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Bin Zhou
Qilu Hospital of Shandong University
Zhongze Zhou
Lanzhou University
Yihao Zhao
Qilu Hospital of Shandong University
Shijie Zhang
Qilu Hospital of Shandong University
Jun Chen
Qilu Hospital of Shandong University
Benkang Shi
3856870070@qq.com
Qilu Hospital of Shandong University

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Reported Intraoperative Equipment Problems, Troubleshooting, and Operative Disposition During Robot-Assisted Nephroureterectomy: An FDA MAUDE Analysis

Bin Zhou[a,b†] , Zhongze Zhou[c†] , Yihao Zhao[a] , Shijie Zhang[a] , Jun Chen[a*] , Benkang Shi[a*]

[a] Department of Urology, Qilu Hospital of Shandong University, Jinan, Shandong, China
[b] University of Health and Rehabilitation Sciences
[c] Department of Urology, The Second Hospital & Clinical Medical School, Lanzhou University, Lanzhou, Gansu 730000, China
[†] These authors contributed equally to this work and share first authorship
[*] Correspondence:
Benkang Shi , Department of Urology, Qilu Hospital of Shandong University, Jinan, Shandong, China (e-mail: 3856870070@qq.com)
Jun Chen , Department of Urology, Qilu Hospital of Shandong University, Jinan, Shandong, China (e-mail: 3475346077@qq.com)

Abstract

Intraoperative equipment problems during robot-assisted nephroureterectomy (RANU) are poorly characterized. We searched FDA Manufacturer and User Facility Device Experience (MAUDE) reports received from January 1, 2015, through September 30, 2026, and included reports documenting both RANU and an intraoperative equipment problem. Related reports were linked; equipment problems and troubleshooting were analyzed per distinguishable failure, and operative disposition per operation. Of 870 unique MDRs screened, 168 were included, representing 153 distinguishable failures in 151 operations. Breakage, detachment, or visible structural damage was the most frequently coded primary manifestation (53/153, 34.6%), followed by abnormal movement, jaw operation, or jamming (30/153, 19.6%). At least one of six predefined troubleshooting actions was documented for 87 failures (56.9%), including equipment exchange in 41 (26.8%). A specific final operative path could be identified for 27 operations (17.9%). Completion was explicitly documented for 103 (68.2%), including 84 completed operations with no specified final approach; another 40 had no reported final operative disposition. These reports describe equipment problems and intraoperative responses during RANU, but cannot establish malfunction incidence or device-attributable clinical risk.

Keywords: Robot-assisted nephroureterectomy; Upper tract urothelial carcinoma; FDA MAUDE; Medical device malfunction; Intraoperative troubleshooting; Operative disposition

1. Introduction

Radical nephroureterectomy (RNU), including removal of the kidney, ureter, and bladder cuff, is a standard treatment for high-risk upper tract urothelial carcinoma[1]. Current guidelines recognize open, laparoscopic, and robot-assisted approaches, provided that the principles of complete tumour removal are maintained. Robot-assisted nephroureterectomy (RANU) is now performed across a range of centres, and a large international series has described its surgical and oncological outcomes[2]. These studies are essential for evaluating the operation as a whole. They offer less detail, however, about what happens when a piece of equipment stops functioning during a particular operative step.

RANU depends on several devices working together. The robotic platform provides visualization and instrument control, while dissection, vascular control, ureteral division, and bladder cuff management may also require energy instruments, staplers, clips, access devices, and specimen-retrieval equipment[3]. A technical problem can therefore take different forms and call for different responses. A system error may prompt a restart; a malfunctioning instrument may be exchanged; and a device that remains engaged with tissue or leaves a fragment in the operative field may require immediate manual intervention. Recording only the device name does not capture what failed, how the team responded, or whether the planned operative approach was ultimately used.

Most RANU publications concentrate on perioperative complications, conversion, length of stay, and oncological outcomes[2]. Earlier work has examined technical problems in robotic urological surgery, while analyses of FDA reports have described device malfunctions in robotic prostatectomy and, more recently, robotic thyroidectomy[4–7]. These studies establish the value of examining technical events, but their findings cannot simply be transferred to nephroureterectomy. The equipment used and the point at which a problem arises matter to the operative team. A procedure-specific review may reveal details of troubleshooting that are difficult to recover from aggregated surgical outcomes.

The US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database contains medical device reports submitted by manufacturers, healthcare facilities, and other reporters[8]. Its narratives may describe the observed problem, the actions taken during surgery, and subsequent information supplied in a follow-up report. They are nevertheless records of reported events, with incomplete and sometimes unverified clinical detail. MAUDE does not contain the number of RANU procedures or device uses from which the reports arose. It therefore cannot establish the incidence of malfunction, compare device reliability, or demonstrate that a device caused a patient outcome[9]. Its more defensible use here is to examine the range of problems and responses described in individual reports.

