courtesy of Intuitive Surgical, Inc., (b) Hierarchical Control Structure of the Robotic Surgical System,
(c) System Hazards, Example Flawed Controls that led to System Hazards, and Example MAUDE Reports.

In the next section, we use the results of the CAST analysis as a basis for spelling out some of the challenges in design of future robotic surgical systsms, and for providing insights on the use of safety mechanisms and practices that can improve the safety and effectiveness of robotic surgery.

IV. DISCUSSION AND CONCLUDING REMARKS

The da Vinci surgical system was first approved by the FDA and introduced to the market in 2000 for performing general minimally-invasive laparoscopic procedures. During the next several years, it was approved for various types of surgeries, including urologic, gynecologic, cardiothoracic, head and neck, and colorectal. Since then, there have been several studies on the efficacy of the surgical robots in various classes of surgery and comparison of the outcomes to those of traditional surgeries such as laparoscopy and open surgery (see Table III).

The da Vinci robot has transformed prostatic and hysterectomy surgeries, with less morbidity, less blood loss, and equivalent clinical outcomes compared to open surgery [24]. However, claims that long-term complications will be reduced by better visualization through 3-dimensional magnified views of the surgical field and by smaller incisions, have not been borne out [34]. Also, recent lawsuits have highlighted some of the accidents that have occurred during hysterectomy procedures [1]. The robot could make it possible to perform very complex procedures by accessing the body cavity through small ports using tele-manipulating arms with 7 degrees of freedom as extensions of the human hand and surgical instruments. But the complexity of the robotic platform, the expense of the disposables, the steep learning curve, the difficulty in troubleshooting robot system errors, and various patient complications have made it difficult to extensively adopt the robot in more complex procedures such as in cardiothoracic [35][36][37], head and neck, and colorectal surgeries. As an example, the recently published experiences of an extremely competent robotic team that performed multi-vessel coronary artery bypass grafting (CABG) showed sub-optimal results (higher mortality and morbidity rates) compared to open surgery [27].

Major Findings: Based on the experience of different surgical departments and institutions with the robot, there have been several reports on malfunctions and failures of robotic surgical systems [38]–[51]. A few others have studied the adverse event reports submitted to the FDA MAUDE database [52]–[55]. Tables A7 and A8 (Appendix) show a summary of the related research. However, most of the previous studies targeted two popular surgery classes, gynecology and urology, and analyzed only a subset of reports collected by the FDA. The significant results of our study can be summarized as follows:

- By using a substantially automated language processing tool, we were able to analyze a large set of adverse events (4,798) and recalls (19) reported over the 13-year period of 2000–2012, including 410 patient injuries and 86 deaths.
- We found that after nearly 14 years of deployment of da Vinci surgical system, the rate of reported adverse events on average is declining, but the average numbers of deaths and injuries reported per procedure continue to increase linearly with a rate of 10^{-5} to 10^{-6}.

- Nearly 91% of the adverse events involved device and instrument malfunctions that caused major system downtimes during the surgery because of the need to troubleshoot the problem, by resetting the system or converting the procedure to traditional techniques. Examples of malfunctions include broken/burnt pieces of instruments falling inside the patient (40.4%), arcing of instruments (19.1%), sudden system errors (9.9%), unintended instruments operation (8.8%), and video/imaging problems (4.2%).

- The surgical procedures were interrupted in almost 912 cases (19% of all the adverse events). In these cases, some time was spent on either troubleshooting the errors, identifying whether the error was actually recoverable or non-recoverable by resetting the system (275 cases, 5.7%), or converting the procedure to traditional non-robotic techniques such as open or laparoscopy (640 cases, 13.3%). In about 5% (236) cases the procedure was rescheduled to a later time.

- Out of all the adverse events, 659 reports were related to system errors and video/imaging problems that were the major contributors to the system resets (84%), or conversion (63.9%), or rescheduling of the procedures (80.9%).

- We were able to establish the relative effectiveness of the robotic surgical system and its instruments across *different classes of robotic surgery*. Surgery classes such as *gynecologic* and *urologic* where the robots are extensively used, have much lower rates of deaths (2.4% of adverse events) than more complex procedures such as *head and neck*, *cardiothoracic*, and *colorectal*, for which higher rates of death (17.6%, 11.6%, and 8.8% respectively) and conversions (35.3%, 25.2%, and 26.5%, respectively) were reported.

- Through analysis of specific deaths and injuries using CAST accident analysis tool, we concluded that the likely potential reason for many of the accidents are the inadequacy of safety controls and comprehensive warnings to the surgeon, limited safety and training practices, lack of certification, and limited surgical experience. However, additional careful analysis of accidents based on the investigations done by the manufacturing company and healthcare facilities is necessary to fully understand the causes of the events.

Recommendations: Our systematic accident analysis of representative injury and death reports and detailed review of recovery actions taken by the company to address the recalls show that from a technology perspective, some of the adverse events could be prevented by employing substantially improved safety practices and developing advanced safety mechanisms controls in the design of surgical robots. In fact, in other highly safety-critical industries, such as aviation, a great deal of effort has been spent over the years to ensure that aircraft are safe and secure.

While a direct comparison between aviation and robotic surgery is not possible, we can learn how to attain a high level of safety by studying how industry, government, academia, and society came together to create standards and procedures that have continually achieved an outstanding safety record and mission time reliability of better than 10^{-9} per hour for electronic equipment in commercial aircraft. Some of the factors that have been critical to that success include the following (see Table A10, Appendix):

1) Careful analysis of accidents (by airline authorities and the National Transportation Safety Board (NTSB) [56]) to ensure that mistakes are not repeated and designs are continually improved

2) Extensive use of hazard analysis and sophisticated safety design techniques and controls

3) Oversight and certification by government authorities such as Federal Aviation Administration (FAA).

We believe state-of-the-art technology exists that, if combined with the current robotic technology, can make provable and quantifiable improvements to the safety of future systems for robotic surgery. Some examples include:

- Providing real-time visual feedback to the surgeon on the safe trajectories that can be taken [57], by computing the 3D models of the organs under surgery and surrounding critical tissues and blood vessels, as well as surgeon-specific models of robotic surgical motions [58], can minimize the risk of approaching dangerous limits and potentially prevent inadvertent patient injuries.

- While the current systems provide valuable information such as system error codes during the procedure, they are very passive in learning from previous failures and providing information on troubleshooting. Research in designing new safety engines that provide online monitoring of procedures (including surgeon, patient, and device status) and proactive warnings and comprehensive feedback to the surgical staff on upcoming events could prevent the long downtimes and improve the availability of systems.

- More detailed analysis of past and future incidents using new accident analysis methods (such as Causal Analysis using System Theory (CAST)) as well as safety-driven design using hazard analysis techniques (such as System Theoretic Process Analysis (STPA)) that take into account the role of complex software errors, component interaction failures, and human operators will help us to design safer devices.

- Providing improved training and support for surgeons and surgical staff by developing certification procedures, improved human-machine interfaces, simulators for surgical training, and tools for real-time assessment of skills and expertise of the surgical staff may improve safety profiles significantly in the future.

