ANALYZING PRODUCT FAILURES AND IMPROVING DESIGN: A CASE STUDY IN MEDICAL ROBOTICS

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Abstract: Robotic assistance is utilized in complex surgeries due to claims citing better procedure planning, enhanced user training, and overall improved operation when compared with conventional surgery. Robot-assisted surgery seems to be an increasingly viable and acceptable option to the patient community with continual advances in technology. However, questions arise about the safety aspects of the robotic assistance in surgical procedures as there is a probability that the complexity of the constituent modules in the robotic system could lead to certain malfunctions and failures. The objective of the paper is to review the failures and safety considerations linked with robot-assisted surgery and to make recommendations to enhance certain safety features and protocols. The present project was undertaken as a research project by a sophomore student in Biomedical Engineering.

Malfunctions and failures that occur during robot-assisted surgery may be broadly classified under operator errors and mechanical, electrical, and software failures. Reported electronic failures in robot assisted surgeries mention incidents of burns in patients and the ability to burn flesh due to leakage currents. Software failures in robot assisted surgeries are associated with a lawsuit detailing a situation where a surgical robot froze and the surgery had to be completed by other means. The cited paper claims that damages resulted directly from a software failure and mentions that the manufacturer had not completely eliminated the errors. Operator errors can lead to serious undesirable consequences in surgical procedures and subsequent outcomes. It was reported that a malpractice case was filed involving a mishandled robot-assisted hysterectomy. In this operation, a surgical error occurred in the hands of a not-so-skilled and not-fully-trained surgeon when both of the patient's ureters were severed. A review of literature illustrates the increasing number of lawsuits against surgical robotic assistant systems due to the lack of standardized comprehensive training.

While performing rigorous analysis and applying current technologies may lead to many solutions of the cited problems, achieving a high degree of safety coupled with no failures is required in clinical settings. A systematic approach of thorough root cause analysis of failures and corresponding corrective actions would render the constituent modules and the robotic system safe, resulting in a safer and more effective robotic procedure. A large percentage of malfunctions with robotic systems can be avoided by diligently reviewing, analyzing, and testing the modules and the entire system during the design and subsequent phases while making necessary changes and corrections. Improved safety will result in a greater acceptance of robotic assistants while potentially assuring a higher quality procedure and care delivery necessary for patients.

In conclusion, detailed analysis of failures in medically engineered systems such as robotic assistants in surgery and a proposal of methods to circumvent the problem will enhance their safety, and improve product performance resulting in a higher quality robotic surgery. The techniques learned by students in this project are valuable to biomedical engineering students, especially at the undergraduate level.

Key words- *Surgical robotic assistants, Undergraduate research project, robotic system failures, learning product design, product failure analysis.*

Introduction:

Advances in technology are rapid and they improve daily lives: Existing devices have shorter market cycles, new products and new models enter the market opening up new opportunities to their customers. Previous designs are reviewed and analyzed for further improvements. Along the same lines, medical field has adopted the advances in robotics due to the growth in minimally invasive procedures, the decreased amount of blood loss, and the reduced patient recuperation period [1]. Medical robotic assistants such as the da Vinci are very versatile, being used in surgeries involving brain tumors, hysterectomies, and prostate cancer. Generally the results of robot assisted surgery have been good and society's acceptance is growing. However, a recent heightened awareness of reported problems in the performance of robot assisted surgery, such as the da Vinci surgical system or Robodoc, has come to the forefront [2]. Some factors contribute to failures and some may also contribute to unsafe events during surgery. Such performance failures with robotic assistance necessitate the study and review of robot assisted surgery.

Like every other consumer product that comes in direct contact and has the potential to harm the public, medical robotics is subject to design analysis and strict scrutiny. Even before products can reach the public they are subject to use, abuse and tests. Only after these products are cleared, by regulatory agencies such as the FDA, are they are allowed to reach customers. This process has been the basis for many U.S. products thus fostering an environment of safety in the field of medical devices, efforts towards patient safety are unparalleled anywhere else in the world [3]. The high quality of safety facilitates high growth in medical devices for manufactures domestically as well as globally [3,4].

