Evaluation of the mechanisms of damage to flexible ureteroscopes and suggestions for ureteroscope preservation

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Abstract

Aim: To investigate the causes and costs of flexible ureteroscope damage, and to develop recommendations to limit damage. Methods: The authors analysed repair figures and possible causes of damage to 35 instruments sent for repair to a leading UK supplier over a 1-year period, and calculated cost figures for maintenance of the instruments as opposed to repair and replacement costs. Results: All damages were handling-induced and therefore did not fall under the manufacturer’s warranty: 28% were damaged by misfiring of the laser inside the instrument; 72%, mainly crushing and stripping of the ureteroscope shaft tube, were likely to have occurred during out-of-surgery handling, washing and disinfection. Seventeen (4%) instruments were not repaired and consequently taken out of service due to the extensive costs involved. Eighteen (51%) ureteroscopes were repaired at an average cost of 10 833 USD. Conclusion: Damages to flexible ureteroscopes bear considerable costs. Most damages occur during handling between surgical procedures. Thorough adherence to handling procedures, and courses for theater staff and surgeons on handling flexible instruments may help to reduce these damages and prove a cost-saving investment. The authors provide a list of recommended procedural measures that may help to prevent such damages. (Asian J Androl 2005 Dec; 7: 433–438)

Keywords: ureteroscopes; manufacturer’s assessment; durability; instrument handling

1 Introduction

Flexible ureteroscopy (URS) is widely practised as a diagnostic and therapeutic urological procedure. Ureteroscopes were originally constructed as large 12–14 F (French; 3F=1mm diameter) instruments. This size was associated with significant drawbacks because of traumatization of the ureter. With the introduction of semi-rigid instruments with a tip diameter of 6.9–9.4 F, URS became easier and more user-friendly for the surgeon and less traumatic for the patient [1], which led to its wider acceptance as the treatment modality of choice in many cases of ureteric pathology. However, with semi-rigid URS, it remained difficult to reach the upper third of the ureter and intra-renal surgery was not possible. With the advent of fully flexible ureteroscopes of an outer tip diameter of 7.5 F, it is now possible to examine the entire collecting system, permitting endourologists to treat a variety of conditions with a retrograde approach, such as caliceal diverticula with and without stones [2, 3], upper tract transitional cell carcinoma [4, 5], pelvi-ureteric junction obstruction [6] and calculi in most if not all parts of the kidney [7, 8].

To avoid dilatation and trauma of the ureter and to ease the introduction of the ureteroscope, the outer di-
ameter of the distal tip of the scope should be < 9 F. Inevitably, with decreasing size the instruments have become very fragile. This does not only affect the delicate mechanisms inside the instruments, but also the handling intraoperatively and postoperatively. Reports of between 6 and 15 uses per instrument before damage [9], and average repair costs of around 7 500 USD per instrument have discouraged many users. Currently there are four main manufacturers of flexible ureteroscopes worldwide. The instruments are the Olympus URF-P3 (KeyMed, Southend-on-Sea, UK), the DUR-8 (ACMI, Southborough, MA, USA), the DUR-8 Elite (ACMI, Southborough, MA, USA), the Storz 11274AA (Karl Storz, Tuttlingen, Germany) and the Wolf 9F (Henke Sass Wolf, Tuttlingen, Germany). These five instruments have been assessed as to their ease of insertion, their deflection mechanism, maneuverability, rigidity, image quality, and overall satisfaction as judged by two independent endourologists [10]. However, the instruments have not been assessed and compared in terms of durability. To our knowledge, no significant data have been reported as to how and why ureteroscopes get damaged. Also, whereas there are a number of individual recommendations to avoid instrument damage, to our knowledge there have not been any comprehensive reports listing these recommendations together. Therefore, the aim of this study was to elucidate the nature of damages to the instruments and to propose measures to avoid these during operation and storage.

2 Materials and methods

We reviewed the repair and cost records of a representative number of all ureteroscopes in clinical use in the UK that were supplied by KeyMed, one of the four main manufacturers of flexible ureteroscopes in the UK, over a 1–year period (February 1, 2002–January 31, 2003). This manufacturer supplied a large proportion of the flexible ureteroscopes sold in the UK during the time period studied, when flexible URS was still an emerging technique.

