Safety Implications of Robotic Surgery:
Analysis of Adverse Event Reports of da Vinci Surgical Systems

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Conflicts of Interest

There are no conflicts pertaining to robotic surgery.

I've come "not to bury the robot" but to "raise awareness of it"!

Marcus Antonius

da Vinci Surgical System

Overview

- Analyzed all safety-related incidents for **da Vinci Surgical System** reported to the **FDA MAUDE Database** between years **2000-2012.**
- Estimated **likelihood of robotic injuries, deaths, and malfunctions** over the years
- Used state-of-the-art natural language processing techniques to extract the **types of robot malfunctions** and their **impact on patient safety** and **progress of surgery**
- Assessed **effectiveness of robot in cardiothoracic surgery vs. other surgery classes,** including Gynecology, Urology, General, Head and Neck, Colorectal.
- Compared likelihood of deaths, injuries, and conversion or rescheduling per adverse events in **robotic vs. non-robotic cardiothoracic surgery**

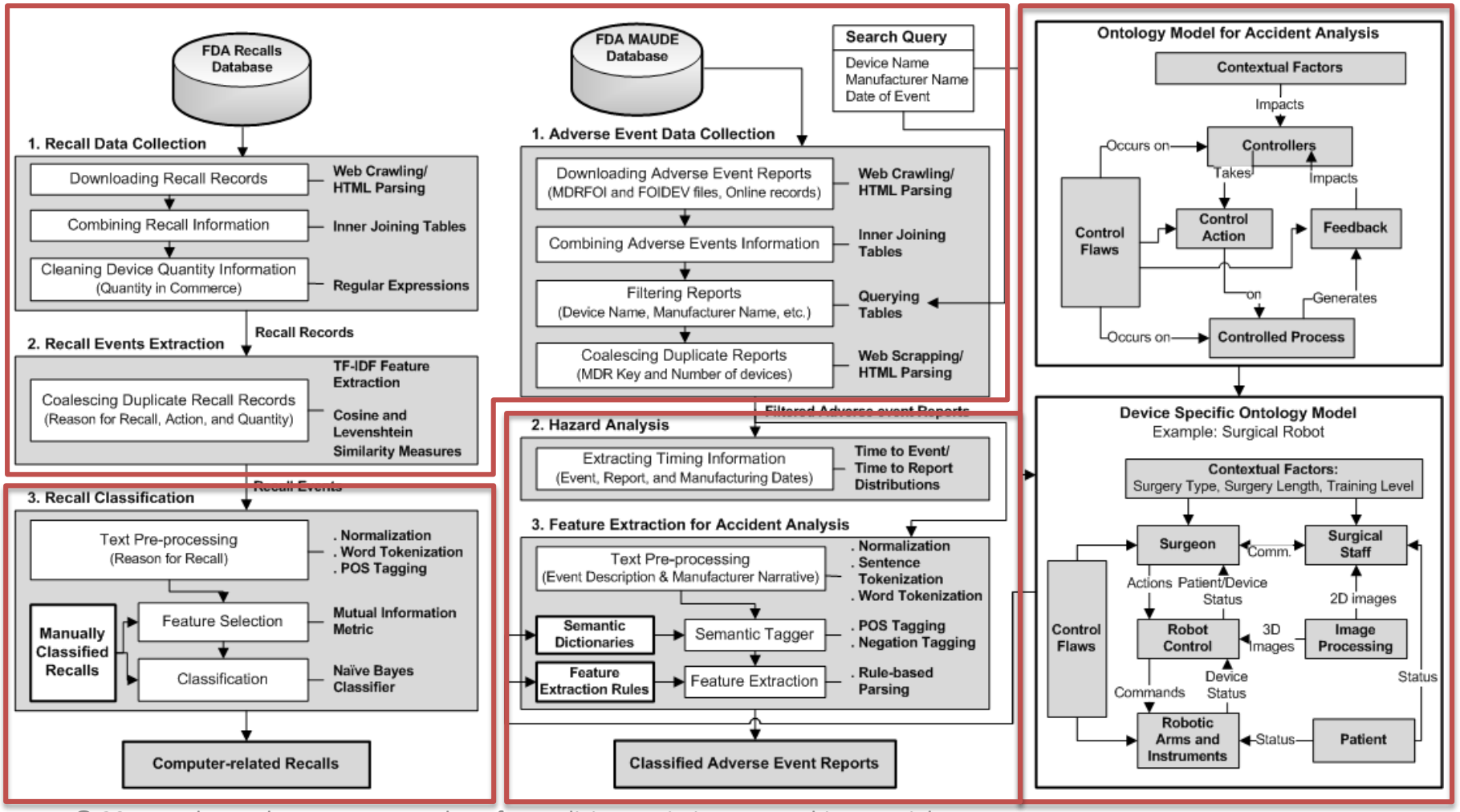
Major Findings

- Overall **adverse events rates are decreasing,** even though absolute numbers continue to increase.
