The reused-disposable scope in flexible ureteroscopy for stones as a cost-conscious approach: Reporting the outcomes of a real-world practice multicenter study of 2183 patients by the team of worldwide endourological researchers group

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# **ABSTRACT**

**Introduction:** We aimed to assess complications and stone-free rate of flexible ureteroscopy (FU) reusing disposable scopes (RDS) after repeated sterilization.

**Methods:** Data from adults from 11 centers were retrospectively reviewed (January 2020–December 2022). Inclusion criteria were proximal ureteral/renal stone(s). All cases were performed using an RDS to save costs for patients who come from economically challenged environments. Residual fragments (RFs) were defined as single fragment ≥4 mm or multiple fragments of any size within 3 months. Continuous variables are presented as median and interquartile range. **Results:** Two thousand one hundred and eighty-three patients were included, of whom 67.0% were male. Median age was 48.0 (36–59) years. The median stone diameter was 10.2 (9–14) mm. Flash sterilization was used in 90.2% (plasma in 60.5%). Approximately, 88% had FU with an RDS used ≤2 times (12%: 3–5 times). RDS needed to be changed intraoperatively in 3.9% of cases due to its malfunction. Commonly, defects in RDS function were reported in upward (1.6%) and downward deflection (6.5%) and image quality on white balancing (4.7%). Fever >38C was seen in

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13.7% of cases, and sepsis in 0.5%. RFs were found in 31.4% of cases. Lower pole (odds ratio [OR] 5.63) or pelvis stone (OR 4.67), faulty scopes (OR 12.8), and total operation time (OR 1.05) were factors associated with higher odds of RFs. Stone size (OR 1.09), positive urine culture (OR 1.67), interpolar stone (OR 1.68), and prestenting (OR 1.37) were factors associated with higher odds of fever/sepsis. **Conclusions:** RDS was used as a cost-conscious approach with a low rate of serious infections but with a high rate of RFs.

### INTRODUCTION

Flexible ureteroscopy (FU) is recognized as a first-line minimally invasive approach for renal stones up to 2 cm.<sup>[1-3]</sup> Since the introduction of the first single-use flexible scope, there is sufficient evidence comparing the utility and success rates of FU with single-use scope (SUS), and re-usable scopes. Advantages of SUS include better ergonomics,<sup>[4]</sup> avoiding nuances of re-sterilization, possible reduction of postoperative infections, and higher stone-free rate (SFR) due to the full range of functions per case.<sup>[5]</sup>

We asked colleagues regarding the practice of FU by reusing SUS after repeated sterilization, akin to reusable fiberoptic or digital scopes. We received a positive reply from 11 centers willing to share data for analysis. Surgeons remarked unanimously that the reason for this practice is to save costs for patients.

This study aimed to understand the outcomes of FU for renal/proximal ureteric stone(s) with regards to residual fragments (RFs) and their effect on sepsis using what is defined as Reused-Disposable Scopes (RDS).

## **MATERIALS AND METHODS**

The Team of Worldwide Endourological Researchers group, a research wing of the Endourological Society collaborated on a multicenter database for FU for renal and proximal ureteric stones using RDS. Procedures were performed between January 2020 and December 2022 in 11 centers from 6 countries [Supplementary Figure 1]. Inclusion criteria were adult patients who underwent FU for proximal ureteric or renal stones using any RDS scope only. Distal ureteric stones, procedures for endoscopic combined intrarenal surgery, and simultaneous bilateral endoscopic surgery were excluded. In patients presenting with a positive urine culture, a full course of antibiotics according to sensitivity was given before surgery. Antibiotic prophylaxis was performed according to each center's protocol and as per local sensitivity. Sepsis was defined according to the Third International Consensus Definitions (sepsis-3) by the presence of at least two clinical criteria that comprise the quick sequential organ failure assessment score.[6]

Patients were assessed postprocedure according to the local standard of care, with X-ray and/or ultrasound or noncontrast computed tomography (CT) scan. RFs were defined as single fragment ≥4 mm or multiple fragments of any size diagnosed within 3 months. Secondary treatment was performed if significant RFs were present or at the discretion of the treating physician.

Data on how many times each RDS had been used prior, the method of sterilization, the scope mechanism at the time of use, and the maximum times a scope would be used as per surgeons' discretion was acquired.

