

Robotic Instrument Failure—A Critical Analysis of Cause and Quality Improvement Strategies



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OBJECTIVE	To introduce a quality improvement initiative tracking robotic instrument failures on a per case basis. It is imperative to understand rates of failure, financial implications of failures, and identify factors suggesting common mechanisms of failure.
MATERIALS AND METHODS	Starting in January 1, 2014 a quality reporting system for failed robotic equipment began. Staff was instructed to submit an incident report when a robotic instrument failed and the instrument returned to central processing. Instruments were then returned to the manufacturer (Intuitive Surgical Inc, Sunnyvale, CA) for analysis and reimbursement. Results of failure analysis by the manufacturer, including reimbursement rates, were recorded and correlated with the procedure and surgical specialty.
RESULTS	A total of 3935 robotic cases were performed during the study period with a reported instrument failure incidence of 6.2% (247 total instruments). Etiology of instrument failure was as follows: tip or wrist (46.9%), cable (30.0%), unknown (12.6%), control housing (5.3%), and shaft (3.2%). Highest instrument failure incidence was seen in colorectal surgery cases at 4.0%, Urology had the lowest at 2.7%. Manufacturer reimbursement rate was 57.9%; the most common reason for denial being mishandling/misuse of equipment, determined by manufacturer analysis.
CONCLUSION	Herein, we have demonstrated that improved process flow of reporting is necessary to better track incidence and etiology of instrument failures. Cost savings comes from improved training of not only surgeons but operating room and central processing staff in handling equipment to prevent high rates of reimbursement denial. UROLOGY 131: 125–129, 2019. © 2019 Elsevier Inc.

Robotic surgery offers significant benefits in the performance of complex minimally invasive surgeries including an ergonomic surgical console, improved dexterity, and tremor filtration, robotic instruments with EndoWrists that are capable of 7 degrees of surgical movement, as well as 3-dimensional magnified optics.^{1,2} Disadvantages of the robot include lack of haptic feedback, learning curve, and costs. The number of robotic surgeries has continued to increase since achieving Food and Drug Administration (FDA) approval, with >1.5 million robotic procedures performed between 2000 and 2013 alone.² With increased use comes increased scrutiny and examination, presenting an ongoing need for careful examination of outcomes, complications, and equipment failures.

Initial research in the field of robotic equipment failure has focused mainly on what is deemed “device failure,” as this is the type of failure that commonly results in aborted

surgeries or conversion to open surgery. As instrument failure is usually fixed rapidly by swapping in fresh equipment, less research has been conducted in this area; however, that does not mean that it is an unimportant area to study. As these tools can be quite expensive, it is imperative that we understand and appreciate the rates of instrument failure, financial implications of such failures, and examine any factors that may suggest common mechanisms of instrument failure.

Although Friedman and colleagues³ reported on instrument failures over 2 years that were reported to the FDA, we sought to examine further the exact context of instrument failures at our high volume, teaching institution. Therefore, we designed a study to examine the instruments that failed, the specific piece of the instrument that failed, the mechanism of failure, and manufacturer’s reimbursement for failed instruments to preliminarily explore impact on cost.

METHODS

This study reviewed a robotic equipment quality pathway that was initiated January 2014 to monitor robotic equipment failure. The study period was from January 1, 2014 through June 1, 2017. During this period, robotic operating room staff was instructed to submit an incident report when a robotic instrument failed and

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return the broken instrument to our central processing department. Failed instruments were then returned to the manufacturer (Intuitive Surgical Inc., Sunnyvale, CA) for analysis and reimbursement. Quarterly Da Vinci SI and XI device failure reports were compiled and analyzed. Information obtained from each instrument failure event included: event date, manufacturer's device failure analysis and comments, surgery performed during failure, reimbursement amount, number of device lives remaining, device reference number, and device lot number.

Based on the instrument failure descriptions described by the operating room staff, each event was assigned to a failure category (cables, cautery, tip/wrist, shaft, control housing, or unknown). These categories were used by Friedman and colleagues when querying the FDA reported Manufacturer and User Facility Device Experience database to analyze instrument failures.³ Reports were also coded to identify which portion of the device appeared broken to the operating room staff (tip, shaft, cables, or unknown). Where data were available, the manufacturer's analysis of the event was also coded into a category (cables, cautery, tip/wrist, shaft, control housing, mishandling/misuse, no damage, or unknown). Surgery being performed when the failure occurred was consolidated by surgical specialty (colorectal surgery, general surgery, gynecology, urology, thoracic surgery, unassigned training, or unknown). Calculations for overall instrument failure rate, as well as failure rate by surgical specialty, were performed by using the total number of instrument failures as the numerator and the total number of robotic cases performed at our institution as a whole or within a particular specialty as the denominator.

