**Practice and outcomes of retrograde intra-renal surgery using the Uscope PU3032a single-use flexible ureteroscope (PUSENTM) and Holmium laser in the management of upper urinary tract stones: observation of a reference center**

**Background:** With the advancement of technology, single-use flexible ureteroscopes are beginning to occupy an important place in the management of lithiasis disease. In addition to the satisfactory outcome they offer, they have the advantage of bypassing the traditional problems posed by reusable flexible ureteroscopes. Recently, a 9.2 Fr single-use flexible ureteroscope (Uscope PU3022a) was introduced to the market by PUSENTM. The purpose of this study was to report our practice and outcome with the PU 3022A using the Holmium laser in the management of upper urinary tract stones. **Methods:** From January 2021 to June 2022, 109 patients meeting the criteria were included in the study. Patient characteristics, stone characteristics, procedure, outcome, and complications were studied. **Results:** The mean age of the patients at the time of surgery was 62 years. The sex ratio was in favor of men (64.2%). More than half of the patients had a history of calculus (52.3%). The mean size of the stone was 13 mm (4- 28). The mean density was 1112 HU (300-1900). The average procedure time was 70 minutes (30- 130). In the majority of cases, the stone was solitary (n=172; 66.1%). The location of the stones was caliceal in 51.4% of cases. A double JJ catheter was placed in 96 (88.1%) before the single-use flexible ureteroscope. The ureteral access sheath was used in 95.4% of cases. Per operative difficulties were encountered in 16.5% of the procedures **Conclusions**: In our series, retrograde intrarenal surgery (RIRS) using the Pusen 3022a in the management of upper urinary tract stones gives a good stone-free rate at the first session. It can be used for stones larger than 20 mm. Further large randomized studies are needed to assess the use of this type of flexible. The stone-free rate was 73.4%. Postoperative complications were reported in 5.5% of patients.

**Keywords:** upper urinary tract stone; single-use flexible ureteroscope; Uscope PU3032a; Holmium laser

**Introduction**

Urinary calculi is a public health problem. It is one of the most common pathologies in urology and affects approximately 12% of the world population (1). The goal of urinary stone treatment is to provide the best stone-free rate with the least associated morbidity, using a minimally invasive approach (2). With this in mind, retrograde intrarenal surgery (RIRS) has become a preferred method (3). Thus, the use of ureteroscopes (URS) has developed considerably with new technologies and techniques in recent years (4). With technical characteristics comparable to reusable flexible ureteroscopes (rf-URS) and other additional advantages, single-use flexible ureteroscopes (suf-URS) are beginning to occupy an important place in the management of upper urinary tract pathologies and mainly lithiasis (5). Recently, PUSEN introduced a 9.2 Fr suf-URS (Uscope PU3022a). The purpose of this study was to report our practice in rf-URS and the outcome of upper urinary stone management with PU 3022a using Holmium laser.

**Patients and method**

**Description of the study**

This is a retrospective cohort study conducted in the urology department of the University Hospital of Guadeloupe. Extended over a period of 18 months (from January 1, 2021 to June 30, 2022), it included all patients receiving a first session of ureteroscopy with Holmium laser lithotripsy for upper urinary tract stones. Excluded from the study were: additional URS sessions, diagnostic ureteroscopies, white ureteroscopies, procedures performed with a rigid ureteroscope, procedure failures, and monobloc stone extraction with a Dormia forceps.

We studied and analyzed the parameters related to the characteristics of the patients (age, sex, body mass index (BMI), metabolic disease, previous calculi), of the calculi (mode of discovery, dimension reached, number and size, density), of the operative act (double JJ stent (DJS) placement before and after the act, use of the ureteral access sheath (UAS), difficulty, placement of a DSJ post URS), the result of the fragmentation and its complications.

**Description of operational terms**

* Intraoperative difficulties: any unforeseen situation that occurs during the procedure and makes it difficult, thus complicating the operation or causing it to be stopped.
* Operative time: the total time the laser was used to fragment the stone.
* Post-operative complications: any unforeseen unfavorable evolution leading to additional care, prolonged hospitalization or re-hospitalization.
* Stone-free rate: was assessed on the basis of clinical (endoscopic) and imaging (non-injected CT scan). The criteria used were those of the Endourology Society (6) classified into three grades:
	+ Grade A: absolute absence of stones on CT scan
	+ Grade B: relative residual stone, fragments less than or equal to 2 millimeters
	+ Grade C: residual fragments ranging from 2.1 to 4 millimeters.

