Romanian experience after 4 years with Pusen single-use flexible ureteroscopes

R. Multescu[1,3], P. Geavlete[1,2,3], V. Iordache[1,3], C. Mares C[1,2], A. Militaru[1,2,3], B. Geavlete[1,2,3]

[1] Saint John Emergency Clinical Hospital, Bucharest
[2] "Carol Davila" University of Medicine and Pharmacy, Bucharest
[3] Sanador Clinical Hospital, Bucharest

ABSTRACT

Introduction and Objectives: Lately, single-use flexible ureteroscopes seem to overcome the main limitations of conventional reusable ureteroscopes in terms of acquisition costs, maintenance as well as eventual malfunctions. Our aim was to analyze the efficacy and safety of Pusen PU3022A and PU3033A single-use flexible ureteroscopes.

Materials and Methods: Our study included a retrospective analysis of 132 flexible ureteroscopies performed from February 2019 to March 2023: 79 cases with PU3022A and 53 cases with PU3033A. Lithotripsy was performed with Dornier Medilas H Solvo 30 W laser. We evaluated the ease of access, visibility, maneuverability, technical reliability, efficacy and complications rate.

Results: None of the cases were initially pre-stented. In 8/79 cases (10.1%) pyelocaliceal access with the PU3022A ureteroscope failed due to ureteral diameter, requiring JJ stent insertion. Insertion of the PU3033A ureteroscope up to the pyelocaliceal system was successful in all cases. Intrarenal maneuverability and visibility were optimal for both models. After the procedure, in 24 cases (18.2%) a JJ stent indwelling was not necessary. Mild hematuria occured in 27 cases (20.45%) and was managed conservatively. Eight cases (6.15%) presented fever with complete remission in 36 hours. Evaluation at 30 days postoperatively detected residual stone fragments in 12 patients (9%). No technical malfunctions were documented in any of the studied cases.

Conclusions: Pusen PU3022A and PU3033A are effective alternatives in the flexible ureteroscopic approach of renal lithiasis. Especially the thinner model (PU3033A) can be successfully used in the "No Touch Technique" approach without any ureteral injury

Keywords: single-use, flexible ureteroscopes, urolithiasis

Correspondence to:
Dr. Razvan Multescu M.D., PhD
Saint John Emergency Clinical Hospital, Department of Urology
Vitan-Barzesti 13, 042122, Bucharest, Romania
Tel / Fax: 0213345075
e-mail: razvanmultescu@yahoo.com

Introduction

The first flexible ureteroscopes were developed about three decades ago by Lyon, Huffman and Bagley [1].
Technical developments and miniaturization fueled a remarkable advancement in these instruments, transforming them in more performant and durable tools for diagnosis and treatment of upper urinary tract pathology and especially pyelocaliceal lithiasis.
The latest development in this field was the introduction of single use or disposable flexible digital ureteroscopes who have become an attractive option with many advantages. Lately, single-use flexible ureteroscopes seem to overcome the main limitations of conventional reusable ureteroscopes in terms of acquisition costs, maintenance as well as eventual malfunctions.
The aim of this study was to analyze the efficacy and safety of two models of Pusen (Zhuhai Pusen Medical Technology, Guangdong, China) disposable ureteroscopes used in our activity: PU3022A and PU3033A.

Material and method

We performed a retrospective analysis of cases operated with this technology from February 2019 to March 2023. A number of 132 ureteroscopies were performed with these two models of ureteroscopes: 79 of them with PU3022A and 53 cases with PU3033A.
Pusen PU3022A model (Fig.1) has a 9 F diameter at the tip and 9.2 F diameter of the shaft, a 3.6 F working channel, 275/275 degrees deflection and a field of view of 90 degrees.

