Device failures associated with patient injuries during robot-assisted laparoscopic surgeries: a comprehensive review of FDA MAUDE database

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Introduction: *Robot-assisted laparoscopic surgery has increased in the areas of cardiac and urologic surgery. We sought to determine the number of reported device malfunctions leading to patient injuries.*

Methods: *We performed a review of the MAUDE database of the FDA. Adverse events (AE) were defined as potential and actual product use errors and product quality problems. All incidents involving the ZEUS and da Vinci surgical robots were analyzed.*

Results: *The MAUDE database was last accessed on August 27, 2007. A total of 189 AEs were reported from 2000 to August 27, 2007. Assuming that 50000 robotic-assisted laparoscopic cases have been performed, this represents 0.38% overall estimated failure rate. Twenty-one malfunctions were reported for the ZEUS robotic system between 2001 and 2003, while 168 malfunctions were reported for the da Vinci robotic system between 2000 and 2007. The rate of open conversions due to device malfunction decreased from 94% in 2003 to 16% in 2007. Of the 189 reported device malfunctions, only 9 (4.8%) were associated with patient injury.*

Conclusions: *The increasing use of robotic-assisted surgery has led to an increase in the number of reported device malfunctions, albeit at a very small estimated rate of 0.38%. With experience, the rate of open conversions due to device malfunction decreased. Only a small percentage of these adverse occurrences were associated with patient injury.*

Key Words: robotic surgery, device failure, adverse effects

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Introduction

There has been an increasing number of robotic-assisted laparoscopic procedures performed in the United States. Ever since the first description of robotic-assisted laparoscopic radical prostatectomy in 2001, it is estimated that over 50000 cases have been performed in the United States (personal communication with Intuitive Surgical, Inc).[1,2] In fact, radical prostatectomy is the most common

robotic-assisted laparoscopic procedure in the United States.[3] It is estimated that up to half of the patients undergoing radical prostatectomy choose the robotic approach.[4] This is driven partly by patient demand and partly by the ease of use of robotic-assisted laparoscopy when compared with conventional laparoscopy, especially for novice laparoscopic surgeons. The advantages of a robot-assisted procedure, especially that of da Vinci-assisted, laparoscopic procedures are: three-dimensional vision, seven degrees of freedom rather than only four degrees of freedom, and finally, a more ergonomic seated posture of the surgeon.[5] Together with great enthusiasm towards this new technology, there is a concern about the technical failures of the robotic system while performing complex procedures. Previous single institution studies have reported the mechanical failure rates of da Vinci to range from 0.5% to 2.6%.[6,7] In a multi-institutional survey of 6426 robotic prostatectomies, the critical failure rate leading to open or laparoscopic conversion was found to be 0.3%.[8] However, the mechanical failure rate of the robotic systems (ZEUS or da Vinci) on a nationwide basis has not been studied. Therefore, the aim of this study is to review the reported mechanical failures causing patient injury in the United States as reported to the Food and Drug Administration (FDA).

Materials and methods

The Unites States Food and Drug Administration (FDA) of the Department of Human Services runs a database of Manufacturer and User Facility Device Experience Database (MAUDE) which is a voluntary reporting system of adverse events involving medical devices since 1993. Adverse events are defined as potential and actual product use errors and product quality problems. Not all of the adverse events are associated with patient injuries. The database contains information on medical devices which may have malfunctioned or caused a death or serious injury. These adverse events are reported by the manufacturer or a health care professional (operating room nurse or surgeon). MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under 21 Code of Federal Regulations 803.19. The FDA website was last accessed on August 27, 2007.[9] "ZEUS", "DaVinci", "da Vinci" and "Intuitive" search terms were used. It is important to note that MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices. Therefore, the aim of the study was not to compare the two robot systems.

For each report of the adverse event, the following parameters were collected. The robotic system, part name, model number, lot number, date of manufacture, event date, description of the event, patient injury, conversion to open or non-robotic assisted laparoscopy, procedure performed, and finally whether it was device failure or surgeon error. In addition, MAUDE report number was recorded for cross referencing of the entries.