REFERENCES

[1]   "Has the Halo Been Broken on Intuitive Surgical?" Citron Research, December 19, 2012; http://www.citronresearch.com/wp-content/uploads/2012/12/isrg-final1.pdf.

[2]   "Intuitive Surgical: Angel with Broken Wings, or the Devil in Disguise?" Citron Research, January 17, 2013; http://www.citronresearch.com/wp-content/uploads/2013/01/Intuitive-Surgical-part-two-final.pdf.

[3]   "FDA Investigates Robotic Surgery System after Adverse Event Spike," Medscape Today; http://www.medscape.com/viewarticle/803339.

[4]   Company Backgrounder, Intuitive Surgical, January 2013, http://www.intuitivesurgical.com/company/media/media_kit/company-backgrounder-en-871072.pdf.

[5]   Investor Presentation, Intuitive Surgical, 2013, http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9MTcwOTQ5fENoaWxkSUQ9LTF8VHlwZT0z&t=1.

[6]   Vaessen, C. "Location of Robotic Surgical Systems Worldwide and in France." *Journal of Visceral Surgery* 148, no. 5 (2011): e9–e11.

[7]   U.S. Food and Drug Administration, "Medical Device Databases [Recalls, MAUDE, and TPLC]," March 5, 2013, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm

[8]   U.S. Food and Drug Administration, "MAUDE - Manufacturer and User Facility Device Experience," September 30, 2013, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

[9]   Hauser, Robert G., William T. Katsiyiannis, Charles C. Gornick, Adrian K. Almquist, and Linda M. Kallinen. "Deaths and Cardiovascular Injuries Due to Device-assisted Implantable Cardioverter–Defibrillator and Pacemaker Lead Extraction." *Europace* 12, no. 3 (2010): 395–401.

[10]   Cooper, Michol A., Andrew Ibrahim, Heather Lyu, and Martin A. Makary. "Underreporting of Robotic Surgery Complications." *Journal for Healthcare Quality* (2013). Aug 27. doi: 10.1111/jhq.12036. [Epub ahead of print]

[11]   "Adverse Event Reporting of Medical Devices," Department of Health and Human Services, Office of Inspector General (OEI-01-08-00110), October 2009; https://oig.hhs.gov/oei/reports/oei-01-08-00110.pdf.

[12]   H. Alemzadeh, R. K. Iyer, Z. Kalbarczyk, and J. Raman, "Analysis of Safety-Critical Computer Failures in Medical Devices," *IEEE Security and Privacy, vol. 11, no. 4, pp. 14-26, July/August* 2013.

[13]   "Statements: Analysis of Medical Device Reports by Data shows decline in Overall Adverse Events," Intuitive Surgical, October 3, 2013, http://www.intuitivesurgical.com/company/media/statements/.

[14]   "Intuitive Surgical Comments on Medical Device Reporting Practices," Intuitive Surgical, Inc., March 13, 2013; http://investor.intuitivesurgical.com/phoenix.zhtml?c=122359&p=irol-newsArticle&id=1796011.

[15]   "EndoWrist® Instrument & Accessory Catalog," Intuitive Surgical, Inc., January 2013; http://www.intuitivesurgical.com/products/871145_Instrument_Accessory_%20Catalog.pdf.

[16]   U.S. Food and Drug Administration. *Medical & Radiation Emitting Device Recalls, Class 2 Recall da Vinci S Surgical System IS2000* [Online]. November 6, 2013. Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=71855.

[17]   U.S. Food and Drug Administration. *MAUDE Adverse Event Report, Intuitive Surgical, Inc. Da Vinci S Surgical System Endoscopic Instrument Control System* [Online]. November 6, 2013. Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=1760256

[18]   Knight, John C., and Nancy G. Leveson. "An Experimental Evaluation of the Assumption of Independence in Multiversion Programming." *IEEE Transactions on Software Engineering* 1 (1986): 96–109.

[19]   Bartlett, Joel, Jim Gray, and Bob Horst. "Fault Tolerance in Tandem Computer Systems." In *The Evolution of Fault-Tolerant Computing*, pp. 55–76. Springer Vienna, 1987.

[20]   Lee, Inhwan, and Ravishankar K. Iyer. "Software Dependability in the Tandem GUARDIAN System." *IEEE Transactions on Software Engineering* 21, no. 5 (1995): 455–467.

[21]   "da Vinci® Procedures," da Vinci Surgery, accessed November 7, 2013, http://www.davincisurgery.com/da-vinci-surgery/da-vinci-procedures/.

[22]   Wright, J. D., et al., "Comparative Effectiveness of Robotic versus Laparoscopic Hysterectomy for Endometrial Cancer." *Journal of Clinical Oncology* 30, no. 8 (2012): 783–791.

[23]   Wright, J. D., et al., "Robotically Assisted vs Laparoscopic Hysterectomy among Women with Benign Gynecologic Disease." *Obstetrical & Gynecological Survey* 68, no. 6 (2013): 430–431.

[24]   Hu, Jim C., et al., "Comparative Effectiveness of Minimally Invasive vs Open Radical Prostatectomy." *JAMA: The Journal of the American Medical Association* 302, no. 14 (2009): 1557–1564.

[25]   J. K. Yates, et al., "Complications of Laparoscopic and Robotic Radical Prostatectomy," P*revention and Management of Laparoendoscopic Surgical Complications*, 3rd Edition; http://laparoscopy.blogs.com/prevention_management_3/2011/03/complications-of-laparoscopic-and-robotic-radical-prostatectomy.html.

[26]   Suri, Rakesh M., Jeffrey E. Thompson, Harold M. Burkhart, Marianne Huebner, Bijan J. Borah, Zhuo Li, Hector I. Michelena et al. "Improving Affordability Through Innovation in the Surgical Treatment of Mitral Valve Disease." In *Mayo Clinic Proceedings*, vol. 88, no. 10, pp. 1075-1084. Elsevier, 2013.

[27]   Dhawan, Richa, et al, "Multivessel Beating Heart Robotic Myocardial Revascularization Increases Morbidity and Mortality." *The Journal of Thoracic and Cardiovascular Surgery* 143, no. 5 (2012): 1056-1061.

[28]   Vergez, Sebastien, Benjamin Lallemant, Philippe Ceruse, Sylvain Moriniere, Karine Aubry, Erwan De Mones, Adil Benlyazid, and Yann Mallet. "Initial multi-institutional experience with transoral robotic surgery." *Otolaryngology--Head and Neck Surgery* 147, no. 3 (2012): 475-481.

[29]   Chia, Stanley H., Neil D. Gross, and Jeremy D. Richmon. "Surgeon Experience and Complications with Transoral Robotic Surgery (TORS)." *Otolaryngology--Head and Neck Surgery* (2013): 0194599813503446.

[30]   Breitenstein, S., et al., "Robotic-assisted versus Laparoscopic Cholecystectomy: Outcome and Cost Analyses of a Case-matched Control Study." *Annals of Surgery* 247, no. 6 (2008): 987–993.