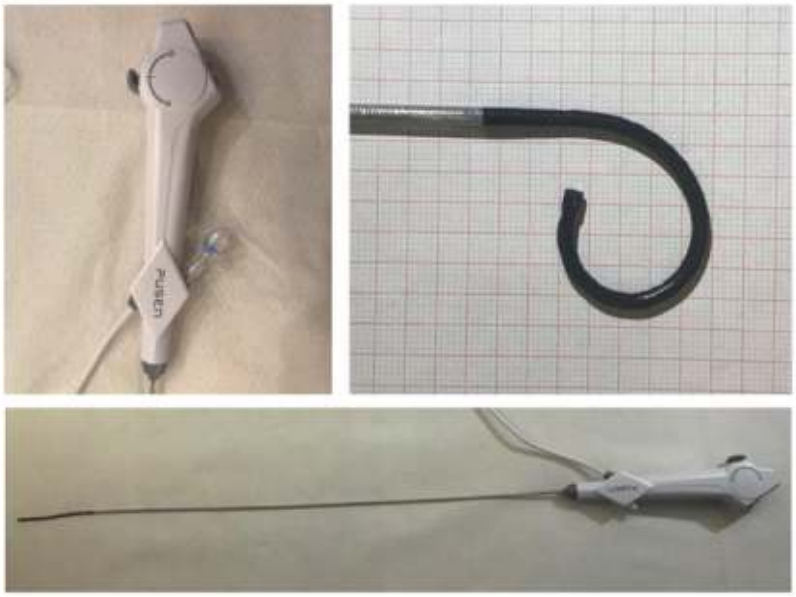


Fig. 1 PU3022A single-use flexible ureteroscope

The Pusen PU3033A model has a much thinner 7.5 F diameter at the tip, 7.5 F diameter of the shaft, a 3.6 F working channel, 275/275 degrees deflection and a field of view of 90 degrees.
Both offer a maximum 1080p (high-resolution) image, settings for different resolutions and different zoom values, with automatic color adjustment. For both models the operating capacity is limited to 4 hours.

Lithotripsy was performed with Dornier Medilas H Solvo 30W laser. For dusting we used low energy (around 0.5J) and high frequency (around 17Hz), for pop-corning we used high energy (>1J) and medium frequency (around 10Hz), and for fragmenting high energy (>1J) and low frequency (<10Hz).

Results

The gender distribution in our series was 53 men (47.73%) and 69 women (52.27%). The patients were aged between 23 and 78 years old. The size of the stones ranged between 0.7 and 2.5 cm. All cases analysed were not initially pre-stented. In 8/79 cases (10.1%) pyelocaliceal access with the PU3022A ureteroscope failed due to a narrow diameter of the ureter, requiring indwelling of a 6F JJ stent for 7-14 days. Insertion of the PU3033A ureteroscope up to the pyelocaliceal system was successful in all cases.

Ureteral access sheath was used in 46/79 cases treated with PU3022A model and in 0/53 cases treated with the PU3033A model.

Intrarenal manoeuvrability was optimal for both models, all the ureteroscopes being able to reach the stones described by the preoperative imagistic evaluation. Visibility was very good, none of the interventions requiring interruption due to poor visibility (Fig. 2).

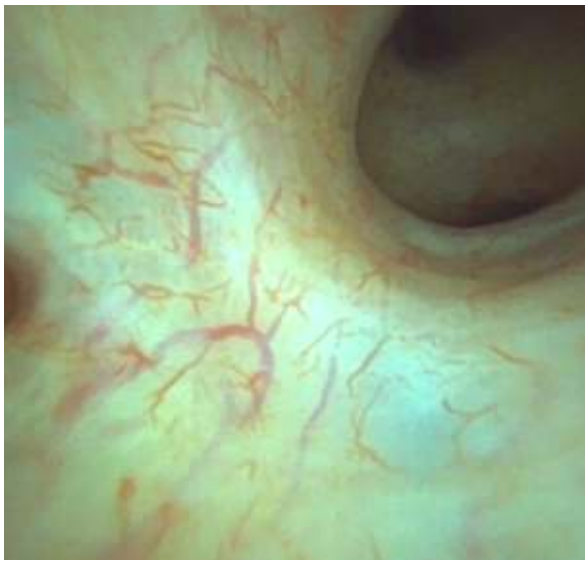


Fig. 2 Intraoperative aspect using Pusen PU3033A model

No lesions of the ureteral mucosa were apparent at the end of the procedure (the evaluation being mandatory when withdrawing the ureteroscope).

