

Bad Out of the Box: A Report on Pre-operative Failure Rates of Reusable Flexible Ureteroscopes at a Single Institution

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Abstract

Purpose: Single-use flexible ureteroscopes offer the advantage of being consistently functional and perfect for immediate clinical use right “out of the box.” Cost is the barrier to widespread acceptance of these instruments. Economic models have been put forth which compare the expense of acquiring and maintaining reusable flexible ureteroscopes to that of using single-use flexible ureteroscopes.¹ However, one poorly defined variable in these models is the frequency of encountering an unsuitable reusable flexible ureteroscope at the beginning of a case. We sought to define this in a consecutive series of patients undergoing flexible ureteroscopy.

Patients and Methods: Prospective analysis of all consecutive cases requiring flexible ureteroscopy over three months was undertaken. A combination of fiberoptic and digital flexible ureteroscopes comprised the available inventory. Per protocol, these instruments were grossly cleaned in the endourology suite after use, and sent to central processing for final cleaning, sterilization (STERRAD) and packaging. Repairs were managed by a third party repair service when needed. Ureteroscopes were defined as acceptable if they provided reasonable visualization, deflection, an open working channel that would accept passage of instruments and no evidence of gross contamination or overt damage/deformity.

Results: Of 228 consecutive cases, a total of 261 reusable flexible ureteroscopes were unwrapped and 93 (90%) cases were initiated with the first instrument opened. In 11 (9.0%) cases, the initial ureteroscope opened was unacceptable for use and required opening an additional ureteroscope(s). In 7 cases, at least 2 instruments were opened. Also, 3, 4, and 5 instruments needed to be opened in 1 case each. One case had to be rescheduled after 4 consecutive instruments were opened and all were unsuitable. Of 17 unfit instruments, 19 problems were noted and included broken deflection (4), dried cleaning solution on the instrument tip (4), inability to pass a laser fiber through the working channel (5), digital camera dislodged from distal bending rubber (2), crushed proximal shaft (1), digital image failure (1), lens trouble causing optical failure (1) and a missing sterilization cap (1). Considering all 119 instruments opened, 17 (14%) were unsuitable for immediate use.

Conclusions: In up to 12.6% of cases, the initially opened reusable flexible ureteroscope is not fit for initiation of the procedure. This rate may vary among institutions depending on repair, processing, and nursing practices but represents one area where single use devices can fill an essential and immediate role.

Background

- Single-use flexible digital ureteroscopes come with many advantages. They include high image quality and flawless functionality while avoiding the disadvantages of cleaning, sterile processing and inevitable costly repairs associated with reusable ureteroscopes.^{2,3}
- A significant barrier to widespread acceptance is cost of the single-use instrument.
- Existing financial models have put forth a cost-benefit analysis which takes into account original purchasing costs, repair fees and reprocessing charges for reusable flexible ureteroscopes.¹ The approximate cost of a typical repair of a flexible ureteroscope is \$4500.
- Delay in procedure time must also be accounted for when a reusable flexible ureteroscope breaks or is not suitable for immediate use.
- We strive to define the rate of encountering a reusable flexible ureteroscope which is unsuitable for immediate use in a consecutive group of patients undergoing flexible ureteroscopy for various indications.



Crushed proximal shaft of flexible ureteroscope.

Objectives

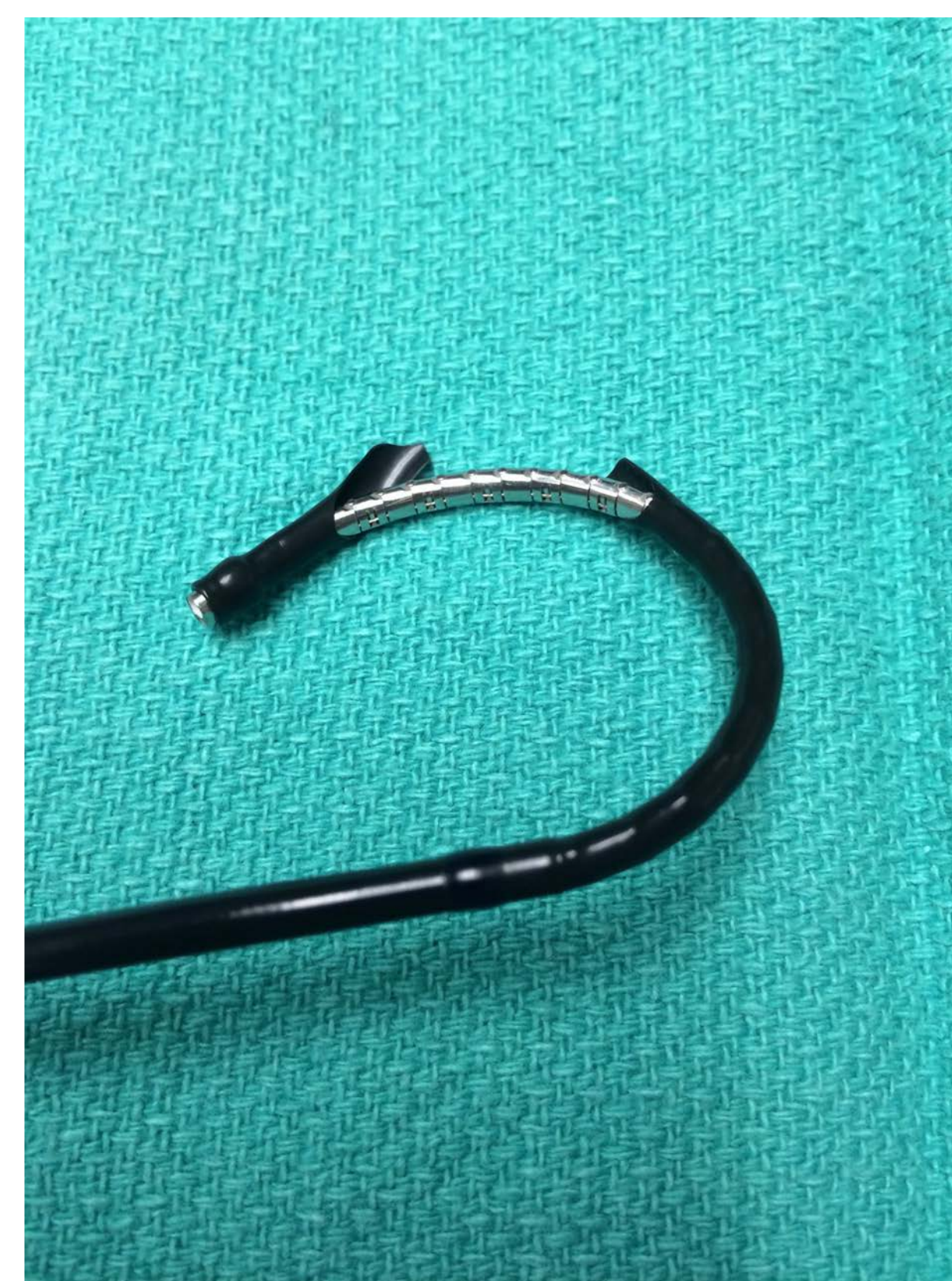
- To determine the rate of encountering unsuitable reusable flexible ureteroscopes at the initiation of a case.