Records were analysed as to the number and nature of damages to the instruments and associated repair costs. The reasons for repair/return and the nature of damage were obtained from inspection reports from the technical staff of the supplier. In order to achieve a balanced assessment, clinicians and engineers together reviewed and discussed the types of damages, their likely causes and mechanisms.

Based on those figures and our own review of published reports, extensive discussions with the company’s technical experts resulted in a number of recommendations for the use and handling of the ureteroscopes.

3 Results

We were able to survey the records of 78 flexible ureteroscopes (Olympus URF-P3) of which 48 (61 %) were returned to the manufacturer during the study period. Thirteen (27 %) were sent in for scheduled servicing as recommended by the manufacturer (every 6–12 months), and 35 (73 %) were returned due to damage. Of the 35 damaged ureteroscopes, 18 (51 %) were successfully repaired and returned to the customer. In 17 cases (49 %), because of major repair costs, the customers chose not to repair the instrument, effectively taking it out of use.

The servicing, damage and repair histories of the 48 ureteroscopes sent in to the supplier were listed in Table 1. Based on detailed engineering reports and photographs of the damaged ureteroscopes, the types of damages were

Table 1. Damages to ureteroscopes. BSR, bending section rubber; N/A, not applicable.

| Reason for return                                      | Suspected cause                                      | n    | No. of service (unrepaired) |
|-------------------------------------------------------|------------------------------------------------------|------|-----------------------------|
| Scheduled service                                      | N/A                                                  | 13   | 0 (0 %)                     |
| Damaged/leaking biopsy channel                        | Misfiring laser                                      | 10   | 5 (50 %)                    |
| Crushed shaft                                         | Trapped in storage cupboard or carrying case          | 15   | 6 (40 %)                    |
| Leak from BSR                                         | Injury from surgical instruments (scalpel, clip, etc.) or disinfection (i.e. soaking in ethanol) | 6    | 4 (66 %)                    |
| Stretched shaft                                       | Over-vigorous cleaning of patient tube               | 2    | 1 (50 %)                    |
| Seized (jammed) BSR                                   | Internal fluid contamination (i.e. leak from BSR due to external injury) | 2    | 1 (50 %)                    |
| Total damages/off service scopes                      |                                                      | 35   | 17 (49 %)                   |
reviewed and discussed by clinicians and engineers with a view to establishing the likely causes and mechanisms of damage. Laser damages caused by the misfiring of the laser inside the scope by the surgeon (28%) were easily identified. Crush and strip damages to patient tubes were typically too extensive (Figures 1–3) to be caused during surgical handling under intra-operative conditions, assuming basic standard surgical expertise. Other damages (listed in Table 1) were also typical for damages occurring during washing and disinfection processes. It can therefore be safely assumed that most, if not all, of these damages (72%) occurred in storage and handling other than during the operation itself.

Repairing flexible ureteroscopes usually carried considerable costs. These were listed in Table 2. The instruments come with a 6-month warranty against failure from manufacture. It was notable that none was returned under the manufacturer’s warranty, hence all costs had to be borne by the customers. The lifespan of the 78 flexible ureteroscopes surveyed ranged from 1 month (major damage occurred on first use) to 4 years. Data on the number of procedures performed during those time spans were not available.

4 Discussion

Flexible ureteroscopes are very delicate instruments notorious for their limited durability and the high costs associated with repairing them. They are composed of several equally delicate components with sensitive technology fitted into a tight space.

The most vulnerable part of the ureteroscope is the shaft (Figure 4). In spite of housing a number of micro-technology components, this must be flexible, crush resistant, and exert torque control. The patient tube has three fused layers: an outer fluid-resistant layer, a middle metal braid layer and an inner metal coil layer. Within the instrument there is also an optical system that consists of a coherent optical fibre bundle for image transmission (6 000 fibres of 70 µm diameter) and an incoherent light transmission bundle. The remaining components of the flexible ureteroscope are the irrigation/biopsy channel (1.2 mm in diameter) and the bi-directional angulation guidewires that allow the scope to change direction without altering its internal diameter (Figure 5).