- **Gynecological and urological** surgeries, where robots are extensively used, had **low death rates** (1.9 - 2.2%) vs. more complex procedures in **cardiothoracic** and **head and neck** (7.7% - 26.5%).
- Majority of reports (92%) were related to **device and instrument malfunctions** and impact patient safety - **injuries, system resets, conversions,** and **rescheduling**
- We found 220 adverse events (4.1%) were related to **robotic cardiothoracic** procedures, with majority related to **mitral valve repair** and **lobectomy**.
- For **cardiothoracic** surgery, **robotic approach is no better than minimally invasive approaches** – Robotic adverse events involve **higher risk** of deaths, malfunctions, conversions, and rescheduling.

Value and Wider Scope of Study

- Provide engineering insights for building enhanced safety engines and innovate methods for safety assessment and design of next-generation medical systems
- A multi-disciplinary project between engineering and medicine
- An on-going collaboration between the researchers at:
  - RUSH University Medical Center
  - University of Illinois at Urbana-Champaign (UIUC)
  - Massachusetts Institute of Technology (MIT)

MedSafe:
Failure Data and Safety Analysis Framework



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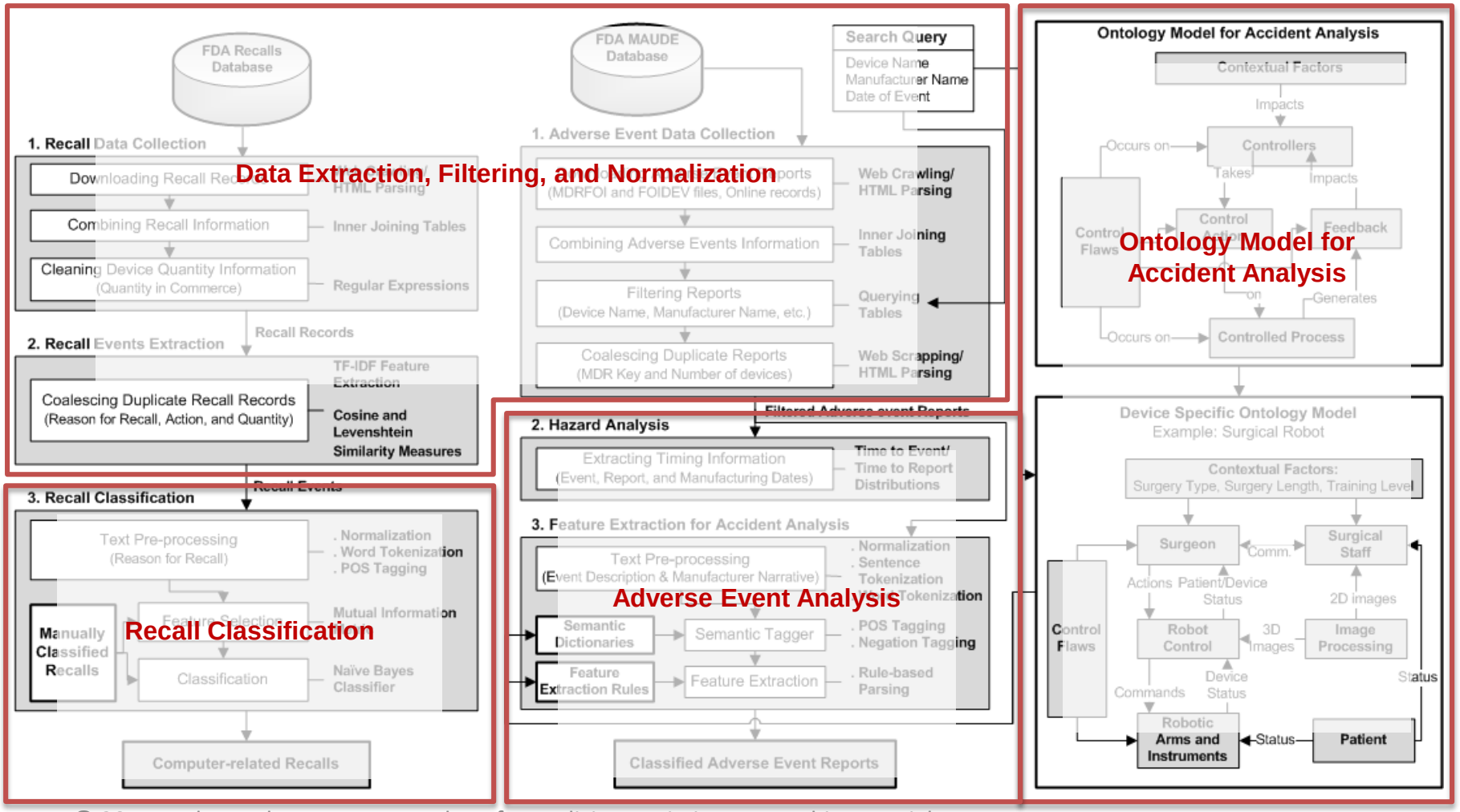


