Introduction of 1.9 mm Trilogy lithotripter in miniature percutaneous nephrolithotomy: Description of technique and case outcomes

Rebecca Kindler[1], Arsha Venkat[1], Natalia L. Arias-Villela[2], William Meeks[3], Emily Galen[3], Joel E. Abbott[4], Meagan M. Dunne[2], Julio G. Davalos[2], Daniel C. Rosen[1]
[1]New York Medical College, Valhalla NY, United States; [2]Chesapeake Urology Associates, Hanover, MD, United States; [3]American Urological Association, Linthicum, MD, United States; [4]Pacific West Urology, Las Vegas, NV, United States

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Corresponding author: Dr. Daniel C. Rosen, New York Medical College, Valhalla NY, United States; Daniel.rosen@wmchealth.org

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ABSTRACT

KEY MESSAGE

- The Trilogy 1.9 mm probe is an effective tool to treat even larger stones, with the use of adjunctive irrigation measures to promote visibility and stone extraction.

Introduction: We aimed to evaluate the novel use of a 1.9 mm Trilogy lithotripter probe with varying locations and composition of renal stones.
Methods: We prospectively enrolled patients to undergo mini percutaneous nephrolithotomy (mPCNL) procedures using the 1.9 mm (instead of the standard 1.5 mm) Trilogy probe from August 2021 to April 2022. Several adjunctive irrigation measures compensated for reduced flow with the larger probe. Primary outcome was treatment efficiency. Patient demographics, preoperative demographics, and comorbidities, as well as real-time surgical data were extracted. Statistical analysis was performed using Kruskal-Wallis tests to compare stone type and location.
Results: A total of 110 patients were included in this study. The median total treatment time was 6.8 minutes, median lithotripsy time was 3.3 minutes, median stone treatment efficiency was 0.34 mm/min, and treatment efficacy was 50.4 (lithotripter time/treatment time). Overall median

lithotripter efficiency was 104.6 mm^3/min. Treatment efficiency was similar among stone composition (p=0.245) and location (p=0.263). Lithotripter 3D and 1D efficiency was also similar among stone composition (p=0.637 and p=0.766, respectively). Lithotripter 1D efficiency was nearly twice as fast in the lower pole compared to other stone locations (p=0.010). Overall broken probe rate for this procedure was 12%, mostly at the beginning, suggesting a learning curve. Five patients had minor complications, including one patient that required admission to the hospital for postoperative pain management.

Conclusions: The 1.9 mm Trilogy lithotripter can be effective in mPCNL procedures with the use of easily implementable adjunctive irrigation techniques, decreasing the gap between lithotripsy time and total treatment time.

INTRODUCTION

Mini percutaneous nephrolithotomy (mPCNL) has gained popularity as a minimally invasive method for the treatment of renal calculi. The tract size generally used in mPCNL is 14F- 22F, compared to standard PCNL (>22F), ultra-mini PCNL (11F-13F), and micro-PCNL (4F-10F).[1-4] While studies have shown decreased blood loss and overall morbidity, mPCNL may be associated with increased operative time for equally sized stones.[1] The smaller tract and scope size limit the diameter of the lithotripter that can be accommodated through the working channel of the nephroscope while maintaining adequate fluid inflow, thereby contributing to these limitations, and leading to an overall preference of use of lasers for this procedure. A small 1.5mm probe has been used for mPCNL but is inherently limited by its diameter. In this study, we sought to describe the technique behind the use of the Storz 12 French mini-nephroscope with the EMS 1.9mm Trilogy probe as well as evaluate and optimize the usage of the probe.

METHODS

Patient selection

All patients enrolled in the study were treated with mPCNL by a single surgeon from August 2021 to April 2022. The research database of all patients undergoing PCNL within the institution is prospectively maintained with real-time data collection by a nurse in the operating room. Baseline demographic and comorbidity data was collected. Stone volume was calculated using *3D Slicer* when DICOM images were available, or manually using an ellipsoid formula. Institutional IRB approval (#20171472) was obtained.

Storz minimally invasive PCNL-medium (MIP-M) system

The Storz MIP-M (Minimally Invasive PCNL- Medium) system was the first mini-nephroscope commercially available in the United States. The scope set is available in a variety of sizes that span micro, ultra-mini, mini and standard PCNL. During this study the 12 French scope was used with the 16.5/17.5 French renal dilator and access sheath. The nephroscope has a 2mm working channel with the use of the 27001GG adapter.

