



Device Failure and Adverse Events Related to Single-use and Reusable Flexible Ureteroscopes: Findings and New Insights From an 11-Year Analysis of the Manufacturer and User Facility Device Experience Database

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OBJECTIVE	To catalog and characterize device failures and adverse events related to flexible ureteroscopes from a national database.
METHODS	Search of the Manufacturer User and Facility Device Experience database was performed for all recorded events related to flexible ureteroscopes between 2012 and 2022. The following information was collected: Problem and cause, timing, complications and injury, prolonged anesthesia, and early termination of procedure. Event severity was graded using a validated tool.
RESULTS	A total of 206 events were identified (reusable/single use ratio, 2.5:1). There were 20 different problem categories reported, which included image loss (26.7%), difficulty removing scope (13.6%), scope damage from basket (4.4%), detachment of scope tip (5.8%) and contamination (4.9%). Faulty device was the predominant cause for an event related to single-use scopes (86.4%); this was seldom the case for reusable (2%). Patient injury occurred in 21.8%, but these were all in reusable scopes. No deaths were reported, but major complications included complete avulsion of the ureter (3.4%) and fully entrapped scope necessitating open surgery (2.9%). While the safety profile for single-use scopes was superior, they were significantly more likely to result in early termination (71.1% vs 37.3%, $P < .001$). This was related to 76.3% of the single-use scopes experiencing sudden image loss.
CONCLUSION	Flexible ureteroscopes are fragile, and a multitude of problems can occur. Many of these can be avoided through correct surgeon technique and robust maintenance services. UROLOGY 177: 41–47, 2023. © 2023 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

With a rise in the incidence and prevalence of urolithiasis, the volume of ureteroscopy (URS) performed worldwide has also increased.^{1,2} A major contributor to the increased adoption of URS as an intervention of choice is the many

innovations and advancements that have taken place in the field of scope technology. This includes improved optic systems, the advent of digital scopes, and miniaturization.^{3,4} More recently, single-use models have been introduced to clinical practice. However, failure of these modern technologies as well as their improper use has the potential to cause patient injury, treatment failure, and prolonged anesthesia. While many potential device failures and adverse events (AEs) are known to urologists, often such knowledge is anecdotal and lies outside of what is routinely reported in studies. To this end, there exist few reports providing such an overview of the AEs and device failures that can potentially occur. Generating greater awareness and education on such relevant points could deliver improvement to patient

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safety, surgical practice, and treatment planning accordingly.

The Manufacturer User and Facility Device Experience is a register of incidents relating to device failures in the United States.⁵ Evaluation of reports in a multitude of surgical fields has led to valuable insights and improved patient safety.^{6,7} However, analysis of this dataset in the setting of endourology and more specifically, URS, remains underreported.

The primary aim of this study was to catalog and characterize device failures and AEs related to flexible ureteroscopes, recorded in this national registry. Our secondary aim was to compare results between reusable and single-use ureteroscopes.

METHODS

Search of the Manufacturer and User Facility Device Experience (MAUDE) database was performed for all recorded events related to URS between 2012 and 2022.⁸ We included all cases involving flexible ureteroscopes. This included single-use and reusable models. Each individual report was reviewed, and the following information was recorded: problem and cause, timing (pre-

operative, intra-operative, post-operative, or at a later surgery), prolonged anesthesia, and early termination of procedure. Event severity was graded using a validated tool, which developed by Gupta et al. for use with this specific database.⁹ Duplicate reports were carefully checked for and removed accordingly. Events with limited or missing information were excluded.

Chi-square tests were used to compare categorical variables using SPSS Statistics v.26 (IBM, Armonk, NY). *P*-values < .05 were considered statistically significant. Given this was publicly available and anonymised data, ethical approval was not deemed to be required.

RESULTS

Over the 11-year period, 206 events related to flexible ureteroscopes (reusable: 147, single use: 56) were recorded. These were from 14 different manufacturers.