Care is also needed in deciding what constitutes one observation. More than one report may describe the same device problem, whereas one operation may contain more than one distinguishable failure. The implicated equipment, the way the failure manifested, the intraoperative response, and the final operative disposition are related but separate pieces of information. We reviewed RANU-related MAUDE narratives with these distinctions in mind. Our objectives were to identify distinct intraoperative device-failure events, classify their reported manifestations, describe the troubleshooting

measures documented by the surgical team, and determine how often the final operative approach could be established from the available text.

2. Methods

2.1 Study design, data source, and search strategy

This retrospective descriptive study used publicly available FDA medical device reports. The eligibility window was defined by the date FDA first received an MDR, from 1 January 2015 through 30 September 2026, inclusive; the operation date did not replace the FDA receipt date for selection. We searched the openFDA device-event API using eight narrative queries covering nephroureterectomy and spelling variants, RANU, ureterectomy, and kidney-and-ureter expressions. We cross-checked API results against FDA downloadable MDR data and narrative files and resolved report numbers cited within candidate narratives. The search snapshot was obtained on 22 October 2026. The exact query log, retrieval timestamps, raw responses, and file checksums were retained. FDA documentation describes the public MAUDE and MDR data sources[8].

On 22 October 2026, we searched the openFDA device-event database using eight separate queries of the report narrative field (mdr_text.text). Search terms included nephroureter*, ureterectomy, "nephro-ureterectomy", "nephro ureterectomy", RANU, "kidney and ureter", "nephrectomy and ureterectomy", and ureteronephrectomy. Each query was restricted to reports with an FDA receipt date from 1 January 2015 through 30 September 2026 (date_received:[20150101 TO 20260930]). We merged results by MDR key and checked the FDA downloadable report-text files for additional candidates. The eight exact queries, retrieval times, source URLs, and file checksums are provided in Supplementary Table S1 and the study audit files.

2.2 Eligibility and reconciliation of reports

An eligible report had to identify a robot-assisted nephroureterectomy, with or without a reported bladder cuff procedure, and describe a device abnormality during the active operation. Eligible equipment included the robotic system or instruments and devices used as operative adjuncts, including energy, stapling, clipping, visualization, or access components. We did not infer RANU from a manufacturer name or an upper tract cancer diagnosis alone. Reports describing only an issue before the operation, problems first detected after surgery, a complication without a discernible device issue, or an unrelated procedure were not eligible. Reports with conflicting or insufficient evidence were not automatically counted as cases.

Multiple narratives under one MDR key were treated as updates to that report. Separate MDR keys were reconciled into one failure event when cross-references and the clinical narrative supported the same occurrence. Different equipment failures during one operation could remain separate events,

whereas final operative disposition was assigned only once to that operation. We preserved the underlying MDR numbers, relevant text, and FDA report links for each retained event. Eleven reports with unresolved procedure or event boundaries were left outside the present main analysis by decision.

2.3 Variables and outcome definitions

Each distinct failure event was assigned one principal implicated equipment group: wristed instrument, cable, or scissors; robotic arm, console, or system; energy device or generator; stapler or reload; visualization component; access, insufflation, or retrieval component; or clip applier or clip. This field identifies equipment involved in the report and is not a verified root-cause classification. FDA event types were retained as regulatory reporting labels; an MDR labelled Injury was not automatically coded as a clinically confirmed injury caused by the equipment.

The reported failure manifestation was coded separately from the implicated equipment. Each distinguishable failure was assigned one primary manifestation based on the device behavior described in the FDA narrative: breakage, detachment, or visible structural damage; abnormal movement, jaw operation, or jamming; system, arm, or controller error or loss of function; energy delivery or electrical abnormality; firing, staple, or clip deployment or formation abnormality; image, illumination, or video abnormality; instrument recognition, connection, or mounting problem; insufflation failure; or a failure whose specific mechanism was not described. When a narrative described more than one manifestation, additional features were retained as secondary descriptors but were not counted again in the mutually exclusive primary categories. These codes describe the reported behavior and do not establish the technical root cause.

Intraoperative management was recorded only when a narrative stated that an action was performed or attempted, not merely proposed. Six prespecified measures were coded as nonexclusive: exchange of a device or component; restart, reset, or reconnection; fragment or detached-part retrieval; continuation without an affected robotic arm; hemostasis or repair; and manual release or removal of a malfunctioning instrument. Lack of a coded action means that none of these six measures was documented; it does not establish that the surgical team took no action.