Safety concerns can be observed in other industries such as Toyota's Lexus ES 350 sedan (2009) which was re-tested after numerous accidents and scrutinized until the problem was isolated and fixed [5]. The company (Toyota) had to recall affected models of vehicles on the road for the public's safety. In that case, it was determined that the design flaw was a thicker than nominal floor mat that could trap the accelerator and thus cause the driver to lose control of the car. Likewise, the da Vinci surgical system has recently gone under a class II recall [6] as some of the robot's features and functions were not tested properly according to FDA standards. This also comes after some allegations that the da Vinci surgical system has burned some patients internally [7], harmed patients through improper operator training [8], or required further (more invasive) surgery to retrieve dislodged instruments [9]. New products sometimes have faults, but by analyzing these faults and correcting the design to avoid errors, the overall quality of the product improves.

The objective of this paper is to review different failures of robot assisted surgery, to isolate different aspects of the design, and to make recommendations to enhance certain safety features and protocols.

Background:

The robot assistant system manufacturer Intuitive is responsible for at least 400,000 surgeries in 2012 worldwide [10]; however, there have been instances of malfunction and failures. Robot assisted surgery has many positive attributes, but for many surgeries 359 FDA error reports linked to the da Vinci surgical system have been filed since July 2000 [fig 4]; 89 deaths have also been reported after the surgery has been completed [11].

Similar to problems reported on the automotive industry, Lexus ES 350, the da Vinci and Robodoc may have design flaws that impede and snowball to hurt the patient/ customer. Problems such as current leakage, improper installation of parts, improper upkeep, sanitation,

improper surgeon training, mechanical and software failures, etc., may hinder surgeons from completing surgery thus harming the patient. This paper seeks only to view the da Vinci surgical system's suspected problems (for test cases) and to suggest ways to solve future problems. This paper will review different lawsuits and analyze the cases in order to improve the design to help ensure a greater level of safety.

Failure analysis of robot assisted surgical systems

As in engineering, product designs must always undergo relevant rigorous testing and improvements to ensure better performance and future investigation into furthering surgical robotics design.

Whenever faults are reported they have to be assessed: For example, when reports of burning and an excessive leak current were reported, Intuitive performed further research into possible problems and solutions. They revealed that the Monopolar Curved Scissors might have developed "micro-cracks," [12] and that these cracks might not be visible to surgeons. These micro-cracks are reportedly the reasons why the robot leaks an excessive amount of current to the patient and, on CNBC a video illustrating the current leak was shown [13]. Intuitive then recalled the scissors and redesigned and improved this part of the overall design in order to improve the system to meet safety requirements with respect to patients.

Other errors may include faulty maintenance and/or errors in the manufacturing process. The battery and other electronic parts may short circuit or even not work in some cases. There are many possibilities for errors due to the large number of subsystems working together. But, by looking at these possible errors as well as looking at current speculated issues, the design can improve thus ensuring patient safety.

Results and discussion:

The failure rate of the da Vinci surgical system is listed at 5% [14,15]. In the following sections, the mechanical, electrical and computer failures as well as the user errors that have occurred are described.

Mechanical Failures

Mechanical failures happen in all industries as in the aforementioned example of Toyota's Lexus ES 350. It stands to reason that mechanical failures would also occur in the field of robot assisted surgery. In one case, a 59-year-old patient with a T2b prostate cancer was scheduled for a trans peritoneal robotic prostatectomy. During the surgery, the Endowrist articulation of the needle driver was dislocated and the instrument was unusable and had to be removed from the patient [9]. Figure 3 illustrates the instrument at the start of breaking off and beginning of its decent in into the patient's abdomen [9].

The broken instrument and its removal was reported to the FDA. When observed more thoroughly, the joint for the needle driver was broken thus allowing this instrument to become dislodged and to then fall into the patient's abdomen. The hospital report noted excessive tension placed on the joints as a major contributor to the mishap [9]. The surgical procedure had to be aborted as the patient's safety was compromised and the device had to be removed. The da Vinci is a minimally invasive device that leaves between four and five small incisions to allow a faster healing time [16], but in this case, the operation was hindered as the device's retrieval quickly became the new objective. The patient had to then undergo extra imaging, followed by a procedure where their abdomen was opened in order to remove the device safely [9].

Failure modes and effects analysis (FMEA) can be performed as the joint design can further be explored to ensure proper performance and some acceptable tolerance to improper use. Predictions based on the consequence to these joints when placed under abuse can easily be modeled and tested to discover design flaws such as their weakness when placed under an increased amount of tension as illustrated in figure 1.

