ORIGINAL PAPER

UROLITHIASIS

Stone fragmentation with subsequent evacuation using a novel single-use flexible cystoscope/nephroscope with integrated direct in-scope suction: An *ex vivo* experimental study

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Introduction This study aims to evaluate the feasibility of stone fragmentation and aspiration of dust and small stone particles via a direct-in-scope suction (DISS) system using a novel single-use flexible cystoscope (PC200, Pusen Medical Technology, Guangdon, China) in a straight position and with extreme bending.

Material and methods An *ex vivo* experimental study was performed on freshly harvested porcine lower urinary systems (bladder and urethra) with natural urinary stones (calcium oxalate dihydrate 70%, urate 30%). In the first set of trials (3 trials) the stones were placed in the bladder and lithotripsy was performed with a scope in a straight position. For the second set of trials, porcine gallbladder was additionally used, circumferentially sutured to the anterior wall of the porcine bladder, and the stone was positioned in the gallbladder (imaginary diverticulum). In the latter trials, lithotripsy was achieved with the scope at an almost 180° bend.

Results Laser lithotripsy was successfully completed in all trials. Stone fragmentation and aspiration were faster in the first set of trials with the cystoscope in a straight position. In the second set, to access the anterior-wall "diverticulum", continuous suction and irrigation were employed. After lithotripsy, the stone fragments were effectively flushed from the simulated diverticulum into the main bladder cavity.

Conclusions Bladder stone lithotripsy using a flexible cystoscope with DISS is feasible. The DISS system offers several advantages, including improved visibility through simultaneous fluid and dust aspiration, as well as enhanced maneuverability of the scope due to suction-assisted positioning.

Key Words: DISS ‹› flexible cystoscope ‹› flexible nephroscope: suction ‹› experimental study

INTRODUCTION

The introduction of a suction feature to single-use digital flexible ureteroscopes and cystoscopes/nephroscopes has brought new challenges and opened avenues for further research. Suction has been utilised in endourology for over 2 decades, traditionally confined to percutaneous nephrolithotripsy to aid in the removal of renal stones. Most recently, however, its use has expanded to include retrograde intrarenal surgery (RIRS) [1]. Suction systems offer several advantages during endoscopic lithotripsy, including enhanced visibility, lower temperature, and reduced pressure within the urinary tract. These benefits contribute to a lower risk of infection and improved postoperative outcomes [2]. Various suctioning devices have been introduced with specific purposes and goals, developed through *in vitro* models, *ex vivo* (porcine) models, and subsequently *in vivo* studies [3, 4]. These can be classified into suction-assisted ureteric access sheaths (S-UAS), direct in-scope suction (DISS), and steerable dual-lumen catheters [1]. DISS involves the removal of dust and small stone fragments via the working channel of the flexible cystoscope/nephroscope and flexible ureteroscope. The system is designed to balance irrigation flow and vacuum suction, ensuring promising stone-free rates (SFR) and maintaining clear visualisation throughout the procedure, addressing the challenge of the snow-globe effect [3, 5]. To date, only a limited number of studies have evaluated direct-in-scope suction (DISS) in both *in vitro* and *in vivo* settings. Furthermore, we have yet to observe the clinical application of available single-use flexible ureteroscopes and cystoscopes/nephroscopes with an integrated direct-in-scope suction system [6]. The aim of the current experimental study was to evaluate the feasibility of stone fragmentation and aspiration of dust and small stone particles via the DISS system using a novel single-use flexible cystoscope (PC200, Pusen, ZhuHai Pusen Medical Technology Co, Ltd, Guangdon, China) in a straight position and with extreme bending.

MATERIAL AND METHODS

Tested instrument

In all experimental trials a novel 15 Fr single-use flexible cystoscope (PC200, Pusen, ZhuHai Pusen Medical Technology Co, Ltd, Guangdon, China) was used. The current flexible cystoscope is equipped with a dual-LED light system, digital high-resolution camera, and has integrated direct-in-scope suction (DISS) achieved through a 7.2 Fr width working channel. The maximum bending angle according to the manufacturer is 210°. The specific handle design allows straight and convenient access to the working channel to introduce accessory instruments (laser fibre, baskets).