Operative disposition was assessed once per operation. Mutually exclusive categories were explicit completion with the original robotic system; use of another robotic system or console; switch to conventional laparoscopy; switch to open surgery; explicit completion without a specified final approach; and no final operative disposition reported. Explicit mention of completion was also recorded as a separate variable. A change of system or surgical approach was not, by itself, considered evidence that the operation was completed.

2.4 Statistical analysis

Equipment group, primary failure manifestation, FDA report classification, and intraoperative management were summarized per distinguishable failure (n = 153). Operative disposition and explicit

documentation of completion were summarized per operation (n = 151). Counts and percentages used the corresponding analytical unit as the denominator. For annual description, an event was assigned to the earliest FDA receipt year among its linked reports. Management measures may overlap and therefore do not sum to 100%. No inferential comparison, rate estimation, time-trend test, or causal analysis was performed.

3. Results

3.1 Report selection and analytical units

The primary keyword searches yielded 870 distinct MDR report keys. An additional 11 MDR keys were identified through cross-references for retrieval audit and were not treated as additional RANU operations. Of the 870 primary hits, 168 reports were retained, 46 were excluded for a specified reason, 645 lacked adequate evidence for the target procedure, and 11 were held unresolved outside the main analysis. The 168 retained MDR reports were reconciled into 153 distinct failure events in 151 operations. Thus, 15 retained MDRs referred to failures already represented by other retained reports, and two operations each contained a second distinguishable failure **(Fig. 1)**