Patients and Methods

- Prospective analysis of 228 Consecutive cases of Flexible Ureteroscopy over 6 months.
- Available Flexible Ureteroscopes included 18 Fiberoptic and 4 Digital Instruments.
- Number of Ureteroscopes needed to be unpackaged in order to initiate the case was recorded as well as problems encountered with ureteroscopes upon opening sterile packaging. Ureteroscope damage incurred during the case was not an endpoint of this study.
- All ureteroscopes are grossly cleaned by nursing immediately after clinical use.
- Central processing is responsible for final cleaning, rinsing, sterilization (STERRAD) and packaging.
- Third party repair service manages repairs as ordered by attending physician.

Clinical Criteria for Acceptable Flexible Ureteroscope Use

- Reasonable visualization
- Reasonable bidirectional deflection
- Working channel able to accept instruments / laser fibers
- No gross contamination
- No over structural damage or deformity to ureteroscope components
- No violation of sterile packaging



Damaged distal bending rubber from improper sterilization technique.



Dried cleaning solution on the flexible ureteroscope tip.

Results

- Of 228 consecutive cases, a total of 261 reusable flexible ureteroscopes were unwrapped and 207 (91.0%) of cases were initiated with the first instrument opened .
- In 21 (9.2%) cases, two ureteroscopes needed to be opened in order to initiate the case. In one case each, 3, 4 and 5 ureteroscopes were opened in order to attempt to start the case.
- One case needed to be rescheduled after 4 consecutive instruments were opened and all were unsuitable for case initiation.
- **Overall, a total of 33 ureteroscopes were unsuitable for immediate use of those 261 which were opened = 12.6% unsuitable for immediate use.**

REUSABLE FLEXIBLE URETEROSCOPES UNFIT FOR IMMEDIATE USE

| | |
|---|----------|
| Broken Deflection | 39% (14) |
| Dried cleaning solution on ureteroscope tip | 14% (5) |
| Inability to pass laser fiber through working channel | 14% (5) |
| Distal bending rubber damaged | 5.5% (2) |
| Dislodged digital camera | 5.5% (2) |
| Digital image failure | 8.3% (3) |
| Broken fiberoptics | 5.5% (2) |
| Crushed proximal shaft | 2.8% (1) |
| Optical failure | 2.8% (1) |
| Missing sterilization cap | 2.8% (1) |

* Of note, 36 instances of damage reported for 33 ureteroscopes

Conclusions

- In this academic, single institutional study, the rate of encountering an unsuitable flexible ureteroscope at the initiation of the case was 12.6%. This may vary among institutions but can aid in cost justification for single use ureteroscopes.
- Etiologies for these problems include processing errors as well as delay in sending ureteroscopes out for repair.
- In addition to case inefficiency, these instrument problems pose potential patient safety issues if not proactively identified prior to instrument use.
- This represents an immediate area for improvement with single-use instrument utilization.
- Sterile processing is currently undergoing retraining on proper handling of urology endoscopes. In a follow up study, we will assess the quality of the reusable ureteroscopes after retraining.
- We are currently working with several companies and have trialed different single use ureteroscopes at different price points. The next step will be to further assess the cost of acquiring single use ureteroscopes versus maintaining reusable ureteroscopes.

References

1. Martin CJ et al. J Urol 2017; 197: 730 – 735.
2. Knudsen B et al. Urology 2010; 75: 534 - 538.
3. Monga M et al. J Urol 2006; 176: 137 - 141.