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
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.

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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

1. Recall Data Collection
   - Downloading Recall Records
   - Combining Recall Information
   - Cleaning Device Quantity Information
     (Quantity in Commerce)

2. Recall Events Extraction
   - Coalescing Duplicate Recall Records
     (Reason for Recall, Action, and Quantity)
   - TF-IDF Feature Extraction
   - Cosine and Levenshtein Similarity Measures

3. Recall Classification
   - Text Pre-processing (Reason for Recall)
   - Feature Selection
   - Classification
     - Naive Bayes Classifier
     - Classification
     - Computer-related Recalls

1. Adverse Event Data Collection
   - Downloading Adverse Event Reports
     (MDRFOI and FOIDEV files, Online records)
   - Combining Adverse Events Information
   - Filtering Reports
     (Device Name, Manufacturer Name, etc.)
   - Coalescing Duplicate Reports
     (MDR Key and Number of devices)

2. Hazard Analysis
   - Extracting Timing Information
     (Event, Report, and Manufacturing Dates)
   - Time to Event/Time to Report Distributions

3. Feature Extraction for Accident Analysis
   - Text Pre-processing
     (Event Description & Manufacturer Narrative)
   - Semantic Dictionaries
   - Semantic Tagger
   - Feature Extraction Rules
   - Feature Extraction
   - Classified Adverse Event Reports

Ontology Model for Accident Analysis

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MedSafe: Failure Data and Safety Analysis Framework

Data Extraction, Filtering, and Normalization

Ontology Model for Accident Analysis

Recall Classification

Adverse Event Analysis

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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

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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.

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

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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)

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%)

92% of all reports

Electrical Arcing
## Cardiothoracic Surgery

### Robotic vs. VATS and MICS

#### Likelihood of adverse patient impacts and malfunctions per event

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Robotic (n = 220)</th>
<th>Non-Robotic (n = 889)</th>
<th>Robotic/Non-Robotic Relative Risk (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>17 (7.7)</td>
<td>22 (2.5)</td>
<td>3.12 (1.69 - 5.78)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Injury</td>
<td>38 (17.3)</td>
<td>299 (33.6)</td>
<td>0.51 (0.38 - 0.70)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Malfunction</td>
<td>96 (43.6)</td>
<td>537 (60.4)</td>
<td>0.72 (0.62 - 0.85)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Instrument Malfunctions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Broken/Fallen</td>
<td>77 (35)</td>
<td>147 (16.5)</td>
<td>2.12 (1.68 - 2.67)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Arcing/Sparking</td>
<td>18 (8.2)</td>
<td>6 (0.7)</td>
<td>12.12 (4.87 - 30.18)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Unintended Operation</td>
<td>18 (8.2)</td>
<td>95 (10.7)</td>
<td>0.77 (0.47 - 1.24)</td>
<td>0.27</td>
</tr>
<tr>
<td>Conversion</td>
<td>53 (24.1)</td>
<td>77 (8.7)</td>
<td>2.78 (2.03 - 3.82)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Rescheduling</td>
<td>10 (4.5)</td>
<td>3 (0.3)</td>
<td>13.47 (3.74 - 48.53)</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

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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

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

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“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.”