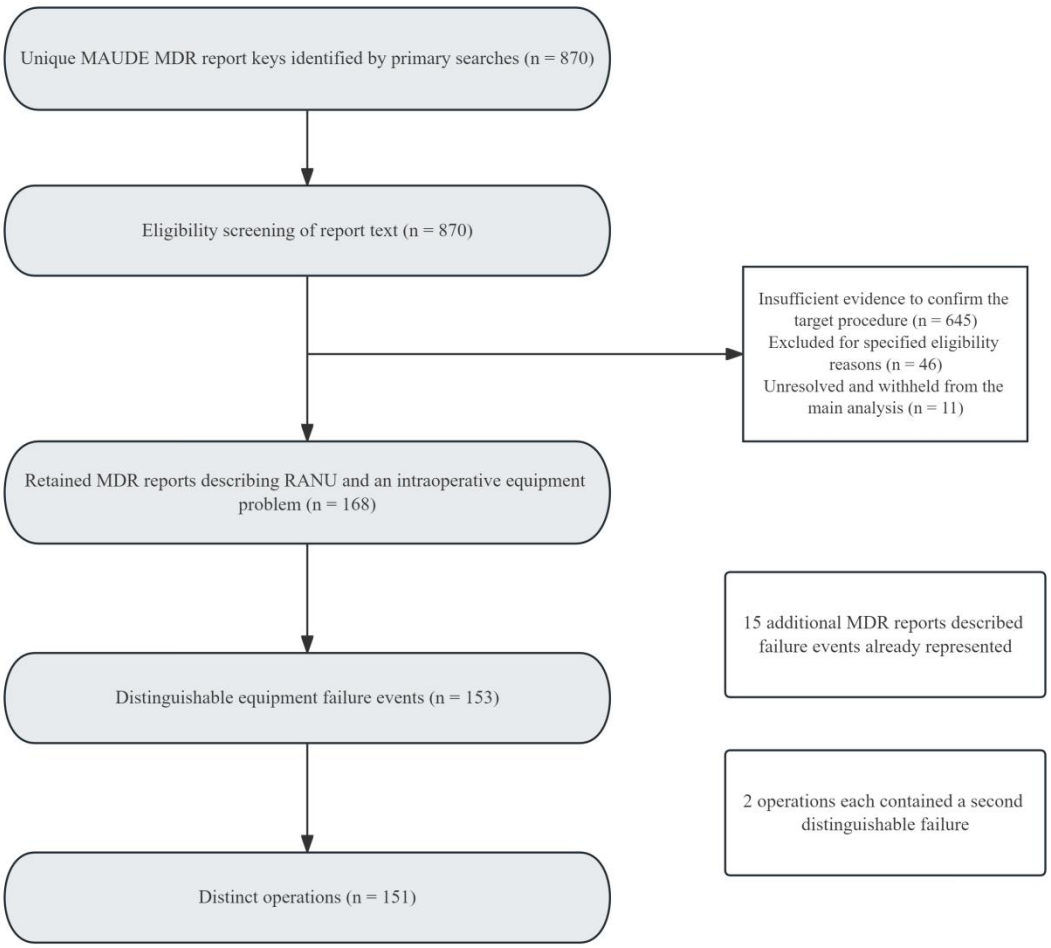


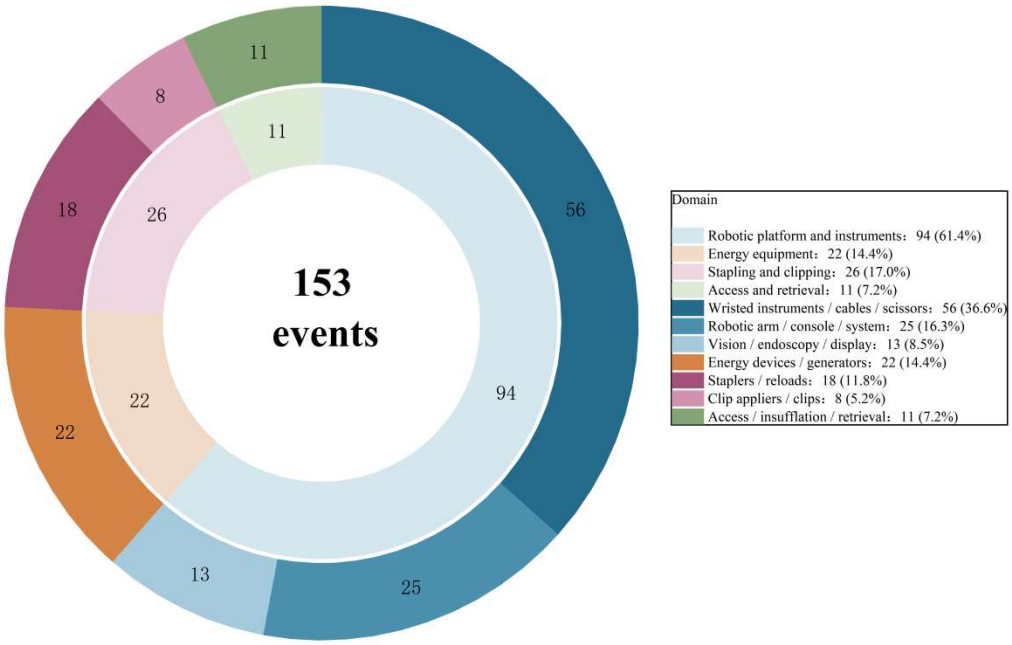
Fig. 1 Screening and reconciliation of FDA Manufacturer and User Facility Device Experience (MAUDE) reports for robot-assisted nephroureterectomy. The 870 unique medical device report (MDR) keys came from the primary searches. Eleven additional keys identified through report cross-references were checked outside the primary-search denominator. The 168 retained MDRs were reconciled into 153 distinguishable intraoperative equipment failures in 151 operations. Fifteen retained reports referred to failures already represented by another report, and two operations each contained a second distinguishable failure.

3.2 Equipment involved and FDA report classification

Wristed instruments, cables, or scissors accounted for 56/153 events (36.6%), followed by robotic arm, console, or system components (25, 16.3%), energy devices or generators (22, 14.4%), staplers or reloads (18, 11.8%), visualization components (13, 8.5%), access, insufflation, or retrieval accessories (11, 7.2%), and clip appliers or clips (8, 5.2%). By the regulatory label of any linked MDR, 18/153 events (11.8%) were associated with an Injury-labelled report and 135 (88.2%) with Malfunction labels only. These labels do not provide an adjudicated patient-injury outcome. **(Table 1; Supplementary Fig. S1)**

Table 1. Equipment groups and FDA report classifications among 153 distinguishable intraoperative failure events

Characteristic	n	%
Equipment group		
Wristed instruments, cables, or scissors	56	36.6
Robotic arm, console, or system	25	16.3
Energy devices or generators	22	14.4
Staplers or reloads	18	11.8
Vision, endoscopy, or display components	13	8.5
Access, insufflation, or retrieval devices	11	7.2
Clip appliers or clips	8	5.2
FDA MDR event classification		
At least one linked MDR labelled Injury	18	11.8
Linked MDRs labelled Malfunction only	135	88.2



Supplementary Fig. S1 Distribution of implicated equipment among 153 distinguishable intraoperative failure events. The outer ring shows seven mutually exclusive equipment groups, and the inner ring combines them into four broader equipment domains. One principal equipment group was assigned to each failure. The proportions describe the included events and do not measure device malfunction incidence or comparative reliability

The primary reported manifestation was breakage, detachment, or visible structural damage in 53 of 153 failures (34.6%), followed by abnormal movement, jaw operation, or jamming in 30 (19.6%) and system, arm, or controller error or loss of function in 20 (13.1%). Energy delivery or electrical abnormalities and firing, staple, or clip deployment or formation abnormalities each accounted for 17 failures (11.1%). Image, illumination, or video abnormalities occurred in nine (5.9%), instrument recognition, connection, or mounting problems in five (3.3%), insufflation failure in one (0.7%), and a failure without a described specific mechanism in one (0.7%). An additional simultaneous manifestation was recorded for 25 failures; these secondary features were not added to the primary-category counts.**(Table 2)**