[31]   Rawlings, A. L., J. H. Woodland, R. K. Vegunta, and D. L. Crawford. "Robotic versus Laparoscopic Colectomy." *Surgical Endoscopy* 21, no. 10 (2007): 1701–1708.

[32]   Spinoglio, Giuseppe, Massimo Summa, Fabio Priora, Raoul Quarati, and Silvio Testa. "Robotic Colorectal Surger*y: First 50 Cases* Experience." *Diseases of the Colon & Rectum* 51, no. 11 (2008): 1627–1632.

[33]   N. Leveson, *Engineering a Safer World: Systems Thinking Applied to Safety*, MIT Press, 2011.

[34]   Huang K. H., S. C. Carter, and J. C. Hu. "Does Robotic Prostatectomy Meet Its Promise in the Management of Prostate Cancer?" *Current Urology Reports* (2013): 1-8.

[35]   Autschbach, R., J. F. Onnasch, V. Falk, T. Walther, M. Krüger, L. O. Schilling, and F. W. Mohr. "The Leipzig Experience with Robotic Valve Surgery." *Journal of Cardiac Surgery*, 2000 Jan-Feb; 15(1):82–87.

[36]   Mohr F. W, V. Falk, A. Diegeler, T. Walther, J. F. Gummert, J. Bucerius, S. Jacobs, and R. Autschbach. "Computer-enhanced 'Robotic' Cardiac Surgery: Experience in 148 Patients." *Journal of Thoracic and Cardiovascular Surgery*. 2001 May; 121(5):842–853.

[37]   Kappert, U., R. Cichon, J. Schneider, V. Gulielmos, T. Ahmadzade, J. Nicolai, S. M. Tugtekin, and S. Schueler. "Technique of Closed Chest Coronary Artery Surgery on the Beating Heart." *European Journal of Cardiothoracic Surgery*. 2001 Oct; 20(4):765–769.

[38]   Eichel, L., T. E. Ahlering, and R. V. Clayman. "Robotics in Urologic Surgery: Risks and Benefits." *AUA Update Series 2005*; 24(lesson 13): 106–111.

[39]   Kozlowski, P. M., C. R. Porter, and J. M. Corman. "Mechanical Failure Rate of da Vinci Robotic System: Implications for Pre-op Patient Counseling" [abstract 1159]. *J Urol* 2006; 175(suppl):s372–s373.

[40]   Borden, Jr., L. S., P. M. Kozlowski, C. R. Porter, and J. M. Corman. "Mechanical Failure Rate of da Vinci Robotic System." *The Canadian Journal of Urology* 14, no. 2 (2007): 3499.

[41]   Zorn, Kevin C., Ofer N. Gofrit, Marcelo A. Orvieto, Albert A. Mikhail, R. Matthew Galocy, Arieh L. Shalhav, and Gregory P. Zagaja. "da Vinci Robot Error and Failure Rates: Single Institution Experience on a Single Three-arm Robot Unit of More Than 700 Consecutive Robot-assisted Laparoscopic Radical Prostatectomies." *Journal of Endourology* 21, no. 11 (2007): 1341–1344.

[42]   Fischer, Boris, Nadja Engel, Jean-Luc Fehr, and Hubert John. "Complications of Robotic Assisted Radical Prostatectomy." *World Journal of Urology* 26, no. 6 (2008): 595–602.

[43]   Lavery, Hugh J., et al. "Robotic Equipment Malfunction during Robotic Prostatectomy: A Multi-institutional Study." *Journal of Endourology* 22, no. 9 (2008): 2165–2168.

[44]   Ham, Won Sik, et al. "Malfunction of da Vinci Robotic System—Disassembled Surgeon's Console Hand Piece: Case Report and Review of the Literature." *Urology* 73, no. 1 (2009): 209–e7-8.

[45]   Kim, Won Tae, Won Sik Ham, Wooju Jeong, Hyun Jung Song, Koon Ho Rha, and Young Deuk Choi. "Failure and Malfunction of da Vinci Surgical Systems during Various Robotic Surgeries: Experience from Six Departments at a Single Institute." *Urology* 74, no. 6 (2009): 1234–1237.

[46]   Park, Sung Yul, Jenny Jin-Kyung Ahn, Wooju Jeong, Won Sik Ham, and Koon Ho Rha. "A Unique Instrumental Malfunction during Robotic Prostatectomy." *Yonsei Medical Journal* 51, no. 1 (2010): 148–150.

[47]   Kaushik, Dharam, Robin High, Curtis J. Clark, and Chad A. LaGrange. "Malfunction of the da Vinci Robotic System during Robot-assisted Laparoscopic Prostatectomy: An International Survey." *Journal of Endourology* 24, no. 4 (2010): 571–575.

[48]   Finan, Michael A., and Rodney P. Rocconi. "Overcoming Technical Challenges with Robotic Surgery in Gynecologic Oncology." *Surgical Endoscopy* 24, no. 6 (2010): 1256–1260.

[49]   Mues, Adam C., Geoffrey N. Box, and Ronney Abaza. "Robotic Instrument Insulation Failure: Initial Report of a Potential Source of Patient Injury." *Urology* 77, no. 1 (2011): 104–107.

[50]   Agcaoglu, Orhan, et al. "Malfunction and Failure of Robotic Systems during General Surgical Procedures." *Surgical Endoscopy* (2012): 1–4.

[51]   Chen, Cheng-Che, et al. "Malfunction of the da Vinci Robotic System in Urology." *International Journal of Urology, no. 19* (2012): 736-740.

[52]   Andonian, S., Z. Okeke, D. A. Okeke, A. Rastinehad, B. A. Vanderbrink, L. Richstone, and B. R. Lee. "Device Failures Associated with Patient Injuries during Robot-assisted Laparoscopic Surgeries: A Comprehensive Review of FDA MAUDE Database." *Canadian Journal of Urology* 15, no. 1 (2008): 3912.

[53]   Murphy, D., B. Challacombe, O. Elhage, and P. Dasgupta. "Complications in Robotic Urological Surgery." *Minerva Urologica e Nefrologica* 59, no. 2 (2007): 191.

[54]   Lucas, Steven M., Erik A. Pattison, and Chandru P. Sundaram. "Global Robotic Experience and the Type of Surgical System Impact the Types of Robotic Malfunctions and their Clinical Consequences: An FDA MAUDE Review." *BJU International* 109, no. 8 (2012): 1222–1227.

[55]   Fuller, Andrew, George A. Vilos, and Stephen E. Pautler. "Electrosurgical Injuries during Robot Assisted Surgery: Insights from the FDA MAUDE Database." In *Proceedings of SPIE*, vol. 8207, p. 820714. 2012.

[56]   "Aviation Statistics: Review of Accident Data," National Transportation Safety Board (NTSB), accessed November 7, 2013, http://www.ntsb.gov/data/aviation_stats.html

[57]   R. R. Shamir, M. Horn, T. Blum, J. Mehrkens, Y. Shoshan, L. Joskowicz, and N. Navab, "Trajectory planning with augmented reality for improved risk assessment in image-guided keyhole neurosurgery," in Proc. IEEE Int. Symp. Biomed. Imaging: From Nano to Macro, Chicago, IL, USA, 2011, pp. 1873–1876.