#### Disclosures and disclaimer

The authors and investigators would like to make the following disclosures and disclaimers:

- A. Disposable scopes are SUS or limited-use scopes as per the manufacturer's recommendations and hence our intention is only to report outcomes of FU if these scopes are sterilized and used. We ascertain that repeat use of SUS is currently not recommended by any guidelines and is not a standard practice
- B. It is not our intention to disregard any standardized policy. There may be medicolegal implications and urologists should follow their local regulations
- C. Data were collected from centers that perform this procedure and declare that appropriate regulatory approvals from their institution have been obtained as well as appropriate written consents from patients on the use of these scopes were obtained by open disclosure statements
- D. While the contributing centers admit that utmost care was taken to follow evidence-based recommendations for repeat use of consumables by strictly following the sterilization principles and infection control regulations in their health care systems, it is no way to be taken as regulatory or standard of care or even as accepted or approved practice
- E. Ethical board approvals were obtained from each center to provide anonymized data that was compiled by the investigating center which had its regulatory approval to analyze this data. Anonymized data were collated in a registry created and maintained by the primary center (Asian Institute of Nephrology and Urology, Hyderabad, India, approval number AINU07/2023).

#### Statistical analysis

Continuous data are reported as medians and interquartile ranges. Categorical data are presented as absolute numbers and percentages. Two separate multivariable analyses were performed for the outcome of RFs and fever/sepsis. Data are presented as odds ratio (OR), 95% confidence interval (CI), and P value. All statistical tests were carried out in R version 4.3.0 (R Foundation for Statistical Computing, Vienna, Austria), with P < 0.05 regarded to indicate statistical significance.

#### RESULTS

Two thousand one hundred and eighty-three cases were

included [Table 1] of whom 67.0% were male. Median age was 48 (36–59) years and 38.8% of patients were prestented to relieve an obstruction or as part of a staged FU intervention. A positive preoperative urine culture was seen in 10.2% of patients, 77.9% of patients received an antibiotic course as per the surgeon's preference or according to institutional protocols before intervention. Solitary renal stones were found in 54.4%.

An RDS used only up to two times before the reported procedure was the most common (88.0%), while 12.0% of patients had FU with an RDS used in more than 2 cases but up to a maximum of 5 times prior [Table 2]. The following scopes were re-used: LithoVue™ (Boston Scientific, Marlborough, MA), Uscope (Pusen Medical Technology, Zhuhai, Guangdong China), Indoscope Sleek (Biorad MediSys, Pune, Maharashtra, India), HU 30 (Shenzhen HugeMed Medical Technical Development Co. Ltd, Shenzhen, Guangdong, China), WiScope (INNOMEDICUS, Cham, Switzerland) and Innovex scope (Anqing Topeak Medical, Anqing City, China) depending on the availability of the scope at each center.

| Table 1: Patient baseline characteristics |                 |  |  |
|---|-----------------|--|--|
| Number of patients                        | n=2183          |  |  |
| Age, median (IQR)                         | 48 (36-59)      |  |  |
| Male (%)                                  | 1463 (67.0)     |  |  |
| BMI, median (IQR)                         | 25 (23–28)      |  |  |
| Diabetes mellitus, n (%)                  | 377 (17.3)      |  |  |
| High blood pressure, <i>n</i> (%)         | 466 (21.3)      |  |  |
| Presentation, n (%)#                      | , ,             |  |  |
| Hematuria only                            | 51 (2.3)        |  |  |
| Pain only                                 | 1586 (72.7)     |  |  |
| Hematuria and pain                        | 338 (15.5)      |  |  |
| Fever                                     | 218 (10.0)      |  |  |
| Urine culture positive                    | 223 (10.2)      |  |  |
| Indications for intervention, n (%)       |                 |  |  |
| Recurrent stone former                    | 741 (33.9)      |  |  |
| Elevated creatinine                       | 346 (15.8)      |  |  |
| Incidental                                | 177 (8.1)       |  |  |
| Pain                                      | 1952 (89.4)     |  |  |
| Clear fragments from past intervention    | 163 (7.5)       |  |  |
| Patient profession needs it               | 42 (1.9)        |  |  |
| Prestented, n (%)                         | 846 (38.8)      |  |  |
| Preoperative antibiotics*, n (%)          | 1701 (77.9)     |  |  |
| Preoperative imaging, n (%)               |                 |  |  |
| CT, noncontrasted                         | 1178 (54.0)     |  |  |
| CT, contrasted                            | 997 (45.7)      |  |  |
| Single stone, <i>n</i> (%)                | 1188 (54.4)     |  |  |
| Stone size (mm), median (IQR)             | 10.2 (9.0-14.0) |  |  |
| Classification (mm), n (%)                |                 |  |  |
| Single < 15                               | 861 (39.4)      |  |  |
| Single ≥ 15                               | 327 (14.9)      |  |  |
| Multiple                                  | 995 (45.7)      |  |  |
| Stone location(s), n (%)*                 |                 |  |  |
| Upper pole                                | 533 (26.0)      |  |  |
| Interpolar                                | 559 (27.2)      |  |  |
| Lower pole                                | 800 (39.0)      |  |  |
| Pelvis                                    | 943 (46.0)      |  |  |
| Proximal ureter                           | 226 (11.0)      |  |  |