In total, there were 20 different problem categories reported (Table 1). The most frequently occurring (26.7%) was complete and sudden loss of image. Other commonly reported problems were difficulty removing the scope (13.6%), scope damage from

Table 1. Overview of problem types.

	Overall	Reusable	Single Use
No. of ureteroscopes	206	147	59
Problem			
No image	55 (26.7%)	10 (6.8%)	45 (76.3%)
Difficulty removing scope	28 (13.6%)	28 (19%)	0
Scope damage from laser	23 (11.2%)	23 (15.6%)	0
Detached tip of scope	12 (5.8%)	12 (8.2%)	0
Contamination	10 (4.9%)	9 (6.1%)	1 (1.7%)
Locked in deflected position	10 (4.9%)	5 (3.4%)	5 (8.5%)
Failure to deflect	10 (4.9%)	8 (5.4%)	2 (3.4%)
Scope damage from basket	9 (4.4%)	9 (6.1%)	0
Leaking	8 (3.9%)	8 (5.4%)	0
Visible damage	8 (3.9%)	7 (4.8%)	1 (1.7%)
Rubber sheath peeling	7 (3.4%)	7 (4.8%)	0
Valve broken	5 (2.4%)	3 (2%)	2 (3.4%)
Exposed wiring	5 (2.4%)	5 (3.4%)	0
Blocked channel	4 (1.9%)	3 (2%)	1 (1.7%)
Flaking of outer coating	3 (1.5%)	3 (2%)	0
Handle lever broken	2 (1%)	1 (0.7%)	1 (1.7%)
Image too poor to continue	2 (1%)	2 (1.4%)	0
Glue sealant leaking	2 (1%)	2 (1.4%)	0
Light cable	2 (1%)	2 (1.4%)	0
Overheating	1 (0.5%)	0	1 (1.7%)
Cause of problem			
Surgeon error	94 (45.6%)	93 (63.3%)	1 (1.7%)
Faulty device	54 (26.2%)	3 (2%)	51 (86.4%)
Inadequate maintenance/sterilization	28 (13.6%)	28 (19%)	n/a
Not clear	8 (3.9%)	2 (1.4%)	6 (10.2%)
Physical handling (including shipping)	6 (2.9%)	5 (3.4%)	1 (1.7%)
Not sent for service soon enough	16 (7.8%)	16 (10.9%)	n/a

basket (4.4%), detachment of the distal scope tip (5.8%), contamination (4.9%), and failure of the scope to deflect (4.9%). The leading cause was surgeon error (45.6%) rather than a faulty device (26.2%). The former was either technical such as firing the laser while its tip was within the scope (11.2%) or use of excess force resulting in, for example, locking of the scope in a deflected position (4.9%). Inadequate maintenance/sterilization (13.6%) and damage incurred by physical handling (2.9%) were other causes. Regardless of scope type, the problem most often either occurred or was identified during the procedure (83%). However, in approximately 1 in 10 cases, the issue was found before URS was commenced such as a result of shipment or handling damage. One case of a detached scope tip was reportedly found during a later URS. More than half (53.9%) of the events resulted in prolonged anesthesia. Most events did not stop the procedure being completed (64.6%), but 16.5% and 17.5% of the cases were terminated due to safety reasons and lack of spare equipment, respectively.

Overall, most events were graded as mild (29.6%) or moderate (47.6%). Only 4 cases (1.9%) were classified as life threatening and all related to patients developing septic shock requiring admission to the intensive care unit. These cases were all directly linked to scope contamination due to inadequate sterilization.

No surgeon or operating staff injuries were recorded. Approximately 1 in 5 (21.8%) events led to a patient injury. These were exclusively associated with reusable scopes. No deaths were reported, but major complications did occur. This included complete avulsion of the ureter (3.4%) requiring laparotomy and fully entrapped scope necessitating open surgery (2.9%).