[58]   Lin, Henry C., Izhak Shafran, David Yuh, and Gregory D. Hager. "Towards automatic skill evaluation: Detection and segmentation of robot-assisted surgical motions." *Computer Aided Surgery* 11, no. 5 (2006): 220-230.
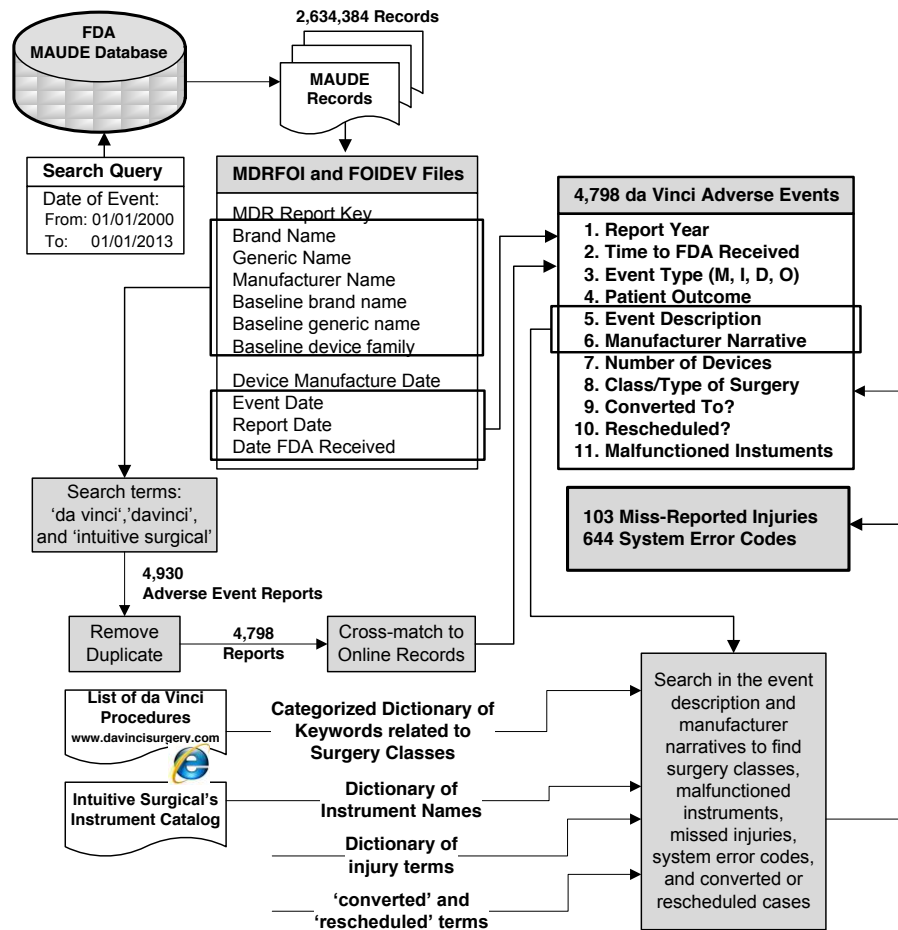
APPENDIX

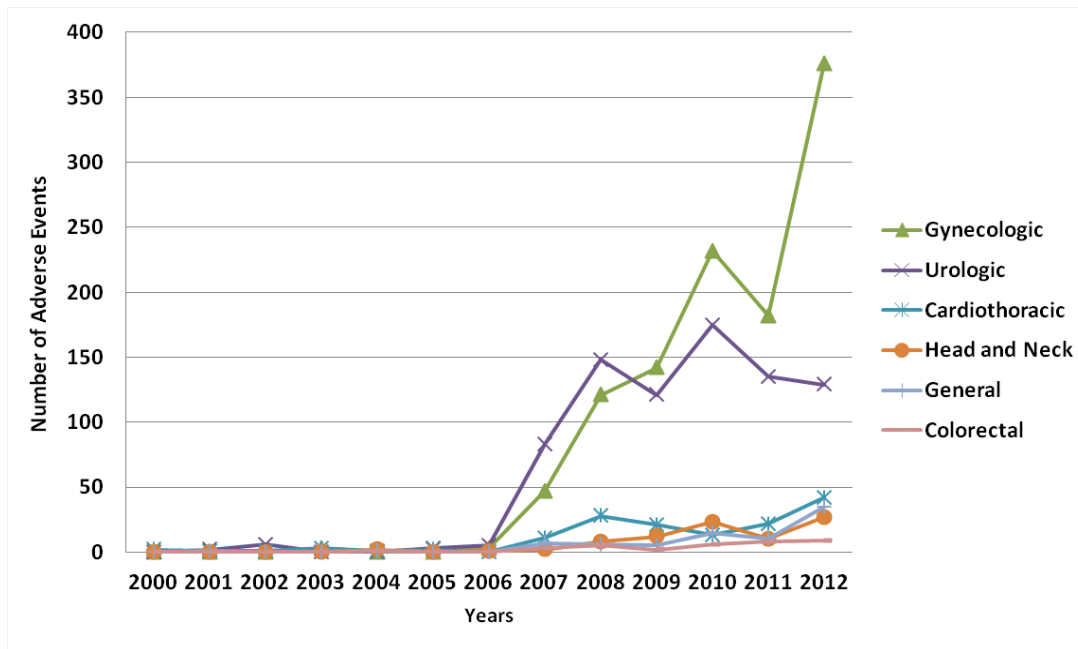**Figure A1 - Methodology for Extraction and Analysis of Adverse Events**

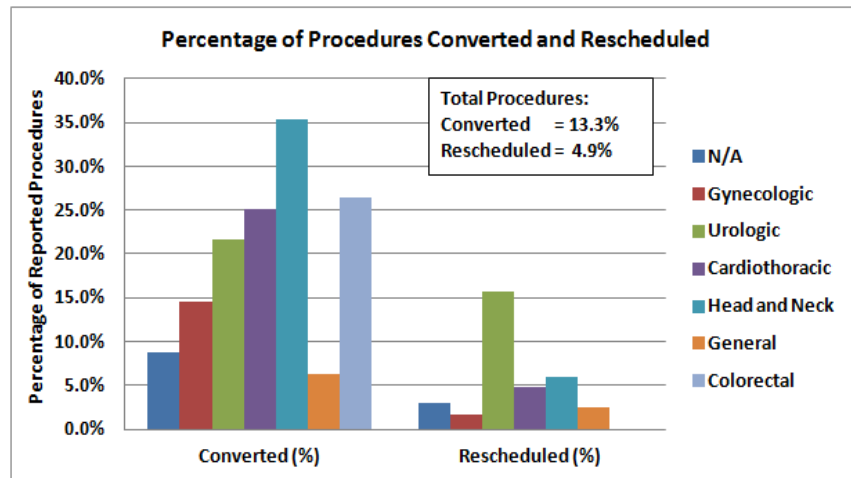**Figure A2 - Number of Adverse Events for Different Classes of Surgery: 2000-2012**