<sup>\*</sup>Any case including those with and without positive cultures, #More than one possible. IQR=Interquartile range, CT=Computed tomography, BMI=Body mass index

Sterilization using the flash technique (90.2%) was the preferred way [Table 2], followed by plasma (60.5%), gas (0.3%), peracetic acid (20.3%), and ethylene oxide gas (17.5%) either independently or as a combination. Median laser time was 21 (15–39) min and operative time defined as the time from the start of ureteroscopy to stent placement was 56 (40–66) min.

Despite a noted scope defect, scopes were still used in 163 patients (7.5%). The most common issue was downward deflection (6.5%) followed by image quality on white balancing (4.7%). On table, RDS was changed in 85 (3.9%) cases; most were due to poor and flickering image quality, whereas in 25 cases, the deflection mechanism failed. In 2 cases (0.09%), the procedure was abandoned due to difficulty in accessing the stone. Type 2 ureteric access sheath Traxer and Thomas classification lesion<sup>[7]</sup> was reported in 3.5% of cases and had stenting done [Table 3]. Postoperative day 1, fever was the main complication seen in 13.7% of cases, while sepsis occurred in only 0.5%. RFs were noted in 31.4% of cases.

| Table 2: Operative characteristics               |                          |
|--|--------------------------|
| Number of patients                               | n=2183                   |
| Number of cases in which the scope was used      |                          |
| before this case, n (%)                          |                          |
| ≤2   | 1921 (88.0)              |
| >2 up to 5                                       | 262 (12.0)               |
| Scope size (Fr), n (%)                           |                          |
| ≥8   | 1386 (63.5)              |
| 7.5  | 797 (36.5)               |
| General anesthesia, n (%)                        | 2056 (94.2)              |
| Ureteral access sheath, n (%)                    | 2138 (97.9)              |
| Sterilization, n (%)*                            |                          |
| Flash sterilization                              | 1749 (90.2)              |
| Plasma   | 1171 (60.5)              |
| Gas  | 5 (0.3)                  |
| Peracetic acid                                   | 392 (20.3)               |
| ETO  | 339 (17.5)               |
| Scope testing results, <i>n</i> (%)              |                          |
| Problem in mechanism noted before/during case,   | 163 (7.5)                |
| but continued and completed case                 | 0= // ()                 |
| Upward deflection affected                       | 35 (1.6)                 |
| Downward deflection affected                     | 142 (6.5)                |
| Image quality affected on white balancing        | 104 (4.7)                |
| Working channel affected                         | 3 (0.13)                 |
| Scope changed during case, <i>n</i> (%)          | 85 (3.9)                 |
| Image quality poor with flickering               | 81 (3.7)                 |
| Deflection mechanism stopped                     | 25 (1.1)                 |
| Problems passing basket/laser in working channel | 12 (0.5)                 |
| Case abandoned due to scope malfunction          | 2 (0.09)                 |
| Case completed using alternate scope for the     | 84 (98.8)                |
| 85 cases   |                          |
| Laser, n (%)                                     | 004 (45.0)               |
| Thulium fiber laser                              | 994 (45.9)               |
| Holmium laser without + with Moses technology    | 1171+18 (54.1)           |
| Basketing, n (%)                                 | 818 (37.5)               |
| Laser time, median (IQR)                         | 21 (15-39)<br>56 (40-66) |
| Total operation time, median (IQR)               | 30 (40-00)               |