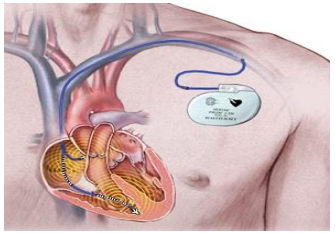
Safety-Critical Medical Devices

Computer-related Failures

Defibrillators

17 Recalls – 415K devices
293 Deaths, 14K Injuries
-Delayed/failed shock delivery
-Premature shutdown

Implantable Pacemakers



1 Recall – 40K devices
60 Deaths, 3,201 Injuries
-Loss of rate response
-Premature battery depletion

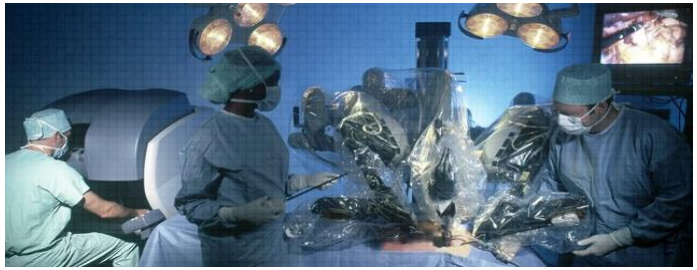
Infusion Pumps

15 Recalls – 945K devices
23 Deaths, 574 Injuries
-Loss of rate response
-Premature battery depletion

Physiological Patient Monitors

10 Recalls – 38K devices
4 Deaths, 79 Injuries
-Delayed audible alarms
-Failure to restart

Surgical Robots



9 recalls – 1587 devices
5,374 adverse events (2000-2012)
86 deaths, 455 injuries, 3,933 malfunctions
-System crash/Lockup during the surgery
-Power loss during the surgery
-Manipulation and control failure

H. Alemzadeh, R. K. Iyer, Z. Kalbarczyk, J. Raman, "Analysis of Safety-Critical Computer Failures in Medical Devices," IEEE Security & Privacy, July-Aug. 2013.

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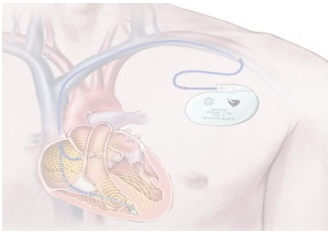

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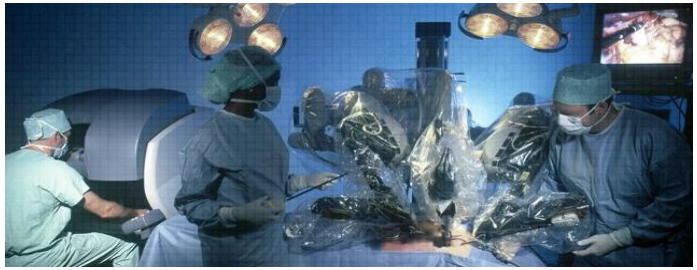