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Figure A3 - Percentage of Converted or Rescheduled Procedures (p < 0.0002)
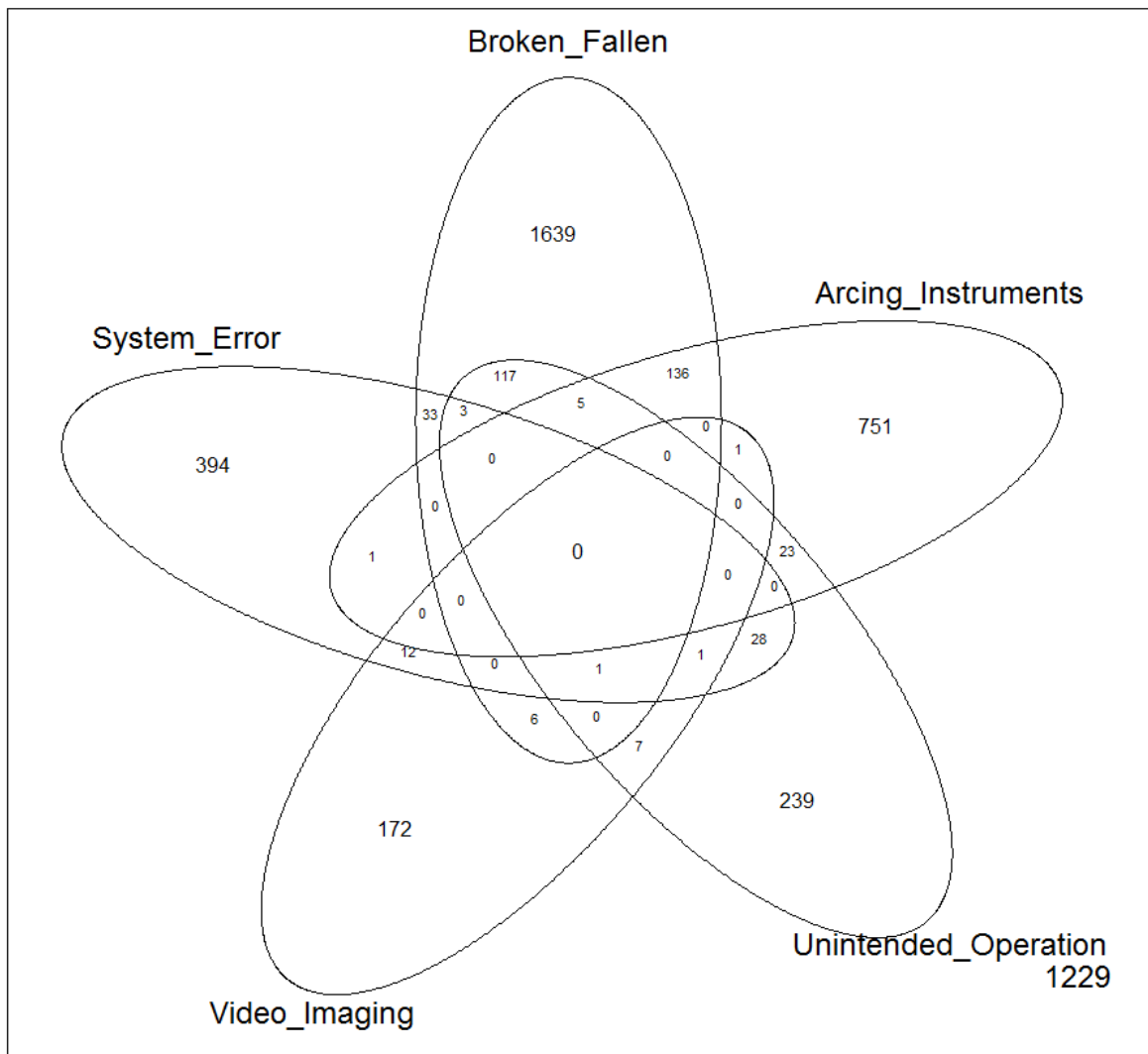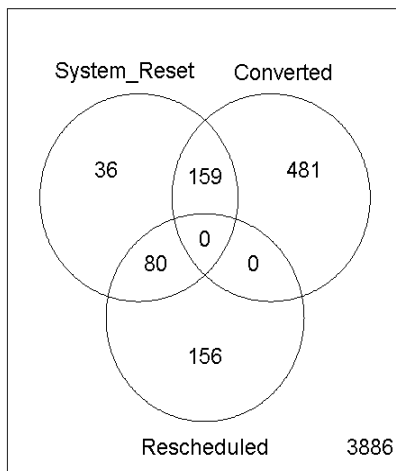

Figure A4 – Intersections between different Malfunction Categories
(A total of 1,229 adverse event reports were not classified by MedSafe in any of the malfunction categories)

Figure A5 – Intersections between System Resets, Converted, and Rescheduled Cases
(For 3,886 adverse events no system resets, conversions, or rescheduling was reported.)

Table A1 - Example Malfunction and Errors with Severe Patient Impacts during Cardiothoracic Procedures
Three of these cases were reported as an event with "Other" patient impact and not as "Injury".

MAUDE Report Number (Year)	Surgery Type	Event	Faulty Component	Patient Impact	Recovery Actions
444144 (2003)	Thoracoscopic Ablation for AF	-Injury was noticed as surgeon was transferring an ablation probe (a non-isi product) from a long tip forceps instrument controlled with the right hand to another long tip forceps controlled with the left hand	N/A	- Epicardial/tissue injury (small hole)	-Converted to open surgery
660137 (2005)	Atrial Fibrillation Treatment	Atricure ablation electrode (isolator transpolar pen) was unhooked from robotic arm and manually manipulated	N/A	-Bleeding of arterial wall -Stroke and aortic dissection	-Cardiopulmonary bypass was initiated
932174 (2007)	Mitral Valve Repair	- Possibly port placement -The robotic arms were never seen to collide but this could have occurred which resulted in pressure on the retractor.	N/A	-Left atrial disrupted -A 3 cm tear occurred in the hood of atrium medial to left atrial appendage extending down towards the mitral annulus	-A patch was brought into place, trimmed, and was sewn using a suture and tied -Sternotomy incision made for further repair
1590517 (2010)	CABG	- Micro bipolar forceps (mbf) instrument jumped forward - When master tool manipulator was moved, the instrument felt stuck and then moved.	Patient side manipulator (psm)	-Patient's artery punctured	-Damaged section of artery was transected and the healthy portion was used to complete the bypass -Company replaced the psm component
2494890 (2012)	CABG	- Arcing from Bipolar forceps instrument	N/A	-Small burn to diaphragm	-Connected ground pads and checked electrical surgical unit