Table 2. Reported manifestations of intraoperative device failure

Primary manifestation	Illustrative report description	Events, n (%)
Breakage, detachment, or visible structural damage	Device breakage with a detached fragment (MDR 6745268)	53 (34.6)

Primary manifestation	Illustrative report description	Events, n (%)
Abnormal movement, jaw operation, or jamming	Stapler jaws did not reopen after clamping (MDR 7326874)	30 (19.6)
System, arm, or controller error or loss of function	Repeated robotic arm fault code (MDR 16684173)	20 (13.1)
Energy delivery, electrosurgical, or electrical abnormality	Instrument cut tissue but failed to seal (MDR 15090562)	17 (11.1)
Firing, staple or clip deployment, or formation abnormality	Stapler failed to fire (MDR 6769910)	17 (11.1)
Image, illumination, or video abnormality	Loss of the right-sided console view (MDR 15492417)	9 (5.9)
Instrument recognition, connection, or mounting problem	Monopolar hook was not recognized by the system (MDR 18805260)	5 (3.3)
Insufflation failure	Insufflator failed to deliver gas (MDR 11798873)	1 (0.7)
Specific failure mechanism not described	Ineffective bipolar hemostasis; mode of failure unstated (MDR 50226300)	1 (0.7)
Total		153 (100.0)

The earliest FDA receipt year was 2024 for 37 events, 2025 for 35, and January–September 2026 for 27. These are counts of selected reports by FDA receipt year, without a denominator of RANU operations or devices in use; they were not analysed as a change in failure risk.**(Fig. 2)**

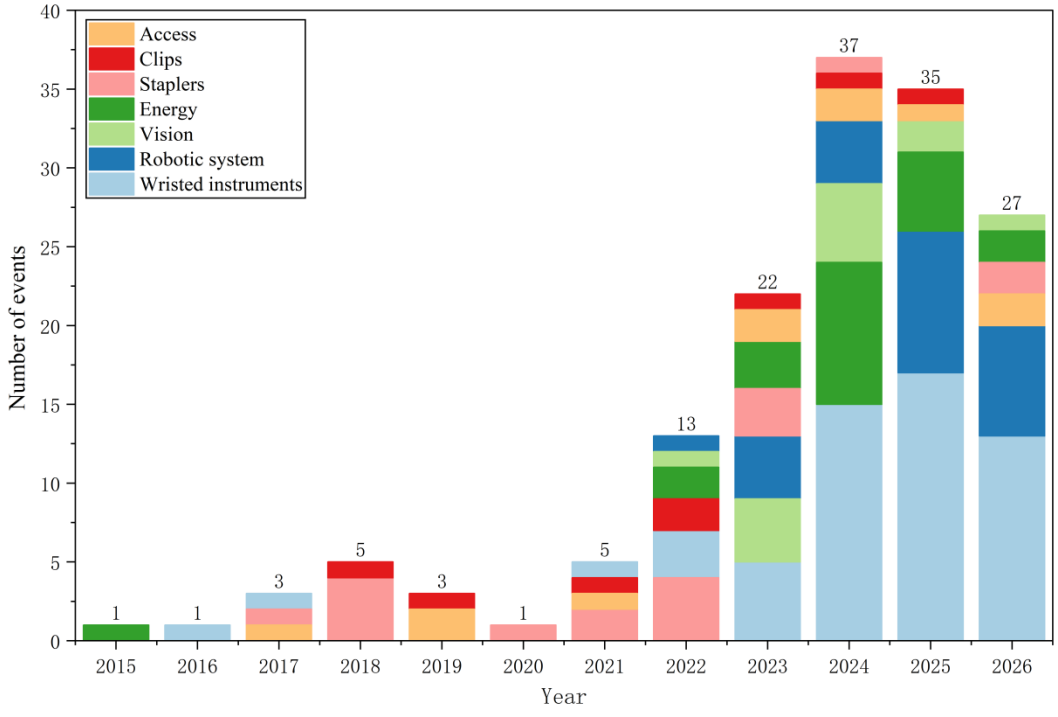


Fig. 2 Distribution of 153 distinguishable intraoperative equipment failures by earliest FDA receipt year and implicated equipment group. Each failure was assigned to the earliest receipt year among its linked MDRs and to one principal equipment group. The 2026 bar includes reports received through 30 September 2026 only. These counts do not represent annual malfunction incidence or a change in device risk