Device reference numbers were cross-referenced with the manufacturer to identify and consolidate reports from Si and Xi versions of the same instruments. The devices were then sub-categorized further into the categories listed in the Intuitive Surgical, Inc. catalog (EndoWrist Monopolar Cautery Instruments, EndoWrist Bipolar Cautery Instruments, Ultrasonic Energy Instruments, EndoWrist Needle Drivers, EndoWrist Graspers, EndoWrist Scissors, Clip Applicators, EndoWrist Scalpels, and Specialty Instruments).

Lives remaining were defined as the number of potentially reimbursable lives as determined by Intuitive Surgical, Inc. (unused lives +1 to account for the use during which it failed). If lives remaining were unavailable in the manufacturer's report, it was calculated by adding 1 to the lives remaining as specified by the operating room staff.

RESULTS

Out of 3935 total cases examined within the 3 year and 5 months' time period, we identified a total of 247 instrument failures (Table 1). The most frequent location of instrument failures, by a large margin, was seen in the tip or wrist of the instrument and accounted for 116 (46.9%) of the total failures. Malfunctions within this category included tip mis-alignment, jaws not opening or closing, dull blades of cutting instruments, articulation failures, as well as a few others. Cable failure was the cause of 74 failures (29.9%). The remaining failures included 13 failures (5.3%) involving the control housing, 8 failures (3.2%) due to problems with the instrument shaft, and finally, 5 (2.02%) were secondary to cautery malfunction. Of note, the site of failure was unknown in 31 of the 247 where the instruments had simply been reported as broken without the malfunction being identified.

Instrument failure occurred in 6.2% of overall cases. There were 3 instances when 2 devices failed during the same case. When separated by specialty, we found that the highest

Table 1. Comparison of Beaumont Central Processing Department analysis of instrument failure etiology to analysis by the manufacturer

Institution Failure Category	Breakage Events	Percentage of Total Failures (%)
Cables	74	29.96
Cautery	5	2.02
Tip/Wrist	116	46.96
Shaft	8	3.24
Control housing	13	5.26
Unknown	31	12.55
Manufacturer Failure Category	Breakage Events	Percentage of Total Failures (%)
Cables	45	18.22
Cautery	0	0.00
Tip/wrist	33	13.36
Shaft	4	1.62
Control housing	5	2.02
Mishandling/misuse	80	32.39
No damage	16	6.48
Unknown	64	25.91

incidence of instrument failure was noted in colorectal surgery cases 17 of 421 (4.04%), followed closely by gynecology 36 of 911 (3.95), and thoracic surgery 3 of 76 (3.95). The specialty with the lowest incidence of instrument failure was urology with failures noted in only 34 of 1252 (2.7%) of cases. (Table 2)

Of 247 instrument failures, 57.9% were reimbursed (Table 3). Of the 104 that did not get reimbursed, 3 are pending at this time. There were 20 different instrument types that had reported failures over the course of the study period (Table 4). Since 13 different instruments had less than 5 reported failures, the reimbursement rates for these instrument types may be skewed secondary to small sample size. Of the remaining instrument types, the reimbursement rate was highest for the Prograsp Forceps 39 of 41 (95.12%). This was followed closely by the Small Graptor where 9 of 10 (90%) were reimbursed. The instrument type that was most frequently submitted for reimbursement was the Fenestrated Bipolar Forceps ($n = 72$) and 37 (51.39%) were reimbursed. Of the instrument types that had at least 10 incidences of failure, the lowest reimbursement rate was seen with the Hot Shears (Monopolar Curved Scissors) where only 17 of 50 (34.00%) were reimbursed. Even though 2 of these claims are still pending, the reimbursement rate for this instrument type would only rise to 38.00% if the claims are paid. (Table 3)

A total of 104 of 247 (42.11%) instruments that were submitted were not reimbursed. Of those, 3 have claims that are still pending. When examining reasons for denial, the most common

Table 2. Analysis of instrument failure rate by specialty

Specialty	Breakage Events	Failure Rate (%)
Colorectal surgery	17	4.04
General surgery	36	2.94
Gynecology	36	3.95
Urology	34	2.72
Thoracic surgery	3	3.95
Training	1	1.96

Table 3. Reimbursement rate based on etiology of failure determined by manufacturer analysis