Table A2 - Example Error Codes and Related Safety Mechanisms of da Vinci System

System Error Code	Description	Type of Safe State that System Transits To	No. of Adverse Events
#20008	The angular position of one or more robotic joint's on the specified manipulator, as measured by the joint's primary control sensor (encoder) and the secondary sensor (potentiometer), were out of specified tolerance for agreement	Recoverable	62
#23008			42
#20013			34
#23013			20
#21008			18
#21013			17
#23002			8
#20009			7
#22003			5
#212	A voltage tracking fault reported by the digital signal processor (dsp): When the actual voltage to drive current through the motors deviates from the expected voltage by a specified amount.	Non-recoverable	31
#23	-Hardware wheel "wdog" has tripped on one of the digital communication links in the system (due to an excessive number of retries on hardware message packets). This means that the system cannot reliably communicate over that digital link and therefore cannot continue normal operation. - Communication faults in the low voltage differential signal carrying information about the patient side manipulator. - Communication faults between two system components.	N/A	28
#1	A power supply voltage was out of range.	Non-recoverable	19
#3	A redundant switch was missing its ground sense, or the contacts did not report as expected at startup	N/A	15
#23017	A motor did not respond as expected and the measured motion did not match the internal stimulation of the motor.	Recoverable	14
#2	A reference voltage was out of range	N/A	14
#31030	One of the camera controller units in the doco has failed to power on after multiple attempts or has shut down after initially powering up.	N/A	14
#5	One or more fans are not moving as desired	N/A	10
#297	An electronic component was reporting an incorrect configuration.	Non-recoverable	9
#252	Master supervisory controller does not receive an expected message within a specified time.	Recoverable	8
#23020	One of the switches in an specific manipulator is showing inconsistent signals on it's two switch leads.	Recoverable	7
#25589	During the power up self-test, the remote arm controller board (rac) brakes failed the brake voltage test.	Recoverable	6
#25588	A sympathetic error and occurs during the self-test upon system power up when a loop response test fails.	Recoverable	6
#23007	On startup, one or more robotic joints on the manipulator did not make the prescribed test motion to within the specified tolerance.	Recoverable	6
#21003	The arm did not perform the commanded motions during startup within a specified tolerance	N/A	5
#281	A processor did not complete a step during system startup within the allotted time	Non-recoverable	5
#23034	After a specified amount of time, a valid event has not been seen for one of the remote compute engine switches	Recoverable	5
#45049	A communication timeout with the software running the da vinci onsite application	Recoverable	4

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Table A3 – Example Recalls of da Vinci da Vinci (S) Accessories (Years 2000-2012)

Recall Record Numbers	Device Name (Model Number)	Date	Malfunction Type	Reason for Recall	Company Recovery Action	Num. of Devices
Z-0660-2007	8mm EndoWrist Bipolar Maryland Instrument	Mar 28 2007	Computer Software	The product was incorrectly programmed as training instruments, allowing it to be used for 30 surgical procedures instead of 10.	Urgent Letter + Return	8
Z-1811-2008	da Vinci S Cardiac Probe Gasper Instrument (For model IS2000)	Sep 17 2008		There is a software interface problem that will not allow the IS2000 system to recognize the instrument, which causes the loss of operability of the instrument; delay in surgery; and loss of dexterity.	Urgent Letter + Return	11
Z-0723-05	da Vinci 8 mm EndoWrist Curved Scissors	Apr 22 2005	Mechanical	Blades on the scissor may break and separate from the main unit as a result of corrosion damage.	Notification Letter	278
Z-0669-2008	da Vinci S 5 mm Instrument Cannula	Jan 31 2008		5mm Cannula may have sharp edges on the inner diameter that may cause particulate shavings to be skive (scraping) from the instrument shafts during surgery.	Urgent Notification Letter + Instructions	89
Z-0657-2008 Z-0658-2008 Z-0659-2008		Jan 31 2008		There may be a ridge on the side of the cannula which has the potential to abrade instrument shafts and generate black particulate matter.	Urgent Notification Letter + Replace	896
Z-1348-2008	da Vinci S 8mm Instrument Cannula (For model IS2000)	Aug 06 2008		(1) Incorrect dimension on Luer on smoke evacuation cannulae not allowing for secure attachment function. (2) Incorrect labeling.	Urgent Letter + Remove	39
Z-2104-2012 Z-2103-2012 Z-2101-2012 Z-2102-2012 Z-2105-2012 Z-2106-2012	da Vinci S 4 Arm Disposable Accessory Kit (For model IS3000)	Jul 27 2012		Specific lots of the Instrument Arm Drapes were manufactured with a sterile adaptor that may have difficulty engaging an instrument.	Urgent Recall Letter + Return	92,390
Z-0258-2008	da Vinci 8 mm EndoWrist PK Dissecting Forceps	Jan 24 2008	Labeling and Sterilization	Mislabeling-electrical isolation requirements: devices were incorrectly labeled with a CF symbol (suitable for direct cardiac application), not their proper BF Symbol on the instrument housing.	Urgent Letter + Instructions + Update Labeling	1,136
Z-2339-2012	Tip Cover for 8m Monopolar Curved Scissors (Disposable)	Sep 10 2012		There is potential for the sterility of the product to be compromised.	Notification Letter + Instructions	11,121

Table A4 - Example Death Adverse Event Reports

MAUDE Report Number	Date Report Received	Event Description Summary	Surgery Type	Surgery Class	Reason
2563461	May 2012	The surgeon cut the patient's iliac artery and vein while performing node dissection, causing bleeding from those vessels. A hemo-clip was applied to the affected area, however, the clip tore through the area causing significant hemorrhage from the pelvic vessels. The surgical procedure was converted to open laparotomy techniques. The patient expired.	Hysterectomy	Gynecologic	Staff Mistake
2567858	May 2012	Approximately 45 minutes into a procedure when the assistant at the patient side cart (psc) performed a tool change to switch the instruments in the patient side manipulator (psm) arms, the patient's aorta was punctured. The procedure was converted to traditional open surgery. The patient was in stable condition right after the procedure however expired the following day.	N/A	N/A	
2066439	Apr. 2011	After a mitral valve repair procedure, the patient's blood pressure had dropped due to a leak in the mitral valve. A sternotomy was performed to repair of the valve; however, the patient expired before the repair.	Mitral Valve Repair	Cardiothoracic	
2105804	May 2011	During a procedure to remove the lower lobe of left lung due to bronchioloalveolar carcinoma, the patient's stomach and diaphragm were punctured resulting in sepsis. The patient underwent a 5 month hospital stay and eighteen months as a near invalid and then expired.	Remove Lung	Cardiothoracic	Surgery Complications
2539834	Apr. 2012	During placement of the uterine manipulator, the patient's bowel was ruptured. The surgeon repaired the patient's bowel, but post op. patient experienced cardiovascular complications and expired (demise attributed to a t-berg).	Bilateral Salpingo-oophorectomy	Gynecologic	
2890369	Dec. 2012	A tenaculum forceps instrument was not moving as it should. No patient harm, adverse outcome or injury was reported to have occurred during the procedure. However, after the surgery patient was re-admitted to the hospital due to a perforated bowel and expired.	Myomectomy	Gynecologic	
2746253	Sep. 2012	The surgeon experienced visualization problems due to the patient's anatomy. After several hours the procedure was converted to traditional open surgery. During the open procedure a rectal laceration was discovered, and an emergency repair was performed. The patient experienced heavy blood loss and was transported to an intensive care unit and later to a rehabilitation center and eventually expired from cardiac arrest.	Prostatectomy	Urologic	Potential Technical Issues