Results

A total of 189 adverse events were reported, Table 1. There are no published reports of the actual

TABLE 1. **Number of reported adverse events and open conversions**

Year of event	ZEUS	ZEUS open conversions	da Vinci	da Vinci open conversions
2000	0	N/A	1	0
2001	2	2	3	0
2002	5	0	1	0
2003	14	0	21	5 open, 4 lap (43%)
2004	0	N/A	16	15 (94%)
2005	0	N/A	30	27 (90%)
2006	0	N/A	60	44 (73%)
2007	0	N/A	36	6 (16%)
Total	**21**	**2 (9.5%)**	**168**	**97 (58%)**

TABLE 2. **ZEUS system: number and percentage of malfunctioning parts**

Malfunctioning parts	Number	Percent of all adverse events
Microwrist	6	28.5%
Needle driver	6	28.5%
Debakey graspers	4	19%
Metzenbaum scissors	3	14%
Fenestrated graspers	2	9.5%

number of robot-assisted laparoscopic cases in this period. According to Intuitive Surgical Inc, 50000 urologic cases have been performed in the United States (personal communication with Intuitive Surgical, Inc). Therefore, the estimated overall failure rate is 0.38%. For the ZEUS system, the number of adverse events increased from two in 2001 to 14 in 2003. Out of the 21 reported adverse events, two were converted to open and another was rescheduled because of error messages from the microwrist motor packs. The majority of the remaining 18 adverse events were secondary to broken articulinks of the microwrist or needle drivers, Table 2. There were no deaths or patient injuries reported with the ZEUS system. The types of procedures performed with the ZEUS system were not reported.

There was a similar pattern of adverse events for the da Vinci system. The number of adverse events increased from 16 in 2004 to 60 in 2006. The total number of adverse events reported was 168. These involved 12 prostatectomies, 10 cardiothoracic cases, and 6 gynecologic cases (myomectomies and hysterectomies). The type of surgical procedure was not reported in the remaining 140 cases. There were seven cases rescheduled, four cases done with traditional laparoscopy, and 97 (58%) open conversions. Of the 108 adverse events that were converted or rescheduled, 104 (96%) were due to errors or malfunction of the instrument control system, including system errors, emergency stop and blurred vision. The rest were due to malfunction of the robotic arm, Endowrist Prograsp, monopolar or bipolar cautery. The rate of conversions for reported adverse events decreased from 94% in 2003 to 16% in 2007. The majority (70%) of the adverse events involved malfunctioning of the instrument control system, Table 3. Of the adverse events reported, only nine (4.8%) cases were reported to have caused patient injury, Table 4. It is important to note that there was no device malfunction in two of the nine cases (5 and 8). They were included in the table since they were reported to the FDA MAUDE. Except for unintentional camera movement due to software error, all other injuries could be attributed to user error.

TABLE 3. **da Vinci system: number and percentage of malfunctioning parts**

Malfunctioning parts	Number	Percent of all adverse events
Instrument control system	118	70%
Monopolar curved scissors	18	10%
Bipolar cautery	8	4.7%
Forceps (Cadiere and others)	7	4.2%
Cannula	6	3.6%
Endowrist	4	2.4%
Harmonic curved shears	3	1.8%
Needle drivers	2	1.2%
Unable to straighten arm	1	0.6%
Clip applier	1	0.6%

TABLE 4. **Patient injuries reported with the da Vinci robot system**

Case	Year	Procedure	Event	Patient injury
1	2003	Not reported	Unintended camera motion	Hematoma
2	2004	Cardiac	SVC tear from instrument pinching	Open repair of the SVC tear
3	2005	Cardiac	System failure	Atrial wall bleeding leading to open conversion and repair
4	2005	Cardiac	Torn aortic valve	Cardiopulmonary bypass and repair of aortic valve
5	2006	Prostatectomy	No device malfunction	Death 27 days postprostatectomy
6	2006	Hysterectomy	Maryland bipolar shears	Superficial skin burns
7	2007	Prostatectomy	Hole in silicone cover of monopolar cautery	Iliac vein laceration
8	2007	Myomectomy	Unrecognized bowel injury	Laparotomy and repair
9	2007	Prostatectomy	Frayed cautery cable	Burn around port site

Discussion

The introduction of laparoscopy to urologic surgery was heralded by Clayman et al in 1991 when they performed the first laparoscopic nephrectomy.[10] Since then, the utility of the laparoscopic approach has been expanded to include a wide variety of procedures, including the most complex extirpative and reconstructive cases. With the new technology came unprecedented gains in recuperation, cosmesis and postoperative pain control. However, wider adoption has been plagued by the steep learning curves associated with urologic laparoscopic procedures. The limited range of motion of the instruments and the lack of depth information from the imaging system, and the difficult ergonomics hindered faster permeation and adoption of the laparoscopic approach.

With the arrival of robot-assisted laparoscopy, a majority of these limitations were minimized or altogether eliminated, resulting in rapid acceptance of the robotic assisted laparoscopic surgery. The procedure that benefited the most was radical prostatectomy, which experienced gains with faster convalescence, reduced transfusion requirements, and better pain control.[3] Cardiothoracic, general surgical and gynecologic procedures have also been adapted to this approach. The ergonomic design of the of the surgeons console, the seven degrees of freedom offered by the instruments attempts to mimic the dexterity of human hands in open surgery.