Failure Modality	Reimbursement			Total
	Approved	Denied	Unknown	
Abrasions	10	-	-	10
Bent	1	-	-	1
Bent grips tips	17	-	-	17
Broken cables	16	1	-	17
Broken input disks	3	-	-	3
Derailed grip cables	12	-	-	12
Dislodged instrument conductor wire	8	-	-	8
Dislodged grips pin	1	-	-	1
Failed functional cut test	8	-	-	8
Frayed cables	7	-	-	7
Frayed pitch cables, abrasion on distal instrument tube	2	-	-	2
Grip/tip failure	2	-	-	2
Lodged component	1	-	-	1
Mishandling/misuse	-	79	-	79
No damage found	17	2	-	19
Recognition failure	1	-	-	1
Unknown	37	18	3	58
User error	-	1	-	1
Total	143	101	3	247

reason was the manufacturer's finding of mishandling or misuse by the operator, which accounted for 79 of 101 (79%) of denials. Of the remaining denials, 21 of 101 (20.79%) did not receive reimbursement for an unknown reason, and 2 of 101 (1.98%) were found to have no damage. It is important to note that although 17 of 247 instruments that were submitted were found to have no damage on the manufacturer's analysis, all but 2 were reimbursed by the manufacturer. (Table 4)

DISCUSSION

In 2008, Lavery et al. sent questionnaires to many experienced robotic surgeons to quantify their failures rates and

mechanisms. Although some data on instrument failure were included, failures were categorized as "recoverable" or "nonrecoverable" mechanical failure with little to no standardization or consistency. Overall, of 8240 cases the surgeons reported only 41 instrument failures (0.5%), which is notably lower than others cited in the literature^{2,3} and the current study's findings that are presented here.⁴

A recent study examining the rate of adverse events in robotic surgery used the Manufacturer and User Facility Device Experience database to examine and further estimate adverse event incidences in robotic surgery.¹ In this study of 1797 robotic cases, the investigators found just 43

Table 4. Reimbursement rate based on instrument type

Instrument Type	Approved	Denied	Pending	Total	Reimbursement
					Rate (%)
<i>Curved scissors</i>	-	1	-	1	0.00
<i>EndoWrist stapler 30 curved-tip</i>	1	-	-	1	100.00
<i>EndoWrist stapler 45 instrument</i>	2	-	-	2	100.00
<i>Fenestrated bipolar forceps</i>	37	35	-	72	51.39
<i>Large clip applier</i>	-	1	-	1	0.00
<i>Hot shears (Monopolar curved scissors)</i>	17	31	2	50	34.00
<i>Large needle driver</i>	4	-	-	4	100.00
<i>Maryland bipolar forceps</i>	1	3	-	4	25.00
<i>Medium-Large clip applier</i>	-	1	-	1	0.00
<i>Mega needle driver</i>	3	-	1	4	75.00
<i>Mega sutureCut needle driver</i>	11	10	-	21	52.38
<i>Needle driver</i>	3	4	-	7	42.86
<i>Permanent cautery hook</i>	1	-	-	1	100.00
<i>PK Dissecting forceps</i>	7	8	-	15	46.67
<i>ProGrasp forceps</i>	39	2	-	41	95.12
<i>Small graptor (grasping retractor)</i>	9	1	-	10	90.00
<i>Small grasping forcep</i>	4	-	-	4	100.00
<i>Stapler</i>	-	2	-	2	0.00
<i>Tenaculum forceps</i>	2	2	-	4	50.00
<i>Vessel sealer</i>	2	-	-	2	100.00
Total	143	101	3	247	57.89

total failures, with 19 of those specifically being instrument failures. Further, they found the instrument shaft was the most common etiology of instrument failure 9 of 19 (47.4%) while the instrument tip accounted for only 2 of 19 (10.53%) of instrument failures.¹

Our findings were similar to many, though not all, of the prior investigations utilizing the same instrument failure categorizations in that the most common instrument to fail was the tip or wrist. However, unlike other studies we found that cable failure was the second most common, and cautery was the least common instrument to fail. Although the reason for tip or wrist failure is not entirely clear, others have suggested that it may be a result of the instrument tip and wrist being the most easily identified portion of the instrument.³ Conversely, it may be that this portion of the instrument is more susceptible to damage and subsequent malfunction. As the most common instrument to fail, further study is needed to understand the mechanisms behind tip and wrist failure.

Our device failure rate of 6.2% was slightly higher than the figures identified by previous studies, with figures ranging from 0.4%-8% with a mean of 3%.^{2,5} Although not entirely clear, the variations in rates may be due to differences in study methodology. In the current study, failures were not recorded real time by the physician but were reported after the fact by the operating room staff. Furthermore, missing information (type of procedure or instrument problems) was present in almost 48% of instrument failures. This highlights the difficulty of obtaining accurate information from our staff and an opportunity for improvement in our processes.