The overall design of these subsystems can then be looked at individually and possible design solutions can be derived from the FMEA process, such as, testing the breaking strength of the small joints and to attach sensors to each device that consistently measure the forces exerted on them. These sensors would then be integrated with the computer and would indicate when the joints approach their tension capacity. By improving the design of the joints to include a more durable material that has many of the similar properties as in the current design, or by magnetizing the joints so that in the event it does become dislodged, the instrument at the end will remain attached are just some examples to approach the problem solution; [Figure 2].

The same report recommended that placing cameras closer to the instruments would allow for a better viewing of the instruments, so as to see the tell-tale signs preceding a joint's possible fracture. Building upon this idea, possibly integrating extra cameras with the alarming system would allow the surgeon to continue the surgery, but would then allow them to better view a device's malfunction as it would zoom into the machine's troubled area.

Instead of applying these possible design solutions to just the affected device mentioned, these solutions could be applied to the previous design, since all devices have a similar joint structure.

The da Vinci has been applied mostly to the field of laparoscopic surgeries [17]. A 47 year old woman was undergoing a standard laparoscopic surgery when the lower blade of the da Vinci's ultrasonic scalpel came undone and fell into the her abdomen. The surgery was aborted and like the aforementioned effort was directed at removing the fallen part [18].

The publication does not indicate whether this was yet another case of excessive tension on the robot's joints or if this was an installation/ maintenance errors. However, the addition of a sensor/ alarm system would be helpful in preventing the instrument from falling, as the surgeon would made aware in a timely fashion via a message on the screen and zoomed in image of the joint affected whether an instrument is in danger of becoming dislodged.

Reviewing the reported mishaps, it was found that there are more than just instruments that appear to fall in and hurt the patient. Using an FMEA approach to prevent damage, the joints of each da Vinci arm may also have some of their own weaknesses. Misuse of those joints should be further tested to see whether the arm joints can withstand excessive forces such as tension as well. In the meantime, sensors should be placed on these joints as they also potentially present weak points on the robot and, in an FMEA point of view, these parts should come under close scrutiny as they have the potential to seriously harm the patient. Instruments can greatly harm patients if they fall into the abdomen, but if an arm were to fall off during surgery, the possibilities for damage would be much greater than those of a single blunt instrument.

This also brings up another possibility to prevent harm and that would be for the surgeon or technician to prepare the da Vinci or other surgical robot pre-procedure to make sure each section is working properly so as to present an extra layer of security thus enabling a greater level of patient safety.

Electrical Failures

In one case, a New York woman reportedly died from burns suffered to her intestines and arteries. The main culprit was noted as an excessive leakage current from the un-insulated arms

of the da Vinci robot [19]. As stated in the article, the arm might not have been properly insulated, and might leave the patient more susceptible to leakage currents that have the ability to burn flesh [20]. This may then fall under a maintenance issue. Still, the manufacturer must give strict guidelines and outline what the possible outcomes are if improper maintenance leads to failure.

In order to counter the possibility of future burns due to inadequate maintenance, the electrical components may be designed to be placed inside the robot with insulators to attempt to prevent a large leakage current causing problems.

Software Failures

The da Vinci has very few software errors recorded, but in one case, a patient sued the manufacturer after undergoing a prostatectomy at Bryn Mawr hospital in June 2005. In this case, there were error messages coming up on the screen and the surgery had to be aborted [21]. The robot was then examined by both the hospital staff and the manufacturer, neither of which could apparently find the software problem nor were able to fix the problem.

Later on, the patient found he was bleeding whenever he went to the bathroom and that he suffered from erectile dysfunction which he attributed to damages from the aborted surgery. He sued the manufacturer but the ruling stated that he did not provide enough evidence to show without a reasonable doubt that the software issues experienced in the surgery was the root cause of his new medical issues [21].

In this case, testing the robot out prior to surgery may help highlight possible problems during the surgery and if the surgeon should look for alternative surgical procedures.

The Robodoc has gone under scrutiny as it was once labeled as inaccurate for being between 0 and 2 mm off when going through surgery [22, 23]. The Robodoc was first not suspected to be the reason for patient discomfort but rather ill-fitting parts/ orthopedic replacements. When designs were scrutinized and further research was done, the inaccuracies were discovered and were found to be the direct result of the imprecise two dimensional imaging system. When addressed and upgraded to a three dimensional system, many complaints disappeared and the system was placed back on the market [23].