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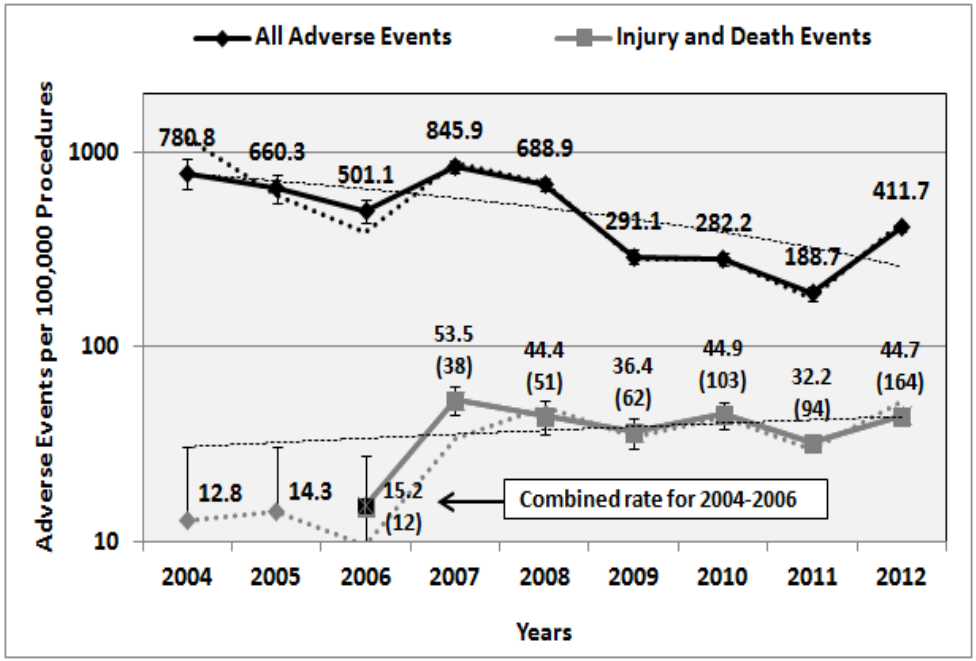
Robotic Surgical Systems Adverse Events

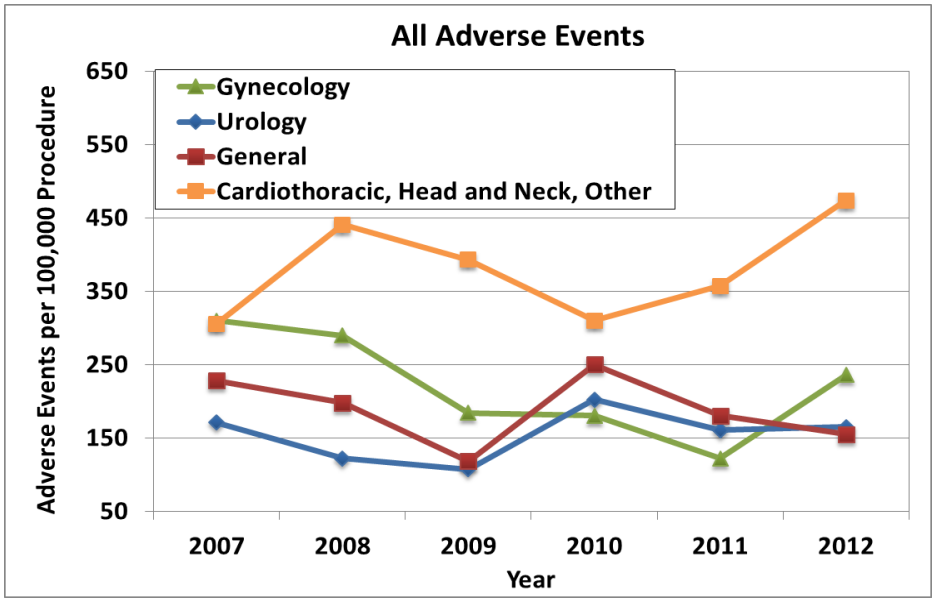
- **5,374 adverse events** and **19 recalls** (109,709 devices and instruments) reported to the FDA
  - **86 deaths, 455 injuries,** 3,933 malfunctions
  - **220 cases (4.1%)** were related to **Cardiothoracic** surgeries
- An **increasing reporting of adverse events, 2.5 times more since 2007**
- **BUT number of procedures and installed devices have increased exponentially** since 2004.
  - **A 500% increase** in the number of procedures **since 2007**
  - Number of devices installed in 2012, almost **32 times the number of devices in 2001**.