The current study also examined the reimbursement rates for our reported instrument failures to identify any trends in reimbursement. Failed instruments submitted by our institution had a reimbursement rate of 58%. The most common reason for lack of reimbursement was, per the manufacturer, mishandling or misuse of the equipment. When compared to the manufacturer's analysis of the instrument failures, there were also 16 incidences where no damage was found to the instrument. These instruments were not returned; however, the institution was reimbursed based on remaining half lives.

The manufacturer's analysis goes into greater depth than our institutional analysis. As an example, when we recorded a problem with the tip or wrist, the manufacturer's analysis may report that the reason for the failure is due to mishandling or misuse in the form of closing the tip with excessive force. Therefore, as shown in table one, there is a discrepancy in institution and manufacturers analysis of failure. As a result of our study, we have enhanced our collaborations with the manufacturer to reduce mishandling or misuse, improve our reimbursement rate, and reduce overall equipment failures. Tracking instrument failures and working to limit preventable causes ultimately will lead to improved outcomes.

Unique to our study is the analysis of surgical specialties reporting instrument failure. We found highest rates of failure in colorectal and gynecologic cases. The reasons

for higher failure rates in different specialties is unknown but may be influenced by differences in procedures between specialties and surgeon learning curves. At our institution, robotic gynecological surgery has been performed for over 13 years while colorectal surgery started 2 years ago. The lowest failure rate was seen in Urology, which may be a result of roughly 17 years of robotic surgery experience within the specialty or volume of cases performed. The strength of our pathway is that our results are presented and discussed quarterly at our institution's multispecialty robotic meeting. Awareness and poor trends are addressed at these meetings and plans for correction and improvement are devised and implemented.

Although others have examined larger populations,^{2,3} we expanded our investigation in an effort to identify and examine the exact context of the instrument failures, as well as manufacturer reimbursement for these failed instruments. Additionally, our data includes an accurate sample of instrument failures, from a single-center, rather than a national database of voluntarily reported instrument failures. Another unique feature of our study is the comparison of the robotic manufacturer's assessment of the broken instrument to our own assessment to identify any trends or improvements that can be made in the future to maximize reimbursement.

Because of quality improvement initiative was in its infancy, incomplete data are a study limitation. For example, the total number of instruments ordered and/or used were unavailable which limited our ability to fully examine failure rates per instrument type, and approximately half of failures were missing information. Nonetheless, we were still able to identify those instruments that failed most often, reimbursement rates, and established a starting point for our ongoing quality improvement initiative.

CONCLUSION

Robotic surgery is becoming increasingly more prevalent; however equipment failures can be costly both in terms of fiscal and patient outcomes. Collaborations between clinicians and industry can help to identify instrument problems and implement improvements where warranted. Ongoing research is needed to standardize data collection regarding instrument failures, and examine the impact of failures on surgical outcomes and reimbursement within specialties and procedures.

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EDITORIAL COMMENT



This is an interesting study which analyzes data of a hospital quality improvement process over 3.5 years in a high volume center. The authors should be commended for providing data on an aspect of robotic surgery that is of paramount importance not only for patient safety but also for operative costs. Several of the findings in their report merit special mention. It is particularly interesting that the highest rate of instrument failure by specialty was in colorectal surgery and the lowest in urologic surgery. Unfortunately there is no breakdown of the specific types of instruments that failed but that observation raises the question of whether failures are surgeon specific or instrument specific? Unfortunately 48% of the failures lack data regarding specialty. Further it is unfortunate that we are given no information regarding whether there was a higher rate of instrument failures in more experienced surgeons versus surgical trainees. The study underscores the importance of establishing standardized and specific definitions of instrument failures so that data can be reported uniformly across different institutions.

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AUTHOR REPLY

We are grateful for and sincerely appreciate the comments made by Dr. Gargollo. The inconsistencies of our data collection reflect the infancy of our quality improvement initiative. The lack of uniform data reporting underscores the need for improved training of our operating room and central processing department. With more consistent data reporting, future studies can delve deeper into the specificities of instrument failures. We agree it would be interesting to examine the association between surgeon specialty or experience and the incidence of instrument failure. However, the intent of our manuscript was to highlight our program and our ability to improve quality and develop cost savings to our institution. It is important for surgeons and institutions to work closely together to develop and maintain cost saving strategies within robotic surgery programs.

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