Table A5 – Example Adverse Event Reports: MDR Report No.: 2240665

Event Date: 07/17/2008 **Event Type:** Injury **Patient Outcome:** Required Intervention, Life Threatening
Event Description: This report is being filed based an isi investigation concluding 08/08/2008. (b)(4) was received on 08/01/2008 from the (b)(6). It was reported that during da vinci s bilateral internal mammary arteries revascularization procedure, the customer experienced a system error code #23. With the assistance of an isi (b)(4), the site powered down the system to clear the fault. The site continued with the procedure, however, the system error reoccurred. The site disabled the endoscopic camera manipulator (ecm) to continue the case. The site then elected to manually manipulate the camera and endoscope for approximately 5 to 6 hours when a loss of carbon dioxide insufflation occurred resulting in the heart pushing up into the endoscope two times causing lacerations to the patient's right ventricle. The procedure was converted to a thoracotomy to performed a non robotic repair of the damaged ventricle with several stitches and to complete the planned procedure. After the 14 hour procedure, the patient could not be extubated necessitating a tracheostomy. As of (b)(6), the patient remained under care at (b)(6).
Manufacturer Narrative: The investigation conducted by (b)(4) concluded that the system error code #23 experienced by the customer was associated with a configured embedded sterilizer setup joint (cfg, essj) and remote arm controller (rac). The embedded sterilizer for setup-joint is the printed circuit assembly (pca) inside a system arm that monitors the potentiometer for each of four joints and their associated backup potentiometers. The rac consists of five printed circuit assembly boards which operate together to provide control of the system arms. The system was repaired by replacing the affected cfg, essj and rac. System error code #23 is reported by software to denote that the hardware wheel "wdog" has tripped on one of the digital communication links in the system. This means that the system cannot reliably communicate over the digital link and therefore cannot continue normal operation. Communication faults occasionally occur due to typically either faulty electronics or poor connections in the communication link. The error 23 fault indicated by the system in this case pointed to a communication error involving the ecm's rac and essj modules. The system was repaired as the (b)(4) both removed the electronics that could have experienced an intermittent failure and re-secured all of the connections involved. Field experience has shown that these measures are effective in resolving this type of system communication issue. As of (b)(6) 2007, the site has continued to use the system and has not reported recurrences of this issue.
Brand Name: DA VINCI S SURGICAL SYSTEM **Type of Device:** ENDOSCOPIC INSTRUMENT CONTROL SYSTEM **Manufacturer:** INTUITIVE SURGICAL, INC. **Report Date:** 08/11/2008

Table A6 – CAST Analysis for Example Adverse Event Report of Table A6

Violated Safety Constraints:
• Robot instruments/arms should not move or cut or apply energy to an unintended position on the patient's body:
  – Heart pushed up to the endoscope two times.
• Procedure should not continue for a prolonged time:
  – Procedure continued for 14 hours.

Physical Robot:
• **Safety Requirements and Constraints (Possibly) Violated:**
  – Inform the main surgeon and staff of robot emergency status and corresponding recovery procedures.
  – Prevent uncoordinated manipulation of arms and instruments.
  – Inform the main surgeon and staff of the status of organ under surgery.
• **Failures and Inadequate Controls:**
  – Inadequate information was displayed about the system error to the main surgeon.
  – Inadequate instructions/procedures were provided on how to resolve the system error.
  – No control for the manual manipulation of endoscope arm.
  – Inadequate information was displayed on distance between organ and instrument.
• **Physical Contextual Factors**
  – The system error code was due to an electronic component failure and was not cleared by system resetting.
  – The loss of carbon dioxide caused the organ push up to the endoscopic camera.
  – The patient could not be extubated necessitating a tracheostomy.

Nurse/Patient-side Surgeon:
• **Safety Related Responsibilities**
  – Monitor status of patient and robot and communicate it to main surgeon.
  – Monitor the status of other required devices such as insufflation device.
• **Contextual Factors:**
  – Under stress to finish the surgery safely
  – Fatigued after 5-6 hours of surgery
• **(Possibly) Unsafe Decisions and Control Actions**
  – No coordination with main surgeon on the status of insufflation device?
  – No feedback to the main surgeon about the organ pushing up to the instrument?
• **(Possible) Process Model Flaws**
  – Believed that insufflation device is working fine?
  – Believed that main surgeon will know about loss of carbon dioxide?
  – Believed that main surgeon sees the status of organ through the console?

Main Surgeon:
• **Safety Safety Related Responsibilities**
  – Perform the main surgery actions by moving manipulators on the console safely.
  – Communicate with the company to get feedback or troubleshoot problems.
  – Send commands to the assistant surgeon/nurse during the surgery.
  – Monitor the time of surgery and decide on the best time to convert or stop the procedure.
• **Context**
  – Under stress to finish the surgery safely, fatigued after 5-6 hours of surgery
  – Cardiothoracic surgeons usually not very skilled with laparoscopic type of surgery
  – Loss of objectivity: Determined to finish the robotic surgery?
• **(Possibly) Unsafe Decisions and Control Actions**
  – No follow-up with the company to let them know that the error not cleared after resetting the device.
  – Manual manipulation of camera and endoscope for 5-6 hours.
  – Changing to the conventional surgery very late, not keeping track of time
• (**Possible) Process Model Flaws**
  – Believed the surgery could be finished more efficiently by manual manipulation of instruments.

Safety Recommendations: • The surgeon console should provide more detailed information about the system errors, including the procedures to troubleshoot the problem and recommendations on safest actions to take to resolve the error. • The robotic system should keep track of time spent on the surgery and the surgeon's actions such as manual manipulation of arms and provides warnings based on surgery type, patient's history, and surgeon's experience.

Table A7 – Related Works on Failure Rates and Malfunctions of da Vinci Surgical Systems