Failures due to Operator Errors

One of the over-arching concerns that medical robotics brings is the possible increase in the severity of surgical mishaps. For example, if a surgeon was to go through a traditional surgery, the possible damage done by dropping an instrument would be felt but might not have been as severe as with a robot's arm falling off onto the patient or having the entire system freezing in place. Operator training then comes to the foreground as only the proper training will alleviate/eliminate possible operating room mishaps.

In one study, surgeons reported not feeling comfortable with operating until experiencing 15 to 18 surgeries [24]. Furthermore, studies have revealed the learning curve that surgeons face when first operating machines such as the da Vinci or Robodoc [25]. Results from these studies reveals a longer operating time, more blood loss, and in different cases where surgeons were not properly/ inadequately trained, possible severe harm to the patient. In the New Hampshire case, both of the patient's ureters were severed as a byproduct of the surgeon's inattentiveness [26]. It was later revealed that this was the surgeon's first attempt at a robotic surgery and that it was not supervised by a senior surgeon. The manufacturer did not require a two person system that might have prevented or at least alerted prior to the incident.

An article published August 23, 2013 highlights the lack of standardized training curriculum by the manufacturer. The lack of a structure creates a gap of knowledge, which may hinder the operator's skills and result in possible burns and other internal injuries [27].
When observed, these operator errors reveal that there is a steep learning curve [25,28,29]. With this in mind, manufacturers have different training sessions for doctors, which are something that most hospitals require for trainees. In the case where a doctor may still make an error; there are different failure modes and appropriate actions that manufacturers can prepare when considering the design, such as through programming the robot to limit movement after incisions are already made so as to not tear or burn surrounding tissue. For example, the program could be set to realize when the surgeon is making the incision and when the robotic arm enters the body. The program could then limit the motion to prevent the arm from moving past the incision to prevent tearing.

Future Work

Future work will include further research into the mechanical design of robots other than the da Vinci and Robodoc. Looking into past reports of other non-surgical robots may also help enlighten on possible design flaws not readily noticed or predicted from just observing the da Vinci or Robodoc systems.

Conclusion

There have been significant advances in the field of medical robotics, and systems such as the da Vinci and Robodoc have been employed successfully. However, some malfunctions and failures have been reported. These reported cases are analyzed and suggestions are made to improve the robot assistant system's performance and efficiency, while enhancing patient safety. It is essential for biomedical engineering students to learn how to perform failure analysis to design a safe and efficient product.