Given this particular construction, downsizing the instruments to a clinically optimised diameter made them inevitably more fragile than larger instruments, with one or several of the components of the shaft being the most frequently damaged [9]. The same study found that flexible ureteroscopes required repair following 6–15 single uses; it would have been of great interest to assess the number of procedures performed during those time spans. Data on these numbers were not available.

Table 2. Costs associated with damaged ureteroscopes.

| Damage                                | Cost per scope (in $US) | Mean (in $US) | Total cost per year (in $US) |
|---------------------------------------|-------------------------|---------------|------------------------------|
| Scheduled service                     | 120–363                 | 300           | 3 900                        |
| Reparable damage                      | 910–10 596              | 10 833        | 195 000                      |
| Irreparable damage; need for replacement | 7 470–22 500           | 12 944        | 220 050                      |

Figure 4. Photograph of a flexible ureteroscope with the flexible shaft (patient tube) indicated between the arrows.
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usage histories of the damaged instruments assessed in our study. Unfortunately, we did not gain access to the individual instruments’ histories and were unable to determine the number of usages from the available data. Nevertheless, our own experience with two identical instruments was that they were damaged after 7 uses (laser injury) and 13 uses (crushed shaft), respectively. This is consistent with the published reports [9].

However, several authors have suggested that the routine application of ureteroscopic accessories could make a substantial difference in endoscope durability. Through the regular and routine use of accessories such as the ureteral access sheath, ultra-thin 200 µm holmium laser fibers, and Nitinol devices for manipulation of stones, the longevity of flexible ureteroscopes has been prolonged beyond that previously reported series to 27.5 uses on average [11]. The ureteral access sheath has been shown to facilitate access to the upper urinary tract and reduce the stress on the tip of the ureteroscope following the advancement of the instrument through the ureteral orifice [12, 13]. Nitinol devices (such as graspers and baskets) and ultra-thin laser fibers reduce the strain on the angulation mechanism of the scope and preserve its deflectability to a high degree, which is particularly important in the management of lower pole calculi [12, 14, 15].

In addition, maintaining a straight alignment of the part of the ureteroscope that remains outside the body during a procedure can enhance deflection of the working tip, preventing undue stress and strain on the working elements [13].

Somewhat to the contrary, another study found no significant impairment in instrument handling by the use of working channel catheters during flexible ureteroscopic laser lithotripsy. These catheters are designed to protect the patient tube from laser damage. As the instruments were more rigid with these catheters inside them, the authors suggested that the ureteroscopes would potentially be more durable and robust [16]. Although the catheters may have some protective effect, it has to be borne in mind that, especially in lower pole stone manipulation and intra-renal surgery, we need to have all possible deflection available. Therefore, these assumptions have to be considered critically.

In a further development, Circon ACMI (ACMI, Southborough, MA, USA) took up the idea of stiffening and thus keeping straighter [13] the more proximal shaft parts of the instruments while preserving a small flexible distal tip. Their DUR-8 model promised increased working tip flexibility with simultaneously enhanced overall durability of the instrument. Indeed, initial studies showed a continued function for these instruments of at least 25 single uses before repair [13]. More recently, the company marketed the DUR-8 Elite which introduced a secondary deflection that may be helpful, particularly in accessing the lower renal pole. According to the manufacturer, this additional feature does not compromise the longer durability achieved with the DUR-8. Significant clinical numbers have yet to be published to make a confident statement.

Cleaning techniques have also been suspected to damage the instruments. A variety of cleaning techniques are available, from manual methods to automatic disinfection [17]. It has been reported that neither the cleaning technique used nor the number of personnel involved in the cleaning and maintenance of flexible ureteroscopes has a significant effect on their durability or function [18].

It is commonly believed that misfiring the laser within or too near the patient tube damages most flexible ureteroscopes [19]. Our data suggest that laser burns account for only 28% of damages.