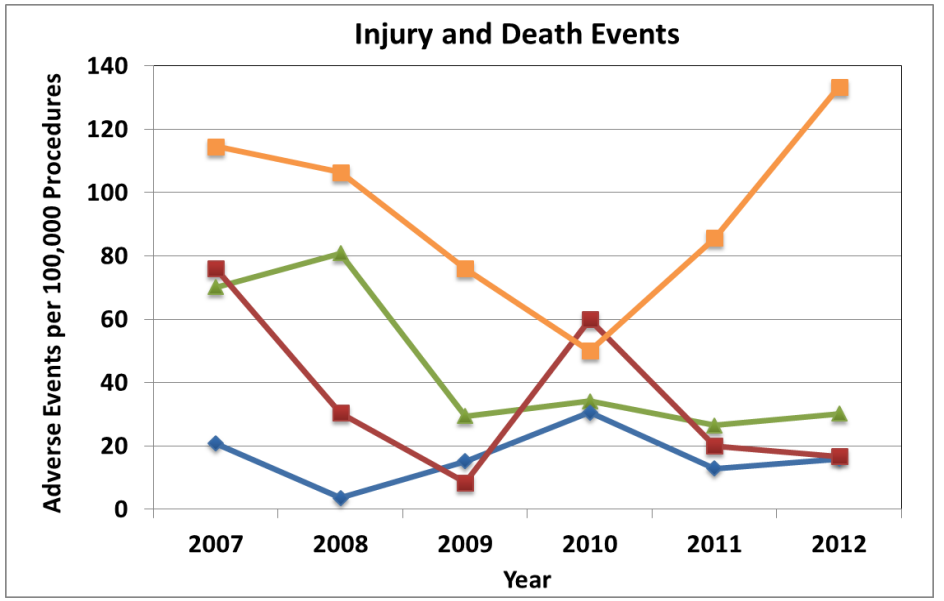
Estimated Rate of Robotic Surgery Adverse Events per 100,000 procedures in the U.S.

Likelihood of Adverse Events

Different Classes of Surgery



- Higher rate of adverse events per year for cardiothoracic and head and neck classes compared to gynecology, urology, and general surgery.



- Increasing trend in rate of cardiothoracic and head & neck adverse events since 2010.

Impacts of Adverse Events

Different Classes of Surgery

- Majority of adverse events reported for gynecology (25.1%) and urology (16.4%) procedures (hysterectomy and prostatectomy).
- Higher likelihood of death per adverse event for cardiothoracic (7.7%) and head and neck (26.5%)
- Highest conversion per adverse event for urology (21%) and cardiothoracic (24.1)
- Comparisons of outcomes vs. traditional techniques for cardiothoracic and head and neck are rarely done.

Surgery Class	Num of Adverse Events	Num of Deaths	Num of Injuries	Num of Malfunctions	Num of Converted Cases	Num of Rescheduled Cases	Common Surgery Types (Num of Adverse Events)
Gynecologic	1348 (25.1%)	25 (1.9%)	223 (16.5%)	914 (67.8%)	174 (12.9%)	20 (1.5%)	-Hysterectomy (979) -Myomectomy (170) -Sacrocolpopexy (74) -Oophorectomy (23)
Urologic	882 (16.4%)	19 (2.2%)	83 (9.4%)	462 (52.4%)	185 (21.0%)	129 (14.6%)	-Prostatectomy (750) -Nephrectomy (72) -Pyeloplasty (20) -Cystectomy (16)
Cardiothoracic	220 (4.1%)	17 (7.7%)	38 (17.3%)	96 (43.6%)	53 (24.1%)	10 (4.5%)	-Mitral valve repair (43) -Lobectomy (36) -Coronary artery bypass (21)
Head and Neck	49 (0.9%)	13 (26.5%)	10 (20.4%)	20 (40.8%)	3 (6.1%)	1 (2.0%)	-Thyroidectomy (15) -TransOral robotic (14) -Tongue base resection (14)
Colorectal	96 (1.8%)	4 (4.2%)	10 (10.4%)	65 (67.7%)	16 (16.7%)	0 (0.0%)	-Cholecystectomy (27) -Colectomy (22) -Lowe anterior resection (18) -Rectopexy (6)
General	71 (1.3%)	2 (2.8%)	12 (16.9%)	46 (64.8%)	6 (8.5%)	3 (4.2%)	-Nissen fundoplication (17) -Gastric Bypass (12) -Liver resection (7)
N/A	2708 (50.4%)	6 (0.2%)	79 (2.9%)	2330 (86.0%)	208 (7.7%)	74 (2.7%)	
Total	5374	86 (1.6%)	455 (8.5%)	3933 (73.2%)	645 (12.0%)	237 (4.4%)	