After the procedure, in 24 cases (18.2%) a JJ stent indwelling was not necessary; in the rest of the cases, a JJ stent was indwelled for 2-3 weeks. Mild hematuria was described in 27 cases (20.45%) and in all of them it was managed conservatively. Fever was described in 8 cases (6.15%), with complete remission in 36 hours. Cases without any complications were discharged 24 hours after the intervention. Ultrasound assessment, and/or Rx and/or CT without contrast material performed 30 days postoperatively detected residual fragments in 12 patients (9%).

No technical malfunctions of the flexible ureteroscopes during the procedure were documented in any of the studied cases.

Discussion

Multiple studies emerge nowadays evaluating the use of disposable flexible ureteroscopes. There are multiple potential advantages generated by the employment of such endoscopes. The reduced risk for postoperative septic complications and the fact that they do not require sterilization and reprocessing are just two of the main ones.

A study by Unno et al demonstrated a statistically significant reduced incidence of urinary tract infections following flexible ureteroscopic approach using disposable endoscopes by comparison to reusable ones. In a multivariate analysis, the single use ones had reduced odds for septic complications

when adjusting for risks [2].

One commonly encountered phenomenon with the reusable ureteroscopes is the fatiguability or deflection loss which may worsen with each procedure, especially with challenging ones (e.g. long lower pole access time) [3, 4]. Of course, when using disposable ureteroscopes, they are always new and potentially achieving optimal factory performances. This usually translate into optimal efficacy of the procedure. Maybe this is the reason why, interventions employing disposable flexible ureteroscopes had a higher success rate by comparison to those performed with reusable ones [2].

For lower pole stones (a particular location for any type of stone treatment methods) flexible ureteroscopic approach with single-use endoscopes had higher stone free rates (although not statistically significant). For this group the operating time was shorter than for the one in which reusable ureteroscopes were used [5]. Especially for these difficult locations, the use of disposable flexible ureteroscopes, together with other technological improvements (new lasers such as high power Holmium:YAG, Thulium fiber lasers, smaller fibers, new accessories) improved the efficacy and safety of this procedure [6].

The disposable ureteroscopes seem to also be safe tools in treating upper urinary tract pathology [7]. Yang et al, in a study comparing ZebraScope single use flexible ureteroscope vs. Olympus URF-V reusable one, found similar operating time, hospitalization duration and complications rates in the two groups [8].

Since almost two decades ago, it was demonstrated that the success of pyelocaliceal access was dependant to the diameter of the flexible ureteroscope [9].

In a randomized controlled prospective study comparing the two models employed in our study as well, Agrawal et al found that the thinner model offer the same manoeuvrability and visibility, while being able to be inserted through a smaller access sheath [10].

Regarding the expenses, one must remember that for the reusable ureteroscopes they include not only the purchase cost but also the reprocessing, sterilization, deposit and repair ones. Studies seem to demonstrate that using disposable flexible ureteroscopes may save costs by comparison to the maintenance of reusable ones. Also, using a disposable one may be a strategic decision when the reusable scope damage is anticipated [11].

Conclusions

Our study demonstrated that Pusen PU3022A and PU3033A disposable flexible digital ureteroscopes are viable alternatives in the flexible endoscopic treatment of renal lithiasis, demonstrating good safety and efficacy. Especially the latest generation PU3033A can be successfully used in the "No Touch Technique" approach without any ureteral injury. Additional clinical trials along with cost analysis will further define the utility and potential impact of single-use ureteroscopes.

References

1. Lyon ES, Huffman JL, Bagley DH. Ureteroscopy and ureteropyeloscopy. Urology. 1984 May;23(5 Spec No):29-36. doi: 10.1016/0090-4295(84)90239-5. PMID: 6719677.