Comparing Between Reusable and Single-use Flexible Ureteroscopes

A single-use scope event was significantly more likely to result in early termination of the procedure (71.1% vs 37.3%, $P < .001$). The main reason for this was due to the issue of image loss. This was not so common for reusable scopes (6.8%), and the manufacturers' evaluations consistently determined the cause to be inadequate maintenance (eg internal leak). In contrast, this was the most frequently reported problem to occur with disposable scopes (76.3%) and was due to device failure. All reports for single-use scopes suggest a seemingly identical problem of complete and sudden power shutdown of the electronic monitor device leading to cancellation of the procedure unless a spare was available.

Events related to reusable scopes were significantly more likely to lead to prolonged anesthesia (62.4% vs 32.2%, $P < .001$). While a faulty device was the predominant cause for an event related to single-use scopes (86.4%), this was seldom the case in reusable scopes (2%) (Table 2).

Patient injury occurred in 21.8% of cases, but these were all in reusable scopes (Table 3). Therefore, the adjusted rate of injury in reusable scopes was 30.6%. The underlying causes were not found to be device related but rather surgeon error (eg excess force leading to avulsion) or inadequate maintenance. The latter refers to separate events where patients developed severe infection, which were linked to the use of specific scopes that had been improperly sterilized and reprocessed.

DISCUSSION

This study provides an overview range of problems that can occur with flexible ureteroscopes. The results highlight that most problems related to reusable scopes are

Table 2. Additional details regarding event.

	Overall	Reusable	Single Use
Time point when problem identified/occurred			
Pre URS	20 (9.7%)	12 (8.2%)	8 (13.6%)
During URS	171 (83%)	120 (81.6%)	51 (86.4%)
Post URS completed	14 (6.8%)	14 (9.5%)	0
During a later case	1 (0.5%)	1 (0.7%)	0
Anesthesia			
Prolonged	111 (53.9%)	93 (62.4%)	19 (32.2%)
Completion of procedure			
Yes	126 (61.2%)	106 (71.1%)	22 (37.3%)
Yes - but additional procedure required	7 (3.4%)	7 (4.7%)	0
No - Rescheduled for safety reasons	34 (16.5%)	28 (18.8%)	6 (10.2%)
No - Rescheduled as lack of spare equipment	36 (17.5%)	5 (3.4%)	31 (52.5%)
Not known	3 (1.5%)	3 (2%)	0
Grading of event			
Mild	61 (29.6%)	49 (32.9%)	12 (20.3%)
Moderate	98 (47.6%)	54 (36.2%)	46 (78%)
Severe	43 (20.9%)	42 (28.2%)	1 (1.7%)
Life threatening	4 (1.9%)	4 (27%)	0

Table 3. Summary of patient injuries.

	Overall*	Management
Patient Injury	45 (21.8%)	
Avulsion	7 (3.4%)	Laparotomy (6× repair, 1× nephrectomy)
Ureteral perforation	12 (5.8%)	Ureteral stent
Bleeding	1 (0.5%)	Procedure abandoned
Sepsis	5 (2.4%)	Intravenous antibiotics
Septic shock	4 (1.9%)	ITU admission
Fully entrapped scope	6 (2.9%)	5× Open surgery, 1 incised ureter
Left part	4 (1.9%)	Repeat URS
Burn to skin	1 (0.5%)	Ointment only

* All occurred in reusable scopes.

not due to a faulty device but rather are a result of surgeon error or inadequate reprocessing. These can lead to potentially serious complications. Reusable flexible ureteroscopes have been established in clinical practice for over 30 years and likely contributes to the low level of technical failure (2%) that is currently recorded with their application. Surgeon error as the underlying cause was much lower in the single-use group. This is arguably unexpected given the most centers using such equipment at the time would have been earlier in their learning curve. It is difficult to know the true cause for this, but given the lower quality of materials (eg plastic) used compared to reusable ureteroscopes appears to translate to less durability. This could therefore mean that when damage has occurred intra-operatively, it is accepted that it is more likely to be lack of material durability rather than surgeon misuse. Another possible reason could be that given the manufacturers were early in their own learning curve, they had a lower threshold to accept that it was manufacturing error. The long period of reusable ureteroscopes in practice also likely means that the manufacturers have a deeper experience of what failures are due to technical failure versus the surgeon.