**Description of the equipment**

The Uscope PU3022a was introduced by PUSENTM (Zhuhai Pusen Medical Technology Co, Ltd., Zhuhai, China). It is a 9.2 Fr flexible ureteroscope (distal end and insertion part) with an average inner diameter of 1.2 mm. Its optical system is characterized by a 90° field of view, a 0° direction of view and a 3-50 mm depth of field. The optical fiber is also equipped with a light. With a working length of 650 mm, its controllable portion can reach up to 270° up and down.

**Description of the statistical analysis**

The BMI was calculated as weight divided by height squared (kg/m2). We used logistic regression analysis to estimate the odds ratios (ORs) and 95% confidence intervals (CIs) for associations between predictive factors of stone free rate and after using disposable f-URS ureteroscopy. All statistical analyses were carried out using Statview software (SAS Institute, Cary, NC). All tests were two-tailed and P values <0.05 were considered significant.

**Results**

From January 2021 to June 2022, 109 patients meeting the criteria were included in the study. The mean age of the patients at the time of surgery was 62 years. The sex ratio was in favor of men (64.2%). In our sample, 42.2% had a metabolic syndrome, mainly diabetes. Patients with a BMI between 25-30 kg/m2 were the most represented. More than half of the patients had a history of calculus (52.3%). Table 1 summarizes the patient characteristics.

The mean size of the stone was 13 mm (4-28). The average procedure time was 70 minutes (30-130). The number of stones per patient varied from 1 to more than 3. The majority had a solitary stone (n=72; 66.1%). Regarding the location, in 51.4% the stone was in the calyces. A DSJ was inserted in 96 cases (88.1%) before the suf-URS. The UAS was used in 104 procedures (95.4%). Table 2 shows the pre- and intraoperative characteristics.

Intraoperative difficulties were encountered in 16.5% of the procedures. Fragmentation was complete in 80 cases (73.4%). The fragmentation result was distributed as follows: 27% grade A, 54 grade B and 19% grade C. Six patients had a postoperative complication. All the data on the outcome and postoperative follow-up are detailed in Table 3.

On correlation (table 4), we noted a concordance between the intraoperative difficulties encountered, the size of the stone, the operative time and the outcome of fragmentation.

**Discussion**

With the advancement of technology, suf-URS have evolved considerably since their conception in 1964 by Marshall (7). Compared to rf-URS, the newer generations of suf-URS do not have the problems of deterioration, deflection over time, costly repairs, transmission of infection, and the need for dedicated sterilization equipment (8). There are several brands of ureteroscopes including the PU3022a from the manufacturer PUSEN. To our knowledge, this is the first large series evaluating the practice and outcome of the PUSEN™ Uscope 3022 in upper stone management.

 In our study, the mean stone size was 13 mm with extremes of 4 and 28 mm. In 67.9%, the stones were between 10 and 20 mm in size. The location of the stones was caliceal (51.4%), pyloric (16.5%), ureteral (12.8%) and multiple (19.3%). For the treatment of renal calculi less than 20 mm and ureteral calculi, the suf-URS is increasingly used as a first-line procedure due to its low morbidity and excellent results. It is an alternative to NLPC in kidney stones larger than 20 mm (9).

According to certain authors (10), the placement of a DSJ before flexible ureteroscopy allows dilation of obstructed ureters and provides better access to the upper tract. This may improve the efficiency of the procedure and increase the stone-free rate. It also facilitates insertion of the UAS. Others (11) found that preoperative stenting prolonged the length of hospital stay and increased hospital costs, with no influence on complication and reoperation rates. They conclude that preoperative ureteral stenting before f-URS for the treatment of upper urinary tract stones is not reasonable. For the Clinical Research Office of the Endourology Society, preoperative JJ stenting increases the stone-free rate and decreases complications in patients with kidney stones, but not in those with ureteral stones (12). In our series, JJ was placed before URS in 88.1% of cases. Based on various published reports and our figures, there is no established consensus on ureteral stenting before URS. However, URS can be performed without prior JJ placement (13).