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Figures

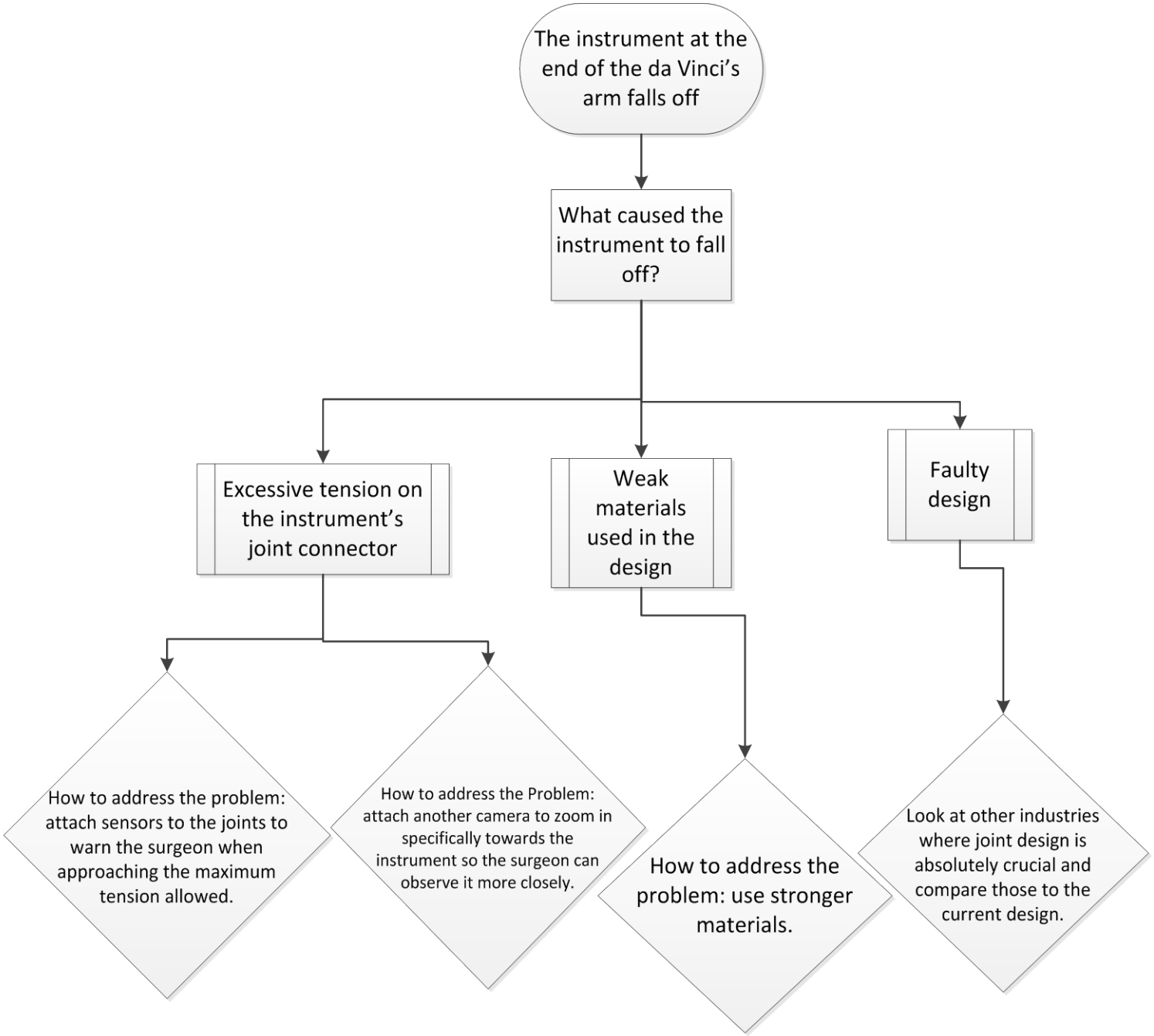

Figure 1: Failure analysis of da Vinci robot and recommendations for how to improve the problems