2. Unno R, Hosier G, Hamouche F, Bayne DB, Stoller ML, Chi T. Single-Use Ureteroscopes Are Associated with Decreased Risk of Urinary Tract Infection After Ureteroscopy for Urolithiasis Compared to Reusable Ureteroscopes. J Endourol. 2023 Feb;37(2):133-138. doi: 10.1089/end.2022.0480. Epub 2022 Nov 9. PMID: 36267020; PMCID: PMC10081697

3. Canales BK, Gleason JM, Hicks N, Monga M. Independent analysis of Olympus flexible ureteroscope repairs. Urology. 2007 Jul;70(1):11-5. doi: 10.1016/j.urology.2007.02.065. PMID: 17656198

4. Multescu R, Geavlete B, Georgescu D, Geavlete P. Conventional fiberoptic flexible ureteroscope versus fourth generation digital flexible ureteroscope: a critical comparison. J Endourol. 2010 Jan;24(1):17-21. doi: 10.1089/end.2009.0390. PMID: 19954350

5. Göger YE, Özkent MS, Kılınç MT, Taşkapu HH, Göger E, Aydın A, Sönmez MG, Karalezli G. Efficiency of retrograde intrarenal surgery in lower pole stones: disposable flexible ureterorenoscope or reusable flexible ureterorenoscope? World J Urol.

2021 Sep;39(9):3643-3650. doi: 10.1007/s00345-021-03656-y. Epub 2021 Mar 18. PMID: 33738574
6. Shrestha A, Adhikari B, Panthier F, Baidya S, Gauhar V, Traxer O. Flexible ureteroscopy for lower pole calculus: is it still a challenge? World J Urol. 2023 Nov;41(11):3345-3353. doi: 10.1007/s00345-023-04606-6. Epub 2023 Sep 20. Erratum in: World J Urol. 2023 Oct 21;: PMID: 37728745
7. Qi S, Yang E, Bao J, Yang N, Guo H, Wang G, Li N, Cui X, Gao W, Ou T, Wang J, Wang Z, Niu Y. Single-Use Versus Reusable Digital Flexible Ureteroscopes for the Treatment of Renal Calculi: A Prospective Multicenter Randomized Controlled Trial. J Endourol. 2020 Jan;34(1):18-24. doi: 10.1089/end.2019.0473. Epub 2019 Oct 4. PMID: 31432716.
8. Yang E, Jing S, Niu Y, Qi S, Yadav PK, Yang L, Bao J, Tian J, Wang J, Li N, Ou T, Wang Z. Single-Use Digital Flexible Ureteroscopes as a Safe and Effective Choice for the Treatment of Lower Pole Renal Stones: Secondary Analysis of a Randomized-Controlled Trial. J Endourol. 2021 Dec;35(12):1773-1778. doi: 10.1089/end.2021.0170. PMID: 34375127
9. Scotland KB, Rudnick B, Healy KA, Hubosky SG, Bagley DH. Retrograde Ureteroscopic Management of Large Renal Calculi: A Single Institutional Experience and Concise Literature Review. J Endourol. 2018 Jul;32(7):603-607. doi: 10.1089/end.2018.0069. Epub 2018 Jun 6. PMID: 29732915
10. Agrawal S, Patil A, Sabnis RB, Singh AG, Ganpule AP, Desai MR. Initial experience with slimmest single-use flexible ureteroscope Uscope PU3033A (PUSEN™) in retrograde intrarenal surgery and its comparison with Uscope PU3022a: a single-center prospective study. World J Urol. 2021 Oct;39(10):3957-3962. doi: 10.1007/s00345-021-03707-4. Epub 2021 May 10. PMID: 33970313
11. Hennessey DB, Fojecki GL, Papa NP, Lawrentschuk N, Bolton D. Single-use disposable digital flexible ureteroscopes: an ex vivo assessment and cost analysis. BJU Int. 2018 May;121 Suppl 3:55-61. doi: 10.1111/bju.14235. PMID: 29656467