The ZEUS Robotic Surgical System, manufactured at the time by Computer Motion Inc. of Goleta, California, received FDA approval in October 2001. The da Vinci Surgical System, manufactured by Intuitive Surgical in Sunnyvale, California, received FDA approval in July 2000 for general laparoscopic surgeries, specifically cholecystectomy and fundoplication. Ultimately, the approval was expanded to include laparoscopic urological surgeries, cardiothoracic and, most recently in 2005, to include gynecologic surgeries.[11] A series of patent infringement lawsuits between these two competitors ultimately led to the merger of the two companies, resulting in the ZEUS being phased out in favor of the da Vinci system. Because of this merger, there are very few cases being performed using the ZEUS system today. This explains the lack of reported device malfunctions since 2004. According to Intuitive Surgical, Inc. (Sunnyvale, CA), there are 656 da Vinci systems installed worldwide, 504 of them in North America. Since its introduction, it is estimated that the da Vinci system has been used worldwide in more than 100000 procedures, and over 50000 procedures in the United States (personal communication with Intuitive Surgical, Inc).

As expected, over the years as the number of robotic-assisted laparoscopic cases increased, the number of reported adverse events also increased. It is important to note that the percentage of open conversions decreased over the years. This reflects the increasing level of surgeon expertise in handling intra-operative complications and malfunctioning instruments. Instrument control system was the most common malfunctioning part in the reported adverse events.

Recently, Zorn and associates reported on their experience of device failure rates.[6] The authors used a single three-arm da Vinci unit in 725 robot-assisted

laparoscopic radical prostatectomies. Device failure rate leading to aborted procedures was 0.5%. All of the system failures occurred at the initial setup prior to the patient entering the operating room. Therefore, the authors recommend complete set up of the robot prior the patient entering the operating room to avoid unnecessary anesthesia. In the same study, technical errors resulting in surgeon handicap occurred at a rate of 0.4%.

In another study, out of 350 scheduled cases for robotic-assisted laparoscopic radical prostatectomy, there were nine (2.6%) cases that were unable to be completed robotically secondary to device malfunction.[7] Six of the malfunctions were discovered prior to induction of anesthesia and the cases were rescheduled. Three other malfunctions occurred intraoperatively; one case was converted to unassisted laparoscopic radical prostatectomy and two cases were converted to open approach. These reported events were: set up joint malfunction, arm malfunction, power error, monocular monitor loss, camera malfunction, metal fatigue/break of surgeon's console hand piece and software incompatibility. In a multi-institutional survey of over 6000 robot-assisted laparoscopic prostatectomies, critical mechanical failure rate was found to be 0.3%, whereas recoverable failure rate was 1.9%.[8] Most of the critical failures were due to failure of the optical and surgical arms. Apart from these reports, the present study is the first national reporting of mechanical failure rates associated with patient injuries according to the FDA.

One of the limitations of the present study is that the MAUDE database is a voluntary system of reporting adverse events. It is likely that there were more robot-related malfunctions that did not result in an adverse event and thus were not reported. It is also plausible that such reports have been filed under a different brand than those searched for in the database.

Apart from personal communication with Intuitive Surgical, Inc representatives, it is difficult to assess the exact number of robot-assisted laparoscopic prostatectomies performed. Assuming that 50000 robotic-assisted laparoscopic cases have been performed, for a total failure rate of 189 would result in 0.38% overall rate. This is comparable to the 0.5% reported by others.[6,8] Therefore, it is important that patients are aware of this mechanical failure rate and that the possibility of rescheduling or converting the surgery exists. It is also important to set up the robot prior to induction of anesthesia to prevent unnecessary anesthesia.[6] Furthermore, surgeons undertaking robotic-assisted laparoscopic surgeries should be able to perform the procedure by conventional laparoscopy or open approach should the robot fail. In addition, it is important to have a company certified technician maintain the robot at regular intervals of 6 months as recommended by Intuitive for software upgrades and interrogation of fault logs. Availability of company technicians and representatives also contribute to intraoperative success in terms of troubleshooting malfunctioning parts.

Conclusions

The increasing use of robotic-assisted surgery has led to an increase in the number of reported device malfunctions, albeit at a very small estimated rate of 0.38%. With experience, the rate of open conversions decreased. Only a small percentage of these adverse occurrences were associated with patient injury. □

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