Single-use scopes seem more likely to incur a problem originating from the original manufacturing. The results show that complete image loss and power outage is a recurrent problem associated with single-use devices. While this results in more cases being abandoned, there were no patient injuries recorded. While there are exceptions, most single-use ureteroscopes have a larger shaft diameter compared to reusable ureteroscopes. In addition, the tip is not tapered in the majority of the models. This carries disadvantages such as the need for use of larger ureteral access sheaths with subsequent increased morbidity.^{10,11} It can also result in failed access completely.¹² The findings in this study do not seem to capture these reported drawbacks. Possible reasons for this include that failed access was not considered an AE and patients may have been pre-stented.

Device malfunction with single-use ureteroscopes has been reported previously, but this has been largely in the setting of pre-clinical studies with a low number of scopes being trialed.¹³

While it is notable that injuries were only associated with reusable scopes, root cause analyses revealed that many were potentially avoidable. Flexible ureteroscopes are fragile instruments. When using accessories such as laser or basket, the individual surgeon should pay close attention to deployment and surgical technique such as observing a minimum distance of laser tip out of scope (eg ¼ of screen) before firing.^{14,15} Thermal laser damage is known to occur most often in the distal 4 mm of the ureteroscope.^{16,17} A recurrent theme from the reports was use of excess force by the surgeon, which resulted in instrument malfunction (eg over deflection) and/or serious injury (eg forceful removal of scope despite resistance, resulting in ureteral avulsion). Our results also serve as a reminder that while the surgeon does carry responsibility regarding their surgical technique, delivery of a safe URS service is truly a team effort.¹⁸ To this end, all staff involved in scope handling and usage should familiarize themselves with instrument anatomy and in particular, the parts most susceptible to damage during the operating and processing life cycle. Semins et al. previously shared findings of their in-house service evaluation and concluded that staff training in this area could reduce processing-related damages.¹⁹ It is known that once a scope has been for a repair, their subsequent durability is reduced.²⁰ Our results suggest that 1 in 10 events related to the reusable scopes could have been avoided if it had been sent for repair before use. Operating staff should be stringent at examining the scope before and after its use. Having sufficient spare equipment available would also prevent a clinically significant caseload being canceled mid procedure, necessitating a further procedure for the patient.

LIMITATIONS

There are several limitations to acknowledge in this study. This includes reporting bias as practitioners are not formally obliged to declare events of this nature. As such, no estimations regarding the true incidence can be calculated. However, it does represent the largest database of its kind in

the world and evaluations such as ours can provide valuable insight into the range of AEs and scenarios that can occur. In addition, it can bring to light issues of concern that fall outside of what clinical studies typically report. These observations can therefore serve as important didactic points for manufacturers and clinicians. Surgical practice and patient safety can potentially be improved accordingly. AEs were examined using a grading tool developed by Gupta et al. specifically database.⁹ However, it has been applied in studies covering a range of operations; it should be noted that it was originally designed for events associated with the robotic DaVinci Surgery system.^{21,22} The first single-use model was only released in October 2015, and therefore a comparison of frequencies over the whole period was not deemed appropriate.²³

CONCLUSION

Flexible ureteroscopes are fragile instruments, and a wide array of problems can occur intra-operatively. In the case of reusable scopes in particular, many of these can be avoided through correct surgeon technique and robust maintenance services. This study found a superior profile associated with single-use scopes but has highlighted a recurrent issue of complete and sudden image loss leading to case cancellation, which appears to have received limited attention in the literature to date. Perhaps a standby scope should, therefore, always be available with the use of single-use scopes.

DATA AVAILABILITY

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICAL APPROVAL

Ethical approval was deemed not to be required given all data are available to the public and are anonymised.

DECLARATION OF COMPETING INTEREST

Patrick Juliebø-Jones - no conflict. Bhaskar K Somani - no conflict. Lazaros Tzelves - no conflict. Mathias Sørstrand Æsøy - no conflict. Peder Gjengstø - no conflict. Christian Arvei Moen - no conflict. Christian Beisland - no conflict. Øyvind Ulvik - Paid consultant to Sponsor Olympus. Olympus had no involvement in this study.