 The UAS during URS facilitates repeated access into the upper urinary tract and calyces, reduces intra-renal pressure, and protects the ureteroscope and ureter during stone fragment extraction (14). F-URS without UAS appear to be safe and flexible ureteroscopes with UAS but require fewer ancillary procedures. An additional advantage is a shorter operative time (15). However, several studies report that the use of UAS could cause severe ureteral wall damage, tissue ischemia by hypoperfusion, and benign ureteral strictures (16). In our series, the UAS was used in 104/109 procedures. No incidents were reported. Kam et al (13) used the access sheath in all their procedures (n= 31; 100%).

 In our cohort, the achieved stone-free rate was 73.4%. Using the Uscope 3022, Salvado et al (17) obtained an overall stone-free rate of 95.2%. The stone-free rate was 80% with the PU 3033A (18). Compared with the two previously cited studies (17, 18), our sample size was large (109 patients versus 71 for Salvado and 15 for Geavlete). Previous studies using other suf-URS devices obtained the following stone-free rate results: 69.4% with the PolyScope (19) 77.78% with the ZebraScope (20) and 85% with the LithoVue (21). Overall, the results depend on the characteristics of the stones, the renal anatomy and the surgeon's experience (17). In our study, the stones were mainly renal (therefore difficult to access) with a predominantly calcific (hard) density.

At the end of the operation, JJ was placed in 93.6 % of our patients. Ureteral drainage after URS is performed to prevent the risk of obstructive syndrome due to enclosure of a residual fragment or to postoperative edema. It could also reduce the risk of postoperative ureteral stenosis (22). For Traxer et al (23), postoperative drainage by DSJ is preferable when fragmentation is difficult, in conditions such as a long operating time (more than 90 minutes), ureteral injury, dilatation of a ureteral stenosis, or residual fragments in particular in the ureter. Lechevallier et al (24) reported that ureteral drainage was not necessary in the case of rapid and easy removal of a small distal stone in one piece. JJ placement is not without complications. It can impact on the quality of life of patients, with an estimated morbidity of 50-80% (25).

 The average operating time varies from one study to another. It was respectively 49.6 ± 22.17 minutes for Patil et al (28), 76.8 ± 40.2 minutes for Mager et al (20) and 80.3 ± 33.7 minutes for Kuroda et al (27). In this study, the average operating time was 70 minutes (extremes 30 and 130). The definition of the operative time depends on the authors. For Whitehurst al (28), it is the time taken from the insertion of the cystoscope to the withdrawal of the endoscope. We have considered the operative time to be the duration of laser fragmentation. In a study establishing a nomogram predicting serious events, it was found that these increased significantly when the operative time exceeded 90 min (29).

 RIRS is now a minimally invasive, safe and effective method. However, during an intervention, unexpected events or complications may occur. Intraoperative complications can be classified as major (ureter avulsion, ureter invagination) and minor (ureter perforation, false routes, abrasions, instrument malfunction or rupture, extravasation, bleeding, difficult access) (30). The per operative difficulties encountered in our series were as follows: 1 case of complex anatomy, 1 case of impacted calculus, 2 cases of thin calyces, 2 cases of material defect, 2 cases of difficult progression, 4 cases of difficult flexion, 6 cases of poor visibility.

 Postoperative complications occurred in 6 of our patients (5.5%). In 2 cases, surgery was necessary. Postoperative complications were generally minor and spontaneously resolved. Some complications can be life threatening and require surgical management (31). These complications also vary from one series to another. 3,5 % (6). In an article published by Kam et al (13) 7.4% had a complication (32). 26,35 % (31).

The purpose of postoperative imaging is to assess the presence of residual stones that may require further surgery. It also allows for the detection of persistent obstruction (33). Follow-up imaging was performed in 58.7% of cases.

**Conclusion**

In our series, retrograde intrarenal surgery (RIRS) using the Pusen 3022a in the management of upper urinary tract stones gives a good stone-free rate at the first session. It can be used for stones larger than 20 mm. The per operative complications of this type of surgery must be known, because if they are controlled, they reduce the rate of re-intervention for additional fragmentation. Further large randomized studies are needed to assess the use of this type of flexible.

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