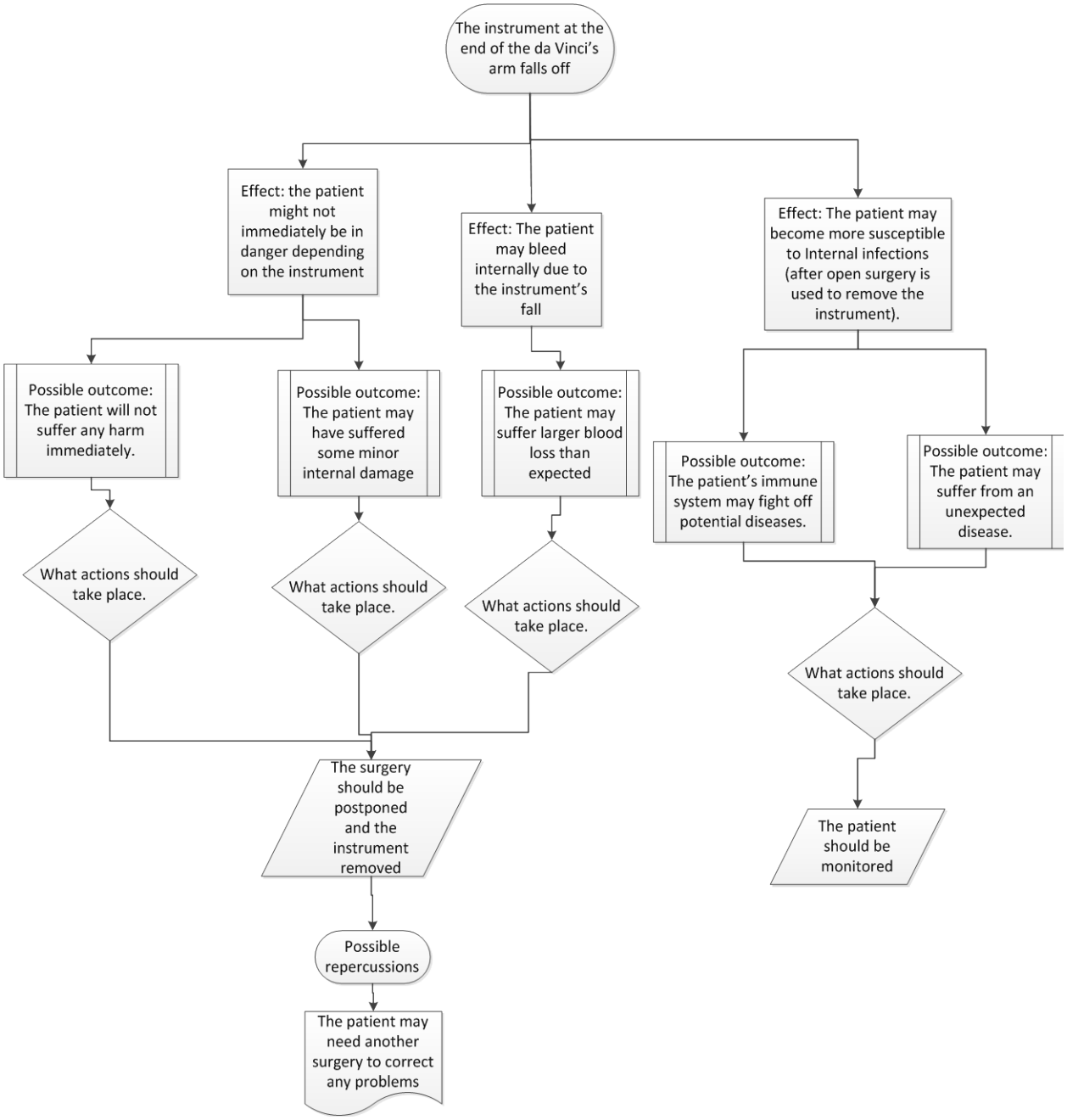

Figure 2: Equipment malfunction and subsequent actions to be taken.

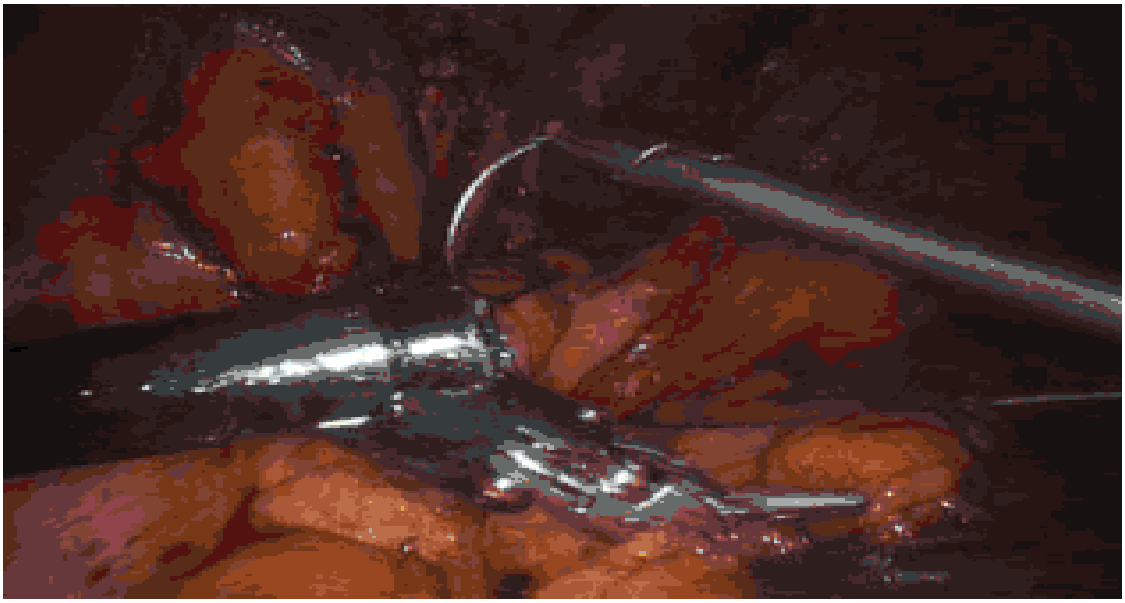

Fig. 3 The broken needle driver inside the abdomen as it breaks off during surgery [9]

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INTUITIVE SURGICAL,I	DA VINCI SURGICAL SY	10/12/2012
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Figure 4: The FDA database of Medical Devices accident report from July 1, 2000 to June 28, 2013 [11]