<sup>\*</sup>More than one modality possible (combination of modalities). IQR=Interquartile range, ETO=Ethylene oxide

Multivariable analysis of RF [Table 4] showed that stone in the lower pole (OR 5.63, 95% CI 2.21–16.4, P = 0.001) or pelvis (OR 4.67, 95% CI 1.72–14.7, P = 0.004), faulty scope changed during the case (OR 12.8, 95% CI 3.21–69.4, P = 0.001), and total operation time (OR 1.05, 95% CI 1.03–1.08, P < 0.001) were factors significantly associated with higher odds of RF, while age (OR 0.96 95% CI 0.94–0.98, P < 0.001) and prestenting (OR 0.32, 95% CI 0.17–0.60) was associated with lower odds of RF.

Stone size (OR 1.09, 95% CI 1.04–1.15, P < 0.001), positive urine culture (OR 1.67, 95% CI 1.05–2.57, P = 0.024), interpolar stone (OR 1.68, 95% CI 1.23–2.29, P = 0.001), and prestenting (OR 1.37, 95% CI 1.01–1.85, P = 0.039) were associated with higher odds of having postoperative fever/sepsis [Table 5].

### **DISCUSSION**

While controversial, the use of SUS as a limited-use RDS is drawn from cost economics and patient affordability in low-income countries. Perhaps, it allows certain patients access to this treatment modality which might otherwise be cost-prohibitive and lead to more invasive treatment options. Therefore, it is paramount that these patients are counseled and consented about the re-use of these scopes, and a vigilant approach is needed to identify and treat any complications.

The reuse of single-use medical devices began in the late 1970s as a cost-saving measure. Approximately 20%–30% of U.S. hospitals reported that they reuse at least one type of single-use device. Reuse of single-use devices involves regulatory, ethical, medical, legal, and economic issues and has been extremely controversial. However, in recent times, there have been arguments that ethically favor this provided they fulfill certain parameters and framework modules based on some established recommendations by certified bodies [9] [Supplementary Table 1].

FU has become a standard of care in adults<sup>[10]</sup> and children,<sup>[11]</sup> and is safe and effective in young and elderly alike.<sup>[12]</sup> Urologists choose disposable scopes for bigger, lower pole, and harder stones to improve the single-stage SFR.<sup>[5]</sup> Digital reusable scopes have some critical issues such as high acquisition costs, limited durability, high repair costs, and sterilization and reprocessing expenditures.<sup>[13]</sup> Companies often advertise that SUS is lightweight and can even minimize the rate of postoperative infection as studies investigating the effectiveness of sterilization of reusable ureteroscopes demonstrate that reprocessing methods were insufficient and could lead to contamination of the instruments which translates as postoperative fever or worse cases may contribute to sepsis.<sup>[14]</sup> Hence, this in theory also poses the same risk for RDS.