Trilogy 1.9 mm lithotripter

The EMS LithoClast Trilogy is a combination lithotripter utilizing both ultrasonic and electromagnetic ballistic lithotripsy combined with suction to fragment and remove stones and is available in 9 different sizes.[5] Generally, the preference is to use the largest probe size possible relative to stone size due to faster clearance times and greater probe durability.[6] Because of the limitations of the size of the working channel and the need to still allow room for irrigation, the 1.5mm probe is most commonly used in MIP-M mPCNL procedures. This study will describe accommodations to allow the ~60% larger probe to be used.

Surgical technique

Before their procedures, patients underwent CT scans for assessment of stone size, stone burden, location, peri-renal anatomy, skin to stone distance, and stone Hounsfield units. Preoperative urine culture and creatinine levels were obtained. Mini-PCNL was performed in either the prone position utilizing a Jackson table with an Allen Frame or in a modified-supine position utilizing the Galdakao-modified Valdivia position. An Endoscopic Combined Intrarenal Surgery (ECIRS) technique was preferentially employed, with an 11/13 sheath generally used for retrograde ureteral access.

The Storz 12Fr French nephroscope with the 16.5/17.5 Fr percutaneous access sheath was used (Figure 1a) and the procedure required three modifications in technique to maintain adequate irrigation and accommodate the Trilogy 1.9mm probe and handpiece (Figures 1b). First, to provide adequate fluid inflow, a 11/13 Fr ureteral access sheath *(BSC)* was placed retrograde into the ureter with a 10 French catheter (*BSC)* (Figure 1c) placed inside the access sheath and attached to irrigation (Figure 1d). Second, IV tubing was cut obliquely and attached to the inflow of the nephroscope to accommodate the large Trilogy handpiece (Figure 1a). Third, the *STORZ* 27001GG port was used to allow the 1.9mm probe to pass (Figure 1e). Stones were extracted using a combination of the suction of the 1.9mm Trilogy Lithotripter and vacuum extraction via the renal access sheath. The modifications allowed both adequate irrigation inflow via the 10 French catheter, additional irrigation antegrade around the lithotripter, and adequate outflow around the nephroscope through the percutaneous access sheath. Of note, care was taken to maintain the probe and handpiece straight, as there was a risk of probe breakage with torque of the handpiece on the probe (Figure 1e).

Primary outcome

The primary outcome of this study was treatment efficiency, defined as volume/minute.

Secondary outcome

The secondary outcomes of this study were post operative prediction of complete stone removal, operative time, operator satisfaction, and device malfunction rate. Prediction of complete stone removal was measured by intraop fluoroscopy and endoscopic evaluation of each calyx using the ECIRS approach. Device malfunction rate was reported as the broken probe rate.

Lithotripter efficiency

Treatment time was defined as the time from beginning of lithotripsy to total elimination of relevant stone from kidney, and lithotripsy time was defined as total lithotripter-on time. Stone treatment efficiency was defined as size of stone/total treatment time and treatment efficacy was defined as lithotripter time/treatment time. Lithotripter efficiency was defined as diameter (or volume in 3D)/lithotripter time in min. In patients with more than one distinct stone, the individual stone treatment was calculated independently.

Complication collection

Complication rates were collected and added to the database at the time that they occurred. The complications were reported to the patients' initial urologists who communicated them to the study team.

Statistical analysis

Statistical significance was set at $p<.05$. *Kruskal-Wallis* tests were used to compare stone efficiency by location and stone type. Statistical analysis was performed using *SPSS (IBM Armonk, NY).*

Source of funding

EMS provided the 1.9mm Trilogy probes and administrative funding for the study. Study execution, data analysis, and manuscript preparation was independently performed by the study authors.

RESULTS

Patient characteristics

The 1.9 mm Trilogy lithotripter mPCNL procedure was performed on 110 patients. Treatment success was defined as removal of all large renal stones with no residual stones or fragments. Table 1 demonstrates patient characteristics. The mean age of patients was 59.5 years and the median BMI of patients was 29. The majority of the patients included in this study were Caucasian (75%). Common comorbidities recorded in patients were current or former smokers, hypertension, and diabetes. 17 patients had positive urine culture preoperatively and were treated with appropriate antibiotics.

There were a wide range of stone locations with the most common primary location being in the renal pelvis (36%), and the most common secondary were lower pole renal stones (28%), as can be seen in Table 2. Median stone burden in patients was 25mm, and skin to collecting distance was 10cm. Patients were more commonly placed in supine position (66%) for duration of the procedure, as compared to prone (34%). Most patients (96%) only required 1 dilated access site, and the remaining 4% had 2 dilated access sites for clearance. The primary access location was the lower pole in 46% of patients, and the primary composition of the stones was calcium oxalate monohydrate (49%).