3.3 Documented responses and operative disposition

At least one of the six prespecified management measures appeared in 87/153 event narratives (56.9%). Device or component exchange was documented for 41 events (26.8%), restart, reset, or reconnection for 30 (19.6%), fragment or detached-part retrieval for 12 (7.8%), continuation without the affected arm for 11 (7.2%), hemostasis or repair for 7 (4.6%), and manual release or instrument removal for 4 (2.6%). None of these six categories was documented for the remaining 66 events (43.1%); this is a reporting limitation rather than evidence of inaction.**(Table 3; Fig. 3a)**

Table 3 Documented intraoperative management by implicated equipment group

Equipment group	Events	At least one measure	Device exchange	Restart, reset, or reconnect	Fragment retrieval	Continue without arm	Hemostasis or repair	Manual release
Wristed instruments, cables, or scissors	56	20	17	0	3	0	0	0
Robotic arm, console, or system	25	20	2	13	0	11	0	0
Energy devices or generators	22	14	7	9	0	0	1	0
Staplers or reloads	18	13	7	1	1	0	6	4
Visualization components	13	8	2	7	0	0	0	0
Access, insufflation, or retrieval devices	11	8	4	0	6	0	0	0
Clip appliers or clips	8	4	2	0	2	0	0	0
Total	**153**	**87**	**41**	**30**	**12**	**11**	**7**	**4**

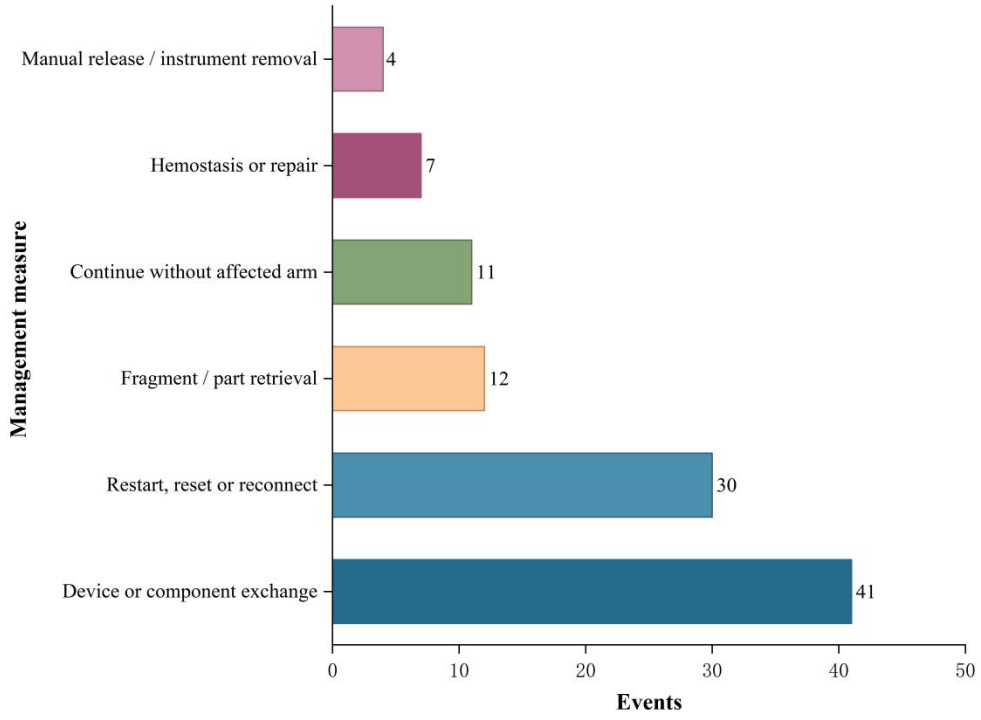


Fig. 3 Documented intraoperative management of 153 distinguishable equipment failures. Bars show the number of failures for which each of six predefined measures was reported as performed or attempted. Measures were not mutually exclusive and could occur in the same failure. At least one measure was documented for 87 failures; none of these six measures was documented for 66 failures

Among 151 operations, 84 (55.6%) were explicitly reported as completed without specifying the final operative approach. Completion with the original robotic system was stated for 14 (9.3%); another robotic system or console was used in 8 (5.3%); 4 (2.6%) switched to conventional laparoscopy; and 1 (0.7%) switched to open surgery. No final operative disposition was reported for 40 operations (26.5%). A specific final operative path could therefore be identified for 27 operations (17.9%). Completion was explicitly documented for 103 operations (68.2%), regardless of whether the final approach was identified. A reported change of system or approach was not counted as completion unless the narrative explicitly stated that the operation was completed **(Fig. 4)**.