| Table 3: Intraoperative and postoperative outcomes                                      |   |  |  |
|---|---|--|--|
| Number of patients  | n=2183                                  |  |  |
| All causes PCS injury needing stenting alone (Clavien 2), n (%)                         | 426 (19.5)                              |  |  |
| Ureteric injury not due to UAS, needing nephrostomy or stenting (Clavien 3), n (%)      | 28 (1.3)                                |  |  |
| Type 2 ureteric injury due to access sheath, needing stenting (Clavien 2), <i>n</i> (%) | 76 (3.5)                                |  |  |
| Postoperative day 1 fever >38°C (Clavien 2), <i>n</i> (%)                               | 299 (13.7)                              |  |  |
| Sepsis needing ICU admission (Clavien 4), n (%)   | 12 (0.5)                                |  |  |
| Residual fragments, n (%)   | 686/2183 (31.4)                         |  |  |
| Single >4 mm  | 492/686 (71.7)                          |  |  |
| Multiple  | 194/686 (28.3)                          |  |  |
| Post-FU re-intervention ( <i>n</i> =686), <i>n</i> (%)                                  | , |  |  |
| Shock wave lithotripsy  | 214 (31.2)                              |  |  |
| FU  | 286 (41.7)                              |  |  |
| Percutaneous nephrolithotripsy  | 14 (2.0)                                |  |  |
| On follow-up  | 172 (25.1)                              |  |  |
| Postoperative imaging, n (%)  |   |  |  |
| Noncontrast CT  | 1006 (46.1)                             |  |  |
| Plain X-rays  | 195 (8.9)                               |  |  |
| Ultrasound  | 419 (19.2)                              |  |  |
| Combination of X-rays and ultrasound  | 563 (25.8)                              |  |  |
| Residual fragments according to imaging modality, $n$ (%)                               |   |  |  |
| CT scan ( <i>n</i> = 1006)  |   |  |  |
| Single >4 mm  | 243 (24.1)                              |  |  |
| Multiple  | 52 (5.2)                                |  |  |
| Plain X-rays (n=195)  | ,                                       |  |  |
| Single >4 mm  | 45 (23.1)                               |  |  |
| Multiple  | 28 (14.3)                               |  |  |
| Ultrasound (n=419)  | ,                                       |  |  |
| Single >4 mm  | 66 (15.7)                               |  |  |
| Multiple  | 42 (10.0)                               |  |  |
| Combination of X-rays and ultrasound ( <i>n</i> =563)                                   | ,                                       |  |  |
| Single >4 mm  | 138 (24.5)                              |  |  |
| Multiple  | 72 (12.8)                               |  |  |

CT=Computed tomography, ICU=Intensive care unit, PCS=Pelvicalyceal system, FU=Flexible ureteroscopy, UAS=Ureteric access sheath

Table 4: Multivariable logistic regression analysis of factor affecting residual fragments

| 3 11 13 13                           |      |           |         |
|--------------------------------------|------|-----------|---------|
|                                      | OR   | 95% CI    | P       |
| Age                                  | 0.96 | 0.94-0.98 | <0.001  |
| Stone size                           | 1.01 | 0.94-1.07 | 0.873   |
| Stone location                       |      |           |         |
| Upper pole                           | 0.96 | 0.39-2.80 | 0.940   |
| Interpolar                           | 1.08 | 0.38-3.40 | 0.893   |
| Lower pole                           | 5.63 | 2.21-16.4 | 0.001   |
| Pelvis                               | 4.67 | 1.72-14.7 | 0.004   |
| Proximal ureter                      | 0.51 | 0.18-1.59 | 0.218   |
| Pre-stenting                         | 0.32 | 0.17-0.60 | < 0.001 |
| Scope used for >2 cases before       | 0.73 | 0.35-1.52 | 0.390   |
| (reference ≤2)                       |      |           |         |
| Faulty scope changed during the case | 12.8 | 3.21-69.4 | 0.001   |
| Total operation time                 | 1.05 | 1.03-1.08 | < 0.001 |

CI=Confidence interval, OR=Odds ratio

For sterilization purposes, different methods were used alone or in combination strictly as per regulations. Flash sterilization was the most common approach (90.2%). "Flash" steam sterilization was originally defined as the sterilization of an unwrapped object at 132°C for 3 min at 27–28 lbs of pressure in a gravity displacement sterilizer in which the flashed item is placed in an open tray or is placed in a

Table 5: Multivariable logistic regression analysis of factor affecting fever/sepsis

| a                         |       |             |         |
|---------------------------|-------|-------------|---------|
|                           | OR    | 95%CI       | P       |
| Age                       | 1.00  | 0.99-1.01   | 0.511   |
| Male gender               | 1.11  | 0.83-1.51   | 0.482   |
| Stone size                | 1.09  | 1.04-1.15   | < 0.001 |
| Positive urine culture    | 1.67  | 1.05-2.57   | 0.024   |
| Stone location            |       |             |         |
| Upper pole                | 1.31  | 0.96-1.78   | 0.088   |
| Interpolar                | 1.68  | 1.23-2.29   | 0.001   |
| Lower pole                | 0.76  | 0.56-1.04   | 0.084   |
| Pelvis                    | 0.96  | 0.71-1.31   | 0.810   |
| Proximal ureter           | 0.87  | 0.51-1.43   | 0.585   |
| Prestented                | 1.37  | 1.01 – 1.85 | 0.039   |
| Flash sterilization       | 0.88  | 0.56-1.44   | 0.603   |
| Scope used for >2 cases   | 0.72  | 0.46-1.10   | 0.145   |
| before (reference ≤2)     |       |             |         |
| Scope changed during case | 1.09  | 0.58-1.92   | 0.788   |
| Total operation time      | 0.988 | 0.977-1.01  | 0.059   |