Ref. No. Year	Surgery Types	Medical Institute	No. of Cases	Total Number of Failures (Failure Rate) Types of Malfunctions	Converted	Rescheduled
[38] 2005	Urologic	UC Irvine	200	Total = 5 (2.5%) Software (4), Mechanical (1)	N/A	N/A
[39] 2006	Radical Prostatectomy (RLRP)	Virginia Mason Medical Center (VMMC)	130	Total = 6 (4.6%) Setup joint (2), Software Incomp. (1), Robotic arm (1), Power-off (1), Monitor loss (1)	Laparoscopic (1) Open (1)	1
[40] 2007	Laparoscopic Prostatectomy	Virginia Mason Medical Center (VMMC)	350	Total = 9 (2.6%) Setup joint (2), Robotic arm (1), Camera (1), Power error (1), Console metal break (1), Software Incomp. (1), Monitor loss (1)	Laparoscopic/ Open (3)	6
[41] 2007	Radical Prostatectomy (RLRP)	University of Chicago Pritzker School of Medicine (2003-2006)	725	Total = 7 (Recover. = 0.21%, Non-Recover. =.05%) Power up failure (1), Optical malfunction (3), Surgeon Handicap (3), Robotic arm (1), Camera (2)	-Completed (3)	4
[42] 2008	Radical Prostatectomy	Klinik Hirslanden, Zurich, Switzerland	210	Total = 2 (1%) Robotic arm (2)	Conventional Laparoscopic	N/A
[43] 2008	Radical Laparoscopic Prostatectomy (RALP)	11 Institutions 700 Surgeons	8240	34 critical failures (0.4%) Robotic arm (14), Optical system (14) Masters (4), Power supply/circuit (6), Unknown error (3)	Laparoscopic(2) Open (8)	24
[44] 2009	Radical Laparoscopic Prostatectomy	Yonsei University College of Medicine, Korea	1	Case report of Surgeon's console failure	Delayed 15 min	
[45] 2009	Urology, General Surgery, Obstetrics and Gynecology, Thoracic Surgery, Cardiac Surgery, Otorhinolaryngology	Yonsei University College of Medicine, Korea (2005-2008)	1797	Total = 43 (2.4%) **-Robot failures (24):** On/off failure (1), Console malfunction (5), Robotic arm (6), Optic system (2), System error (10) **-Instrument failures (19):** Shaft injuries (9), Wire cutting (2), Un-natural motion (2), Instrument tip (2), Limitation in motion (1)	Laparoscopic/ Open (3)	N/A
[46] 2010	Robotic Laparoscopic Radical Prostatectomy	Yonsei University College of Medicine, Korea	1	Case report of mechanical malfunction of an instrument (4th arm)	Laparoscopic (225 min)	N/A
[47] 2010	Robot-assisted Radical Prostatectomy (RARP)	Survey of 176 Surgeons from 4 Countries	N/A	Total failures = 260 Robotic arm (38%), Camera (17.6%) Setup joint (13.8%), Power error (8.8%), Ocular monitor loss(8%), Instruments (7.6%), Console handpiece break (3%), Software (1.9%), Backup battery (0.3%), Instrument identification (0.3%)	Open (18.8%), Laparoscopic (15%) Another robot, with one less robotic arm (8.7%)	57.5%
[48] 2010	Gynecologic Oncology	Mitchell Cancer Institute, University of South Alabama (2006-2008)	137	Total = 11 (8.02%) Robotic arm (2), Light or camera cord(2), Maylard bipolar (1), Power failure (1), Port problem (1),Others(3)	Delayed 25 min	N/A
[49] 2011	Urology, Gynecology, Cardiothoracic, General surgery, Otolaryn- gology, Neurosurgery	Ohio State University Medical Center, James Cancer Hospital (2008-2009)	454	Tip cover failures = 12 (2.6%) Significant patient complications (25%)	Repaired at the time of surgery	N/A
[50] 2012	General Surgery	Cleveland Clinic	223	Total = 10 (4.5%) Robotic instrument (4), Optical system (3), Robotic arms (2), Robotic console (1)	Open surgery (6)	N/A
[51] 2012	Urological Surgery	Veterans General Hospital, Taiwan (2005-2011)	400	Total = 14 (3.5%) Robotic arm/joint (11), Optical system (1), Power system (1), Endoscopic instrument (1), Software incomp. (1)	Completed (10), Laparoscopy (3)	1

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Table A8 – Summary of Related Works on Analysis of MAUDE Data for Robotic Surgical Systems

Andonian et al. found an estimated failure rate of 0.38% for robotic-assisted laparoscopic surgeries by reviewing 189 adverse events related to the ZEUS and the da Vinci surgical robotic systems, reported to the MAUDE database between the years 2000-2007 [52]. Murphy et al identified 38 system failures and 78 adverse events related to da Vinci robotic system, reported between 2006 and 2007, most of which were related to broken instrument tips or failure of electrocautery elements [53]. Lucas et al compared the rates of adverse events in two different models of da Vinci surgical systems (dVs and dV) during the period of 2003-2009 and showed that both device malfunctions and open conversions were reduced by increased robotic experience and newer surgical systems [54]. Finally, Fuller et al. reviewed 605 adverse events of da Vinci system during 2001-2011, and identified 24 (3.9%) reports related to electrosurgical injuries (ESI) that occurred during gynecological and prostatectomy procedures [55].

Table A9 – Example Complex Robotic Interactions with Possible Failure Modes

1) A surgeon or surgical assistant needs to be by the patient's side, inserting the ports/scope/instruments

2) The main surgeon sits at a console some distance away from the patient, with no peripheral vision, and so does not get to see the manipulation of the arms in and around the patient.

3) Any change of instrumentation requires a pause in proceedings, as the patient side surgeon stops and changes instruments. Once the instrument is docked in the port, registered and secured, the procedure can be resumed from where it was stopped. Each of these instrument changes takes about 30 secs- 2 mins, so if there are 10 instrument changes in a case, that add 20 minutes to the total time of procedure.

4) There is no tactile feedback or haptics. Several of the adverse events reported inadvertent injury to the aorta, right ventricle, lungs, etc. Sometimes, vessels have been ripped because of lack of feel and the force delivered by the grasping forceps might significantly exceed safe limits.

5) The field of vision is very limited to the scope and it can be easy to get disoriented, both in terms of horizon and the location within the body.

6) Visualization requires insufflation of carbon di-oxide at a high flow of 6-10 Litres/minute. While this is done in laparoscopy, it is usually not at such a high flow. This high flow of CO_2 can result in it being absorbed and this can cause significant metabolic derangements that affect the heart.

7) Each instrument is allowed to be used only 10 times, after which software shut down occurs, driving up the costs and making instruments also part of the disposable costs. In open and laparoscopic surgeries some disposable instruments are used but they are not as expensive as robotic instruments.

8) There is an obligatory setup time, in addition to longer operative times with the robot. Robotic procedures in all fields of surgery take longer than open or laparoscopic procedures.

Table A10 - Comparison between Two Safety-Critical Industries: Aviation vs. Robotic Surgery

	Aviation	Robotic Surgery
Operation: Type Device Targets	Semi-autonomous Airplanes Passengers	Semi-autonomous Robots Patients
Age	80 years (approx. 1934)	< 20 years (approx. 1999)
Certification: Administrated by: -Device -Operator -Others	Federal Aviation Administration (FAA) -Aircraft certified under 14 CFR 121 -Pilots certified by privilege levels -Crew certified by airlines	Food and Drug Administration (FDA) -Robot approved by 510K -Surgeons trained but not certified -Staff trained but not certified
Training	Required by FAA for pilots	Provided by company for surgeons
Accidents	All accidents investigated by NTSB and other authorities based on the evidence collected from the site of accident	Reported by the users and company to the FDA MAUDE database, on a voluntary basis
Safety Hazards	-Natural: Weather conditions, fire, etc. -Mechanical/Electrical: Engine, electromagnetic interference, etc. -Humans: Incorrect info by control center, pilot/crew errors, passenger misuses, hijacking	-Natural: Patient history/condition/procedure -Mechanical/Electrical: Arm malfunctions, system errors, etc. -Humans: Incorrect info by the company for setup/troubleshooting, pilot/staff mistake, etc.