Case outcomes

Primary lithotripter outcomes are demonstrated in Table 3. Median total treatment (lithotripsy and stone evacuation) time was 6.8 min, median lithotripsy (lithotripter on) time was 3.3 min, median stone treatment efficiency (diameter/treatment time in mins) was 0.34 mm/min, Median lithotripter efficiency by volume was found to be 104.6 mm^3/min. Treatment efficacy (lithotripter time / total treatment time) was 50.4.

Endoscopic and fluoroscopic evaluation at completion of the case demonstrated stone clearance in all but one patient, who had an inaccessible 10mm fragment. No patients required re-treatment with surgery for their stone disease. Surgeon ergonomic and lithotripter satisfaction for this procedure was classified as “exceptional” with a score of 5/5 for most procedures performed. There was a broken probe rate of 12%. This occurred most often in early prone cases due to the angle of the scope and probe, and the relative difficulty keeping these straight compared to the 0-degree approach of the supine position.

Stone composition is also demonstrated on Table 2. One patient with a cystine stone was excluded from statistical analysis due to insufficient sample size. Lithotripsy efficiency was equivalent across stone types ($p>.05$). When comparing stone location, we found that lithotripter 1D efficiency was significantly highest in the lower pole (12.2 mm/min), and lowest in middle calyx or interpolar (6.3 mm/min) ($p<.05$).

Surgeon ergonomic and clinical performance satisfaction was nearly uniformly high (5/5). Clavien Dindo Class II or less complications were noted in 5 patients. No complications > Class II were noted. Only one patient was unable to be discharged the same day and required transfer to the hospital for admission for pain control. They were subsequently discharged without sequelae.

DISCUSSION

While there is no standardized sheath size used for mPCNL procedures,14F-22F sheaths are often preferred. Typically, in patients with smaller stones, a smaller sheath size may reduce renal impairment rates and bleeding.[8] With the decrease in sheath size as compared to standard PCNL procedures, the working channel also must be narrowed, typically resulting in a 5F or smaller.[9]

Lasers are used commonly for stone fragmentation; however, they have slower fragmentation times than kinetic and ultrasonic lithotripters.[9] Recently, there have been attempts to implement a working miniaturized lithotripter (1.5mm) to be used during mPCNL procedures.[9] Such efforts, however, have run into inherent clinical setbacks with surgeons limited in their suction of stones through the narrowed probe. The first use of the 1.9mm probe was cited by Sabnis et. al. and demonstrated effective clearance.[10] With the decreased sheath size, utilizing the largest probe possible can result in quicker stone clearance.

There are many irrigation techniques that have been employed while performing mPCNL procedures to reduce the risk of residual stones.[11] These include both gravity pressurized, mechanically pressurized, and automatic irrigation. Our technique employs both antegrade gravity and retrograde pressurized irrigation with suction through the 1.9mm lithotripter and outflow around the nephroscope. By replacing primarily antegrade with retrograde flow, fragments were guided towards the lithotripter, rather than being pushed away. In our study, the overall treatment efficiency was non-significantly highest in soft stones such as uric acid and lowest in hard stones such as calcium oxalate monohydrate. In our experience, the Trilogy lithotripter was able to carve out a particularly effective niche in soft stones where the suction allowed the lithotripter to effectively clear the kidney without needing to rely on the vortex effect. Laser techniques combined with the vortex effect have been noted to be effective in hard stones such as calcium oxalate, while they have struggled with softer stones.[12] Patients were felt to be stone-free at the conclusion of the procedure in 99% of cases,[13] with 1 case having an intraparenchymal stone that was not pursued.

A limitation in this data exists regarding evaluation of postoperative outcomes. Standard protocol at the institution is to obtain imaging at six weeks with either a renal ultrasound or a CT scan. A significant portion of the patients travel several hours to the practice specifically for access to PCNL, which is not readily available in their area. They are principally managed by their referring urologists who both remove their stents and obtain postoperative imaging. While the urologists are in contact to report any complications or events, the patient is generally not seen by the PCNL surgeon as an in person follow up. This may have led to an underreporting of complications, though there was excellent communication with the community providers for any issues that have arisen previously. Given the high fidelity of combined retrograde and anterograde examination of the kidney for predicting postoperative stone-free rate, this is included as a surrogate outcome.