Study design

An experimental *ex vivo* study was performed. Six experimental trials were conducted with 2 different experimental settings. In all trials 0.5–0.7 g natural urinary stones (calcium oxalate dihydrate 70%, urate 30%) were used. All 6 stones were collected during transurethral resection of the prostate from patients suffering from prostate hyperplasia with concomitant multiple bladder stones. The stones were extracted in toto through the sheath of the resectoscope, without performing any lithotripsy. Written consent was received from patients to keep and use the stone for experimental purposes.

To perform the experiments, 2 freshly harvested male porcine lower urinary systems consisting of urinary bladder and urethra and one porcine gallbladder were used. The ureters were cut close to the urinary bladder, and the sutures were placed on the ureteral ends on both sides to prevent any fluid leakage from the ureters. The *ex vivo* models were fixed to the operating table to limit their mobility (Figure 1). In both settings one stone per trial was placed in the urinary bladder via the urethra through the 26 Fr sheath of the resectoscope. The use of the resectoscope had 2 purposes: first to introduce stones into the bladder and second to dilate the urethra to the size of 26 Fr mimicking the human urethra. Thereafter, the PC200 flexible cystoscope was inserted, and a suture was placed on the urethra and cystoscope allowing the cystoscope to move, but limiting the water leakage from the urethra while filling the bladder. For irrigation purpose two 3 l irrigation bags placed 1 m above the operating table were connected to irrigation port of the flexible cystoscope. The lithotripsy was achieved by the Quanta Cyber Ho 150 W laser (Quanta). Thereafter, a 365 μm laser fibre (Quanta) was inserted, and lithotripsy of the stone was performed. Two settings, 1 J × 15 Hz and 0.7 J × 25 Hz (Virtual Basket), were used to ablate the stone. Intermittent suctioning and filling of the bladder were performed throughout the procedure. Following the ablation of the stone, the bladder was filled, and the suture on the urethra and the flexible scope was withdrawn. The generated stone fragments were expelled by pressing onto the filled bladder mimicking urination. At the end of the trial the bladder was checked with the flexible cystoscope to evaluate the success of the trial and the presence of residual fragments. All trials were performed by a senior urologist with a specialisation in endourology.

In the first set of trials (3 trials) the experiments were performed solely on urinary systems. The stones were just placed into the bladder and lithotripsy was initiated. For the second set of trials, the porcine gallbladder was additionally used to construct a diverticulum in which the stones were positioned. For this purpose, the gallbladder was circumferentially sutured to the anterior wall of the porcine bladder. After completing the suture line, the bladder was filled, and absence of water leakage was tested. Following the placement of stones in the diverticulum (the gallbladder), stone lithotripsy via a PC200 flexible cystoscope was performed. As a result of this setup, lithotripsy was achieved with the scope at almost 180° bend.

The trials were defined as successful if complete stone clearance was achieved following the laser lithotripsy. In the case of any residual fragments the trials were considered as a failure. The time required to break the stone was also recorded. SPSS v25 software (IBM Statistics, NY, USA) was used for the descriptive statistical analysis.

Bioethical standards

Local Ethics Committee approval was received to archive urinary stones for further experimental study purposes.

RESULTS

In the first set of trials with the cystoscope in a straight position, less effort was required to disintegrate stones. Intermittent suction and refilling of the bladder were performed to achieve better visualisation and prevent any increase of the fluid temperature with the laser fibre in place. Less time was required to break stone fragments in the first set of trials with the scope in the straight position. The reported time was 4 min 20 s, 5 min 30 s, and 4 min 45 sec for the 1st, 2nd and 3rd trials, respectively.