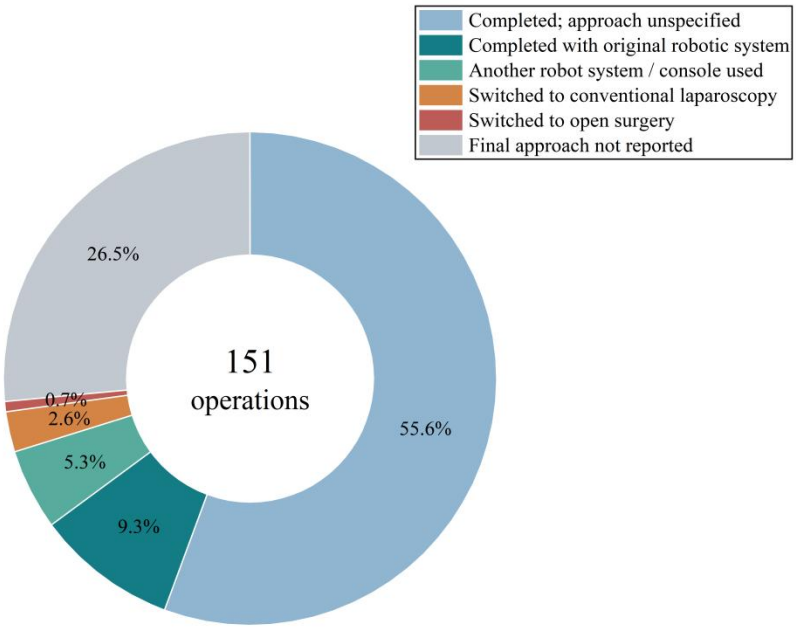


Fig. 4 Reported operative disposition for 151 robot-assisted nephroureterectomy operations. A specific final operative path was identified for 27 operations. Completion was explicitly documented for 103 operations, including 84 for which the final approach was unspecified. No final operative disposition was reported for 40 operations. A change of robotic system or surgical approach was not considered evidence of completion unless the report explicitly stated that surgery was completed

4. Discussion

Earlier studies have examined technical problems across robotic urological procedures and have used MAUDE reports to study robotic prostatectomy and thyroidectomy[6,7]. Large RANU cohorts, by contrast, have mainly addressed perioperative and oncological outcomes[2]. These approaches leave a narrower question open: when equipment behaves unexpectedly during RANU, what does the report say happened next? A device name alone cannot answer it. The observed malfunction, the action taken in the operating room, and the way surgery proceeded are separate pieces of information. Examining them together gives a more useful account of the events described in postmarket reports[9,10].The distinction between reports, failures, and operations was consequential in this cohort. The 168 eligible MDRs described 153 distinguishable failures; some submissions referred to an event already represented. Those failures occurred in 151 operations, including two with a second distinguishable failure. Among the 153 events, wristed instruments, cables, or scissors were the most frequently implicated equipment group, while breakage, detachment, or visible damage was the most frequent primary manifestation. At least one of six defined

intraoperative responses was documented for 87 failures. These findings describe the equipment problems and actions visible in the selected reports. They do not measure the duration of an interruption, the frequency of malfunction among all RANU procedures, or the relative reliability of devices.

Robotic arm, console, or system components were implicated in 25 events, and system, arm, or controller faults were the primary reported manifestation in 20. These figures describe different classifications and need not refer to the same events. Across all equipment groups, restart, reset, or reconnection was documented for 30 failure events, and continuation without an affected robotic arm for 11 failure events. A local response could allow the team to proceed, but the narratives often did not specify the order of attempted measures or the final operating configuration. The management counts therefore cannot be used to calculate how often a particular system fault was resolved by a reset or led to a change of platform.

Wristed instruments, cables, or scissors comprised the largest equipment group among the 153 distinguishable failure events. In addition to robotic dissection, the operation may involve energy delivery, vascular control, clipping, stapling, access equipment, and specimen retrieval. Energy equipment was implicated in 22 failures, staplers or reloads in 18, and clip equipment in eight. Structural damage was the primary manifestation in 53 events, movement or jaw malfunction in 30, and energy or electrical problems and firing, staple, or clip problems in 17 each. These are manifestation counts across equipment groups, not device-specific failure rates. The report of a stapler that would not reopen after clamping a renal artery (MDR 7326874) illustrates why the device’s position at the time of failure matters. Retrieval of a detached device fragment in another report (MDR 6745268) posed a different immediate task. Neither case establishes how commonly such situations arise or whether the documented response prevented harm.