CI=Confidence interval, OR=Odds ratio

specially designed, covered, rigid container to allow for rapid penetration of steam.<sup>[15]</sup> The following healthcare facilities have been employed to facilitate the sterilization process:

- Placement of equipment for flash sterilization near operating rooms to facilitate aseptic delivery to the point of use (usually the sterile field in an ongoing surgical procedure)
- 2. Extending the exposure time to ensure lethality comparable to sterilized wrapped items (4 min at 132°C)
- 3. Using biological indicators that provide results in 1 h for flash-sterilized items
- 4. Using protective packaging that permits steam penetration.

These are considered acceptable for processing cleaned patient-care items that cannot be packaged, sterilized, and stored before use. Interestingly, in our regression analysis flash sterilization was not associated with higher odds of postoperative infections.

Most SUS are made with a limited time usage and most commonly allow for 4 h of usage once plugged into the system. Even though surgeons never take 4 h per FU case, they have to often discard the scope which is a waste of resources. Despite being controversial, this poses the question, if indeed there is a role for RDS, and if used, what is their impact on surgical outcomes? In our series, it is seen that the median operation time was only 57 min (40-70 min) which is similar to reported in the literature indirectly inferring that technically, SUS still has enough potential to support more cases.

In our study, centers that chose to adopt the RDS concept mentioned that the average scope cost was 1000 US Dollars per scope. By sterilizing and reusing a scope, they can divide the instrument cost and make the procedure cost-effective for both hospital and patient. With a divided cost per procedure, this allows for the disposable scope to be treated like a digital reusable scope.

A meta-analysis of reusable versus SUS showed that although disposable and reusable scopes appear to have comparable performance, reusable scopes remain more cost-effective than disposable scopes in high-volume centers and when a substantial number of procedures are performed before requiring scope repair. [16] When applied in this study's context, it means that the RDS concept could be cost-effective for the hospital as the capital cost per scope is much cheaper than digital scopes and this cost gets shared and divided with each subsequent case.

In a cost analysis study, Bozzini *et al.* computed the cost of every FU procedure with reusable ureteroscopes as the sum of the cost of the days of hospitalization and the cost of the daily antibiotic therapy which could vary. Added to this is the mean cost of the repair of the instrument and the mean cost of the sterilization and reprocessing practices. As per their center's cost analysis, FU with reusable scopes was not significantly different from SUS,  $(2321 \in vs.\ 2543 \in)$ , with a similar SFR  $(86.6\% vs.\ 90\%,\ P=0.11)$ . Hence, when this same methodology and ideology, which includes a detailed cost consideration including equipment, cost of sterilization, and workforce is applied to RDS then it defeats the intended cost-saving goal.

We reported a 13.2% incidence of fever and 0.5% incidence of sepsis. Perhaps the fact that most commonly the scope is used only twice, combined with the fact that 70.4% of the patients had preoperative antibiotics that may have limited the risk of sepsis, alongside the use of a UAS in 97.9% of cases had also minimized the same. Bozzini et al. found in a randomized study that infection rates were significantly higher for reusable scopes as compared with SUS (16.6% vs. 3.3%),[14] and none of the patients in the SUS group developed sepsis or had a positive blood culture as compared with 3 out of 90 patients in the reusable scope group. Indeed, a serious cause of concern is the high number of cases with postoperative fever in our series which does raise concern about advocating RDS. In addition, prestenting was also associated with higher odds of postoperative sepsis/fever and this could partially be explained by dwelling time which has been demonstrated to be a risk factor.[17]