Somewhat to our surprise, and in contrast to other reports [18, 19], it emerged that 72% of damages occurred during out-of-patient handling, cleaning and storage where usually the surgeon is not involved. In particular, we noticed a high percentage of instrument shafts (43%) damaged in this way, which most probably resulted from trapping the instrument within the lid of a storage box or cupboard. Our data differ from previous reports [18] in that, in our study, all damages were assessed by engineering staff at the manufacturer’s plant then discussed with clinical staff, as opposed to assess-

Figure 5. Close-up photograph of a flexible ureteroscope tip with working elements.
ment by clinical personnel only; we also assessed a much larger number of damages than previous reports. Furthermore, the purpose of the cited study [18] was to investigate whether different techniques of normal handling and cleaning methods caused more damage than surgical usage. It is therefore not directly comparable to our study, which looked at instruments that were actually non-functional due to customer-related damage.

It appears from our findings that the key to avoiding damage lies not only in more careful operating on the side of the surgeon, but in better training of the support staff. Training of support staff may have been neglected in the past due to the extra costs involved. Without doubt, the costs to the consumer for the repair or replacement of the ureteroscopes are substantial and stand in no relation to the costs of training courses. For many hospitals, the costs of repair are prohibitive. Our data suggest that in 48% of damages they chose to take the instrument back unrepaired, effectively taking a $US20 000 investment out of action.

Many hospitals also avoid the cost of a service contract. The cost of such a contract is negligible compared to that of repairing or replacing the instrument. According to our data, ureteroscopes that were serviced regularly lasted longer (mean > 2 years) compared to those not routinely serviced (mean < 1 year). Depending on the particular instrument a service would involve some or all of the following: 1) full functional assessment; 2) cleaning and disinfection; 3) brushing and cleaning of the channel; 4) exterior cleaning of the instrument; 5) replacement of the outer cover of the bending section; 6) leak testing pre- and post-servicing; and 7) re-adjustment of the angulation wires. In contrast, a major repair would usually involve replacement of the patient tube assembly with the installation of a new optical and light transmission fiber-optic system, a new channel system, and a new angulation system (bending section). Basically, this is a partial replacement of the whole unit except the control body and/or the light guide tube and eyepiece.

Apart from the recommendation in a previous report about the use of special ureteroscopic accessories, extensive discussion with the engineering staff on the basis of this damage analysis led to the following suggestions to avoid damages. The suggestions refer to three categories: 1) use of the ureteroscope; 2) care of the ureteroscope; and 3) maintenance of the ureteroscope.

4.1 Use of the ureteroscope
• X-ray image intensification should always be used to ensure that sharp-tipped accessories (e.g. laser fibers) are only passed when the instrument is in straight alignment and within the urinary tract.
• The ureteroscope should be as straight as possible during insertion to maximize torque and avoid tight curvatures. Insertion may be aided by a guidewire. There are specially designed double-flexible guidewires that have a flexible Teflon coated non-traumatic tip on both ends and a stiff shaft. This avoids damage to the ureter and the instrument but provides good stability to safely introduce the instrument.
• The laser aiming beam should always be used to make the laser tip visible. Accidental firing of the laser within the instrument must be avoided:
  Take your foot off the pedal if you don’t see the laser fiber!
  and
  If you don’t see red, your scope is dead!
(R. V. Clayman, personal communication) may be helpful hints to memorize.

4.2 Care of the ureteroscope
• Kinking or crushing of the patient tube must be avoided. The instrument should be kept in a designated storage cupboard and have its own carrying case large enough for transportation.
• The ureteroscope should be kept on its own trolley and other instruments should not be placed on it.
• Care should be taken not to drop the instrument.
• The leak test should be performed before and after each use of the ureteroscope.

4.3 Maintenance of the scope
• The ureteroscope should be routinely serviced every 6 months.
• The ureteroscope should be disinfected with a solution approved by the design authority.
• As soon as a problem is identified the scope should be sent in for repair without further use.
• The instruments should be traceable, that is, there should be a user log for accountability purposes.

We believe that adherence to these suggestions should dramatically decrease the frequency and severity of damages to flexible ureteroscopes, which in turn would lessen the costs of repair. Laser courses for surgeons and main-
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Maintenance courses for support staff [20] can be very helpful and hopefully will get more popular in future. We hope that, armed with a better understanding of the types of damage and their underlying causes, as shown in this study, endourologists and theatre personnel will follow these suggestions.

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