The gap between managing a failure and establishing the final operative path was substantial. Equipment exchange was documented for 41 failures and reset or reconnection for 30; other reports described fragment retrieval, continuation without an arm, hemostasis or repair, or manual release. These response categories could overlap. None of the six defined actions was recorded for 66 failures, which does not mean that no action was taken. Final disposition was counted once per operation rather than once per failure or MDR. A specific final operative path could be identified for only 27 of 151 operations: 14 were explicitly completed with the original robotic system, eight involved another robotic system or console, four changed to conventional laparoscopy, and one changed to open surgery. Completion was explicitly stated for 103 operations: 84 with an unspecified final approach, 14 with the original robotic system, and five after a switch to another robotic system or console; another 40 operations had no reported final disposition. A change of system or approach was not treated as proof of completion unless the report said so. Thus, a statement that surgery was completed should not

be taken to mean that it was completed with the original robot, and an unreported final approach should not be assigned an outcome.

From an operative perspective, the distinction between exchanging a device and releasing one engaged with tissue or retrieving a fragment may be more informative than the equipment-group label alone. We cannot determine whether a checklist, training programme, or backup arrangement would have shortened an interruption or changed a patient outcome.

MAUDE's principal value for this question lies in its narratives, including supplemental information that may clarify an earlier submission. That value is reduced when a report identifies the device problem but omits the operative step, attempted responses, or final approach. Our retained query expressions, FDA links, source excerpts, and report-to-event-to-operation mapping make the selection and coding decisions inspectable, addressing a recognised reproducibility concern in MAUDE research[11]. More complete reporting would also allow future reviewers to distinguish a successful local remedy from a change in how the operation was completed. Although a recent robotic thyroidectomy study assessed reporting timeliness, we did not calculate event-to-report intervals[6]. The years shown in our figures are FDA first-receipt years, not operation years, and cannot establish a trend in RANU malfunction risk[8].

Several limitations define the scope of these findings. MAUDE is a passive reporting system with incomplete and potentially selective submissions; the number of RANU procedures and device exposures is unknown. Requiring explicit evidence of both RANU and an intraoperative equipment problem may have excluded genuine but poorly described events, and 11 unresolved reports were left outside the analysis. Although flagged codes were checked against source text, screening and coding were not independently duplicated by two reviewers. One primary manifestation was assigned to each failure for tabulation, potentially simplifying events with multiple features. We could not verify operative delay, patient injury, technical root cause, or postoperative outcomes against clinical records. In particular, the final approach was unspecified or absent in 124 of 151 operations. The study therefore provides a traceable description of reported failures and responses, while showing exactly where operative information is lost. A prospective log linked to device use and operative records would be needed to measure the frequency, duration, and clinical consequences of technical interruptions during RANU.

5. Conclusion

This analysis identified 153 distinguishable intraoperative equipment failures during robot-assisted nephroureterectomy in 168 FDA MAUDE reports concerning 151 operations. Structural damage or detachment was the most frequently coded failure manifestation. The reports described responses ranging from device exchange and system troubleshooting to fragment retrieval and changes in

operative approach. However, a specific final operative path could be established for only 27 operations. MAUDE narratives can therefore provide useful detail about how surgical teams responded to reported equipment problems, while often leaving the eventual course of surgery uncertain. These reports cannot establish the frequency of equipment failure or its effect on patient outcomes.

Statements and Declarations

Author contributions

Bin Zhou and Zhongze Zhou contributed equally to this study and share first authorship. Both contributed equally to study conception and design, search strategy development, record screening, data curation, descriptive analysis, visualization, interpretation of the findings, and drafting of the manuscript. Yihao Zhao and Shijie Zhang contributed to review and verification of source medical device reports, data curation, and validation of the descriptive results. Yang Bai contributed to eligibility assessment and preparation and verification of the supplementary materials. Jun Chen contributed to the study design, interpretation of the findings, and critical revision of the manuscript. Benkang Shi supervised the study, provided clinical guidance, and critically revised the manuscript. All authors reviewed and approved the final manuscript.

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Competing interests

The authors have no financial or non-financial competing interests relevant to this work.

Ethics approval

This study analyzed publicly available FDA MAUDE reports. No participants were recruited, and the investigators did not access non-public patient records or directly identifiable patient information.

Consent to participate

Not applicable because no participants were enrolled in this study.

Consent for publication

Not applicable because the manuscript contains no identifiable personal information.

Data availability

The source medical device reports are publicly accessible through the FDA MAUDE database and the openFDA device-event API. MDR identifiers and source links for the included reports were retained in the study audit dataset. The derived event-level dataset, coding decisions, and search audit log are available from the corresponding author upon reasonable request.

Code availability

Custom scripts were used for openFDA retrieval, report reconciliation, and descriptive analysis. The query strings and analysis scripts are available from the corresponding author upon reasonable request.

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