Device and Instrument Malfunctions

Burnt/Broken pieces of instruments (2,279 cases = 42.4%):
- Falling into the patient's body
- **58 injuries** and **103 cases required intervention**

Electrical arcing of instruments (936 cases = 17.4%):
- Burning of the tissues/organs under surgery (**130 injuries**)

System errors, **Video/imaging problems** (661 cases = 12.3%)
- 231 system resets
- 410 cases of procedure conversion
- 192 cases of rescheduling

Unintended instrument operation (466 cases = 8.7%):
- Puncturing or damage to organ **(32 injuries, 2 deaths)**

92% of all reports

Interrupted the **progress of surgery:**
- **System resets** to troubleshoot technical problems **(247 cases = 4.6%)**
- **Conversion** of procedure to non-robotic techniques **(529 cases = 9.8%)**
- **Rescheduling** of procedures to a later time **(205 cases = 3.8%)**

H. Alemzadeh, J. Raman, N. Leveson, and R. K. Iyer, "Safety Implications of Robotic Surgery: A Study of 13 Years of FDA Data on da Vinci Surgical Systems", Coordinated Science Laboratory, Technical Report UILU-ENG-13-2208, November 2013.

Electrical Arcing

Cardiothoracic Surgery

Robotic vs. VATS and MICS

Likelihood of adverse patient impacts and malfunctions per event

	No. (%)			
	Robotic (n = 220)	**Non-Robotic (n = 889)**	**Robotic/Non-Robotic Relative Risk (95% Cl)**	***P* Value**
Event Type				
Death	17 (7.7)	22 (2.5)	3.12 (1.69 - 5.78)	< 0.001
Injury	38 (17.3)	299 (33.6)	0.51 (0.38 - 0.70)	< 0.001
Malfunction	96 (43.6)	537 (60.4)	0.72 (0.62 - 0.85)	< 0.001
Instrument Malfunctions				
Broken/Fallen	77 (35)	147 (16.5)	2.12 (1.68 - 2.67)	< 0.001
Arcing/Sparking	18 (8.2)	6 (0.7)	12.12 (4.87 - 30.18)	< 0.001
Unintended Operation	18 (8.2)	95 (10.7)	0.77 (0.47 - 1.24)	0.27
Conversion	53 (24.1)	77 (8.7)	2.78 (2.03 - 3.82)	< 0.001
Rescheduling	10 (4.5)	3 (0.3)	13.47 (3.74 - 48.53)	< 0.001

Concluding Remarks
The way forward

- **Careful analysis of accidents**
  - More detailed analysis of past and future incidents using new accident analysis methods
  - Improved mechanisms and standards for adverse events reporting
- **Better utilization of advanced safety mechanisms**
  - Safety-driven design using hazard analysis techniques that take not only the physical system, but also its interactions with the human operators
  - Surgery-, patient- , and surgeon-adaptive designs and online monitoring mechanisms
- **Safe real-time diagnosis and recovery**
  - Visual feedback to the surgeon on the safe trajectories
  - Proactive warnings and focused feedback to the surgical staff on upcoming events and their corresponding troubleshooting procedures
- **Developing improved standards and procedures**
  - Oversight and certification of surgical teams by authorities

Comparison to Aviation

Safety Standards & Procedures

	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 or 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.

"We cannot "design" human controllers, but we can design the environment or context in which they operate, and we can design the procedures they use, the control loops in which they operate, the processes they control, and the training they receive."

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