In the second setting with the stone in the anterior wall "diverticulum", more effort and time were required to reach and fragment the stones. Aspiration and refilling of the bladder were performed by the operator not only to maintain good visualisation but also to increase the manoeuvrability of the flexible scope. After successful lithotripsy the stone frag-

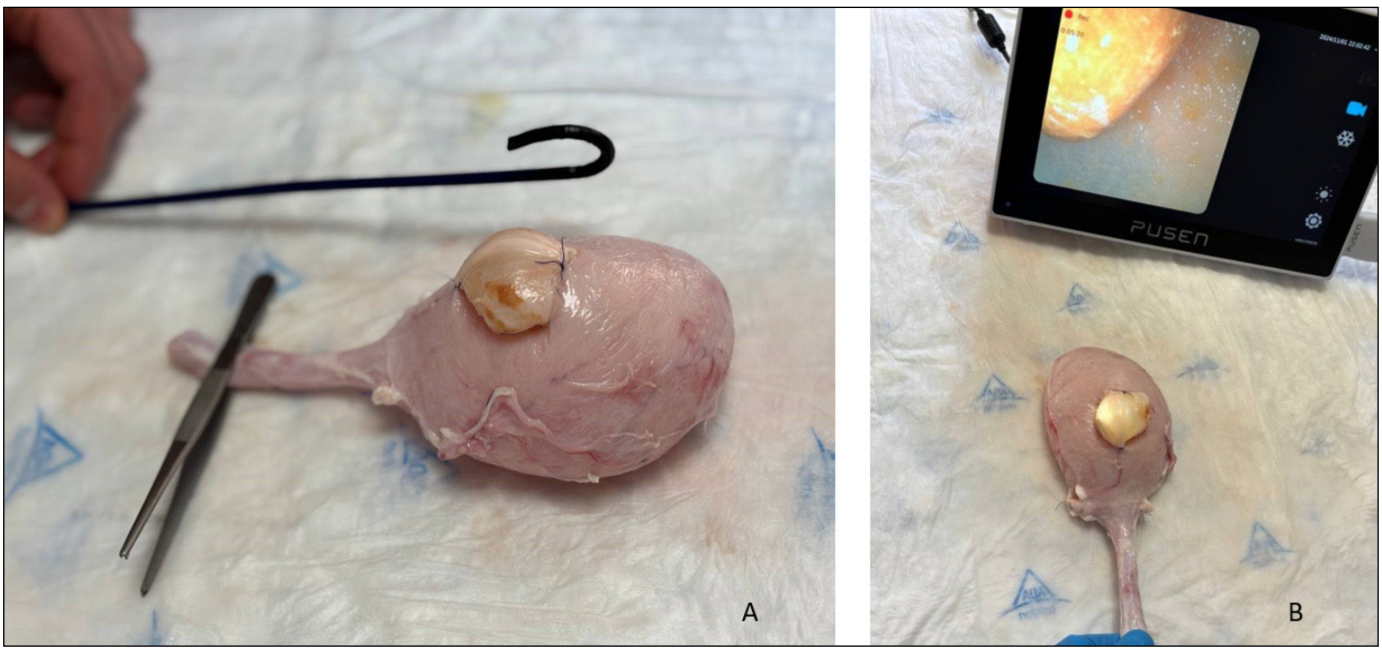

Figure 1. *The constructed ex vivo model:* **A)** *Showing the porcine gallbladder attached to the anterior surface of the porcine urinary bladder.* **B)** *Showing the natural urinary stone placed in the imaginary diverticulum (gallbladder).*

ments were flushed out from the diverticulum into the bladder cavity. The times required to perform the lithotripsy were 12 min 20 s, 9 min 15 s, and 9 min 45 s, for the 1st, 2nd, and 3rd trials, respectively. In all 6 trials complete success was documented with complete stone clearance following emptying of the bladder.

DISCUSSION

This study presents the first *ex vivo* use of a single-use cystoscope/nephroscope with an integrated direct-in-scope suction system, comparing its performance in 2 settings: a straight position and in extreme bending. In both scenarios, complete stone clearance was achieved, despite differences in lithotripsy times. The system's well-balanced irrigation and suction ensured excellent manoeuvrability and visibility, facilitating lithotripsy and ensuring complete evacuation of fragments. This, in turn, could potentially prevent complications associated with the presence of residual fragments [7].

With the advent of more advanced and efficient laser systems, the concept of suction has gained significant interest among endourologists. Suction plays a pivotal role in improving visibility during lithotripsy, facilitating fragment retrieval, and efficiently removing fine debris from intrarenal cavities and the ureter. Additionally, it helps reduce intrarenal pressure, thereby minimising the risk of complications such as bleeding and infections [8–14].