The literature on reusable digital scope damage reports that the shaft of the device is most commonly affected and this limits its longevity. Correspondingly, SUS has the advantage of getting a new scope with full functionality, which theoretically guarantees all patients the same effectiveness. In our study, the maximum number of times a scope was reportedly re-used was for 5 cases after which it was discarded and 8.5% of scopes were noted to have mechanical defects in deflection ability, especially downward deflection, along with poor image quality. These issues could have occurred both due to surgeon handling and sterilization. This was more after reuse from

the third case onwards. This could be why 88.0% of our cases were done with scopes that had 2 previous uses only. Being a frail structure, the ureter can be damaged and avulsed easily during ureteroscopy. The potential mechanisms of its injury include locked deflection of a flexible ureteroscope, bunching of the distal bending rubber in a flexible ureteroscope, and the use of a basket for stone retrieval. Hence, it is irresponsible if urologists were to use an RDS that has any mechanical fault.<sup>[20]</sup>

In our study, RFs were present in 31.4%. of cases and this was much higher than even the FLEXOR study which reported a 21.7% RF using any scope<sup>[10]</sup> and that reported in series comparing disposable versus reusable scopes wherein the RF rates were not affected by the type of scope used. [5,14] Based on our regression analysis, we infer that the elevated rate of RFs could stem from various factors. These may be due to extended operative durations, which may prompt interruptions in the procedure to mitigate the risk of sepsis, as well as insufficient time allocated to thoroughly remove potentially overlooked fragments. Further, lower pole stones do present bigger challenges, and using a reused scope with limited deflection might have dissuaded surgeons from attempting to remove small fragments with the hope that these would spontaneously pass. We acknowledge the limitation of not having adequate data, but it could be that the surgeon was maybe a trainee/ resident, or some intraoperative event(s) might have precluded surgeons from spending dedicated time to carefully examine all calvces to deal with missed fragments. Yet, we report that 163 cases were known to have some defect, and in 85 patients the scope malfunctioned necessitating its change. This would have also contributed to further restricting the surgeon's intraoperative abilities to ensure adequate removal of stone fragments. This is why >4 mm and multiple fragments were left behind, which is significant.

A high RF rate necessitates re-intervention, adding to the cost burden for a patient and defeats the surgeon's primary objective of using an RDS. In our series, the re-intervention rate was 31.4%.

Wear and tear of the scope with repeated use and sterilization will decrease the scope's ability to access the lower pole, negotiate difficult angles, and hence decrease lithotripsy efficiency. This again takes away the advantage of using a disposable scope. Sixty-five patients needed a second scope to complete the case in our series and this is counterproductive for cost saving. We found that stones >15 mm and lower pole stones were associated with RF, which are already known factors for higher RF. Interestingly, we also found that a faulty scope that required change was a factor associated with higher odds of having RFs. Consequently, urologists should always check their RDS for maneuverability and visibility before starting a new case and proceed only if it is fully functional.

Furthermore, the intraoperative complications of both PCS and ureteric injury needing stenting in both 20.25% and 1.7% were much higher than those of the literature. This could be multifactorial. Yet, the high rates in this series do raise the question of whether it could be because of poor scope dynamics and inadvertently caused injury. We are limited by the exact site of injury to make accurate inferences.

## Take-home messages and study limitations

Our results pointed out some key messages:

- 1. RDS is perhaps cost-saving for minimizing the consumables cost and the main reason to use the same but is not standard practice unless regulated. Our study however shows that the need to invest for re-sterilization, the higher risk of postoperative infections and importantly PCS injuries, and high RF and reintervention rates do not in any measure favor a cost-saving procedure by RDS
- 2. If a scope is defective, it is counterproductive for patients and surgeons and we strongly advocate that urologists must put their patient's safety as a priority and not perform FU with such faulty scopes
- 3. Any damaged scope could prolong surgical time and increase the rate of RF and risk of infection. The chance of this happening increases as the number of times that scope has been re-used and hence this practice should be abandoned
- 4. Flash sterilization alone or in combination was not associated with higher odds of postoperative infections. This may have been misrepresented or even underreported and hence our finding is merely an inference. Ideally, we should have culture and swab tests from the scope to prove that there is absolutely no colonization to prevent cross-contamination

This study has limitations starting from its retrospective nature that has its inherent bias. Second, we had no comparative group(s) to test the validity and cost of RDS. Third, not all patients had a postoperative CT to assess their true RFs, hence the SFR could have been even lower than reported and that further weakens the stand for RDS usage. It does however raise a question "Does detection of RF by CT scans paradoxically increase re-intervention?"[22] Another limitation is the true cost saving for the surgeon and the patient which cannot be assessed from this study due to the variable practices and cost across different health systems. Notably, none of the parameters that define a successful FU namely high SFR, minimal complications, and no further re-interventions were achieved and hence adopting RDS is not a cost-effective strategy. Perhaps our study may be an idea for companies making SUS to innovate strategies to move from SUS to durable RDS. It may help cost and benefit the carbon footprint as well. [23]