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EDITORIAL COMMENT



We are accustomed to embracing new technology with a bit of hype, and reviewing its pro's while in trend. However, innovations that don't stand the test of time tend to disappear into thin air, leaving no trace of the details leading to their ill fate. Pat Jones et al. have touched the much anticipated area of timely health technology assessment, reflecting on newly available single-use flexible ureteroscopy (fURS) equipment, by accessing post-marketing data from a crowd-sourced database.

As clearly stated by the Manufacturer and User Facility Device Experience Database (MAUDE) on their official statement, by nature, this passive surveillance database is not to be taken to reflect the incidence or prevalence of events.¹ The stated sources of bias include under-reporting, inaccuracies in documentation, absence of independent verification of the devices implicated, and insufficient data on the frequency of device use. Also, the grading tool introduced by Gupta was validated for the DaVinci robot, which can be plagued by software and robotic interface issues, none of which is expected in ureteroscopes.²

Since disposable scopes were only introduced in 2011, and became commercially available around 2015, the data period (2012–22) would predictably include less single-use instruments compared to reusable optical or digital fURS devices. So again comparing the two in terms of frequency would not be valid.

Conspicuously, “surgeon error” was not only more common with reusable equipment, but almost non-existent with single-use scopes. After all, surgeons were predictably on the uphill limb of their learning curve of using the new generation apparatus.

Scope diameter at the tip and along its shaft, in addition to how the tip is beveled or tapered are the salient scope-related determinants of success or failure in entering and exiting the ureter. These are particularly critical when performing the procedure without an access sheath, but directly impact the choice of access sheath diameter in all other cases. The majority of available single-use scopes are sized 9 F and over, even at the tip, significantly larger than the average reusable ureteroscope. This has been shown to bring about the obligatory use of larger access sheaths which in turn translates to increased morbidity.^{3,4} The authors were invited to explain why this limitation of current single-use instruments remains obscured in their data. For one, could it be that failed access was not recorded as a related event?

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We thank our colleague for his learned comments regarding our recent study. Use of the MAUDE database is not without shortcomings; however, it offers certain insights into events that seem to fall outside the conventional parameters reported in studies. We agree that the dimensions of a ureteroscope are a subtle but important consideration, especially in terms of successful cannulation of ureteric orifice. However, we would point out that while single use ureteroscopes are available in a range of sizes, the vast majority of those included in this study referred to the Lithovue™ that has tapered tip of 7.7Fr. This favourable profile is not an isolated finding, as inspection of models such as Wiscope™ reveals a tip diameter

of 7.4Fr. This alone could account for why the data does not support the theory put forward by the author. Even the PolyScope™, which is technically semi-disposable, has a uniform tip/shaft calibre of 8Fr. Moreover, failed access is a recognised event rather than an adverse event, unless iatrogenic injury is caused in the process.

Continuing this theme, re-usable digital models such as Olympus V3™ and Storz XC™, two of the endourological workhorses used in centres worldwide owing to their reliability, both have tip dimensions of 8.5Fr. Interestingly, in both these models, the tip is wider than the shaft (8.4Fr). It is worth noting that the largest shaft calibres are found in re-usable models with dual working channels e.g. Cobra Vision™ (9.9Fr). We agree that it is not only tip size that matters but also the shape and contour. In this regard, fibre-optic ureteroscopes are still the winners. An example being the Olympus P7™ (4.9Fr/7.95Fr) that offers particular advantages in special populations such as children and pregnancy owing to the bullet shaped tip.^{1,2}

As highlighted in the editorial, surgeon error was much more common in reusable equipment. It may be that from a business point of view and in keeping with the saying that 'the customer is always right', the threshold to accept potential device failure could have been lower in the early period of its release. Furthermore, certain manufacturers would provide a replacement at no charge.

We hope that we have provided a platform to allow for these issues to be observed further. Ergonomic advantages and anticipated modifications such as suction have surely secured their place in urological theatres across the globe.

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