Manual evacuation using suction through the working channel of a flexible ureteroscope equipped with a Luer-lock syringe was shown to be feasible in an *in vitro* setting for submillimetre fragments. This represented the first evaluation of the DISS technique. However, complete stone clearance for fragments <1 mm and <0.5 mm was not achieved, probably due to the heterogeneous composition of stone fragments and the limited size of the working channel [15]. In our study, the working channel measures 7.2 Fr, equivalent to 2.4 mm. In contrast, Schneider et al. [15] report a channel size of 1.2 mm, highlighting the necessity for a larger working channel due to frequent occlusions during the procedure, which required repeated flushing. Keller et al. [16] describe a working channel size of 3.6 Fr (equivalent to 1.2 mm), noting that particles >1 mm could not be completely aspirated, thereby impacting complete stone clearance. Furthermore, potential direct damage to the working channel should also be considered. In our case, this risk was mitigated and overcome by the larger size of the working channel and the single-use nature of the instrument.

In the realm of suction systems, the DISS technique was specifically developed to address and overcome the limitations of S-UAS. One such limitation is the need to bring fragments to the sheath for removal, potentially requiring the use of baskets or other devices, which adds to procedural costs and time. Gauhar et al. [17] reported that the DISS technique demonstrated a safety advantage, with all patients being discharged within 24 hours of surgery. Additionally, they highlighted the successful application of the DISS technique regardless of the number, size, or location of the stones, with no observed damage to the scope. *In vitro* studies have shown that the integrated DISS technique outperforms the syringe technique in handling dust particle sizes of 63–125 μm and 125–250 μm. Furthermore, the combined use of irrigation and aspiration has been proven to enable procedural success by preventing blockages in the working channel while simultaneously ensuring enhanced visibility [6].

The PC200 is the first commercially available single-use cystoscope/nephroscope with integrated direct-in-scope suction. To date, no studies have evaluated the use of suction for fragments resulting from laser lithotripsy of bladder stones. While this novel DISS cystoscope/nephroscope can be used for bladder lithotripsy, it could be also considered for percutaneous nephrolithotripsy (PCNL). As reported, increasing the number of renal access points or forcefully using the rigid nephroscope can raise the risk of complications following PCNL [18, 19]. Flexible nephroscopy has been a significant advancement in the evolution of PCNL, enabling endourologists to access calyces that are otherwise unreachable with a rigid instrument [20], to clear calyces not accessible for rigid nephroscope. It is well-established that the use of flexible nephroscopy reduces morbidity and improves stone-free outcomes, thereby minimising the need for secondary procedures [21]. Taking this into account, the DISS system presents potential advantages compared to standard flexible nephroscopy. It allows for the visualisation of calyces, efficient stone fragmentation within the calyces, and immediate removal of the fragments through aspiration. Our study confirmed the practicality of using the DISS cystoscope/nephroscope to successfully fragment stones, even in situations involving highly acute bending.

We are aware that our study has certain limitations: first, the use of porcine urinary systems and gallbladders, which, while anatomically similar, do not fully replicate the dynamic physiological conditions of the human urinary tract. Differences in tissue properties, fluid dynamics, and urethral compliance may impact the generalisability of the findings. Second, the stones used were composed of calcium oxalate dihydrate and urate. While these represent common urinary stone types, other compositions, such as cystine or struvite stones, were not evaluated, limiting the applicability of the results to all stone types. Third, the findings have not yet been validated in a clinical setting. The performance of the DISS system in real patients, with variable anatomical and pathological conditions, remains to be assessed. Addressing these limitations through further research, including *in vivo* clinical trials with larger sample sizes and diverse stone types, will be essential to fully establish the utility and effectiveness of the DISS system in flexible cystoscopy.

CONCLUSIONS

Bladder stone lithotripsy using a flexible cystoscope with direct-in-scope suction (DISS) is feasible. Among the advantages of the DISS system are fluid and dust aspiration improving the visibility of the lithotripsy procedure, as well as the gained manoeuvrability of the scope, due to the suction.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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ETHICS APPROVAL STATEMENT

The ethical approval was not required.

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