5. The analysis of SFR could have been more accurate if postoperative CT imaging had been utilized to confirm this outcome for all patients, particularly in the case of obese patients and low-density stones. Nevertheless, the practical challenges in obtaining postoperative CT scans for all patients in real-world scenarios, outside of controlled clinical studies, must be recognized. This limitation affects the accurate assessment of whether RFs are truly significant and if reintervention is genuinely necessary. [22] Moreover, it is important to acknowledge the concern regarding radiation exposure inherent in CT scans given that urolithiasis often presents as a chronic condition with frequent recurrence, and relying solely on CT scans would significantly increase radiation exposure for affected patients [24]

6. Our study only reflects the philosophy of the surgeons' reusing consumables as a cost-conscious approach and we are unable to do any real cost analysis outcomes from this study.

# **CONCLUSIONS**

To the best of our knowledge, this is the first study to assess the outcome of FU performed with RDS. Reportedly used as a cost-conscious approach for FU, the need to invest in a good sterilization facility, high RFs, rates of postoperative fever, and the rate of secondary reintervention make this a counterproductive option. The safety of the patients cannot be compromised at all costs using faulty RDS especially if the scope is known to have prior limitations in either mechanism or vision and perhaps it would be better to discard the scope, irrespective of surgeon's experience. Perhaps with multiple SUS in the market, it may be useful to do a structured real cost analysis study but for now, the practices reported are not standardized and RDS cannot be recommended without detailed investigations.

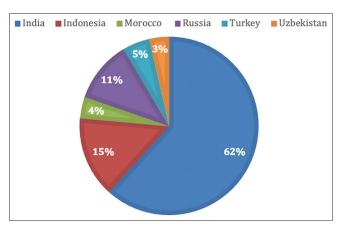
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#### Supplementary Table 1: Established recommendations for reusing single-use devices Recommending body Recommendations International Society Reuse of disposables should not be an ad hoc practice or Guide to infection control in the health-care setting https://isid.org/guide/#1610123027948-493391aa-45db of Infectious Disease treated casually A facility committed to the reuse of single-use devices International society of Guide to infection control in the health-care setting infectious disease should have an institution-specific policy and work with clear https://isid.org/guide/#1610123027948-493391aa-45db guidelines to ensure the safety of patients U.S. food and drug Classifying reusable devices according to the intrinsic risk of https://www.fda.gov/medical-devices/ administration their reprocessing as: Critical devices (contact with blood or reprocessing-reusable-medical-devices/ normally sterile tissue); semi-critical devices (contact with what-are-reusable-medical-devices mucous membranes); and noncritical devices (contact with https://www.govinfo.gov/content/pkg/ unbroken skin) CHRG-106hhrg62970/html/CHRG-106hhrg62970.htm The Joint Commission Determine if the institution has the capability to demonstrate https://www.jointcommissioninternational.org/ International that the device can be adequately cleaned according to the material properties and cleaning methods available The Joint Commission Be aware that reprocessing and reuse may compromise https://www.jointcommissioninternational.org/ International the product's performance, and the manufacturer is not liable when a product is not being used according to the manufacturer's instructions The Joint Commission Detailed procedures, monitoring, and follow-up on adverse https://www.jointcommissioninternational.org/ International patient events which may be linked to this practice The Joint Commission Health-care organizations must have written policies on https://www.jointcommissioninternational.org/ International single-use medical device processing. Critical and semi-critical medical devices labeled as single-use are not reprocessed and reused unless a licensed re-processor does the reprocessing. Devices that cannot be cleaned safely should not be reused International Society Single-use medical device reprocessing should entail Guide to infection control in the health-care setting of Infectious Disease disinfecting, cleaning, sterilizing, packaging, labeling, and https://isid.org/guide/#1610123027948-493391aa-45db storing a used or opened package of a medical device to be placed into service again



Supplementary Figure 1: Centers involved in the study