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Comparisons between lasers and lithotripters have been performed, though they have not demonstrated large meaningful clinical differences between the two. A study by Patil et al. noted that the Trilogy Lithotripter had a better stone fragmentation rate (5.98 ± 4.25 mm3/sec) than the Thulium fiber laser (3.95 ± 1.00 mm^3/sec).[14] The study did not note a significant difference in stone free rates. Future study of stone free rates comparing the Trilogy Lithotripter and lasers is warranted. In this study, which focused on intraoperative performance, surgical success rate was determined using endoscopic and fluoroscopic evaluation[15] at the end of the case, limiting conclusions that can be drawn on true stone free rates as determined by postoperative CT scan. To compare the Trilogy lithotripter to other modalities we used a lithotripter efficiency datapoint, 3D stone volume in mm^3 over treatment time in minutes. We noted a median lithotripter efficiency of 104.6, using volume/minutes. The Patil et al. study had a stone volume of 3718.9mm^3 and a treatment time of 32.48 min in the Trilogy arm and 3425.9mm^3 and 28.63 min in the Thulium arm,[14] equivalent to 114.5 mm^3/min for the Trilogy arm and 119.7 mm^3/min for the TFL arm. Their study had a higher mean stone volume for the Trilogy arm than the TFL arm making it difficult to draw direct comparative conclusions. In our experience, particularly for softer stones, the 1.9mm Trilogy is able to tackle larger stones than a laser, and even partial staghorn stones.

CONCLUSIONS

mPCNL is a popular procedure for management of medium-large stones because of its less invasive nature without compromising effectiveness. The Trilogy 1.9mm probe is an effective tool to treat even larger stones, with the use of adjunctive irrigation measures to promote visibility and stone extraction.

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Disclosures: Dr. Davalos serves as a consultant for BSC, EMS, and Storz. Dr. Abbott serves as a consultant for BSC. EMS provided the lithotripter probes for the study as well as funding for the AUA statistician.

FIGURES AND TABLES

Figure 1. Adjunctive irrigation techniques.

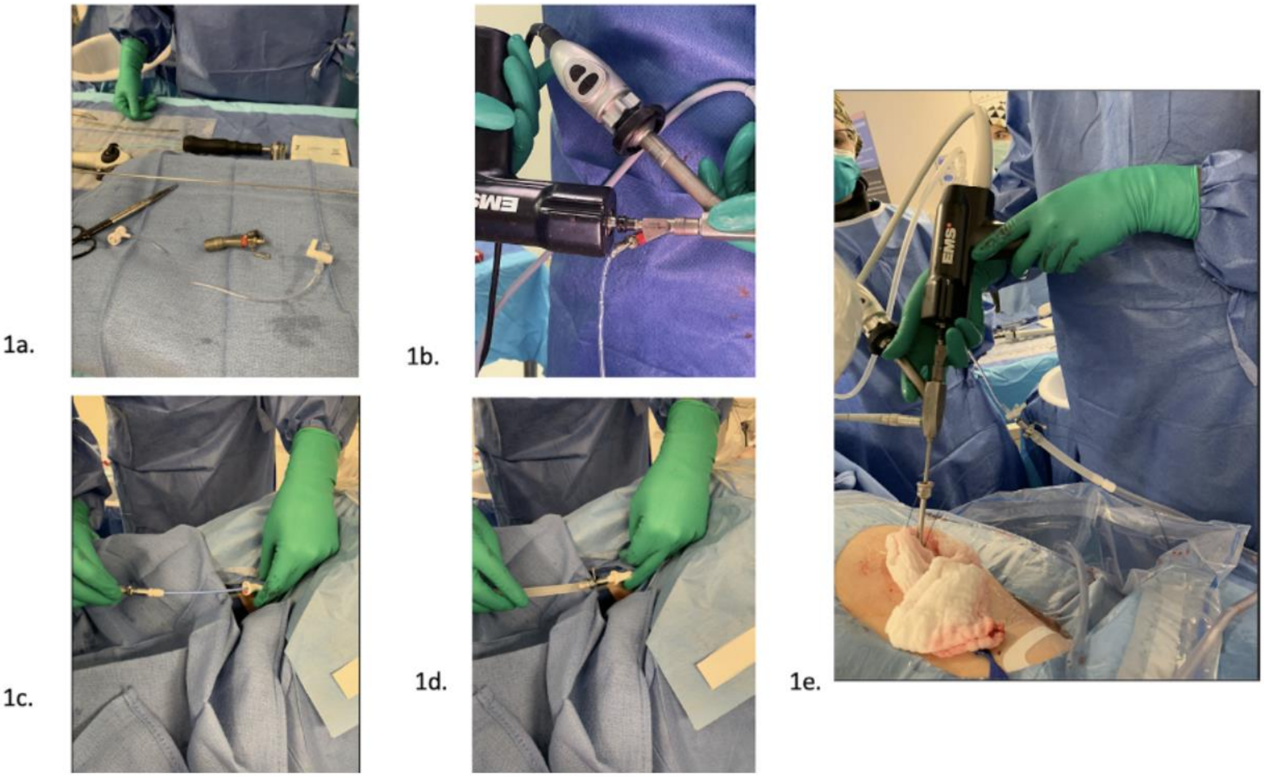
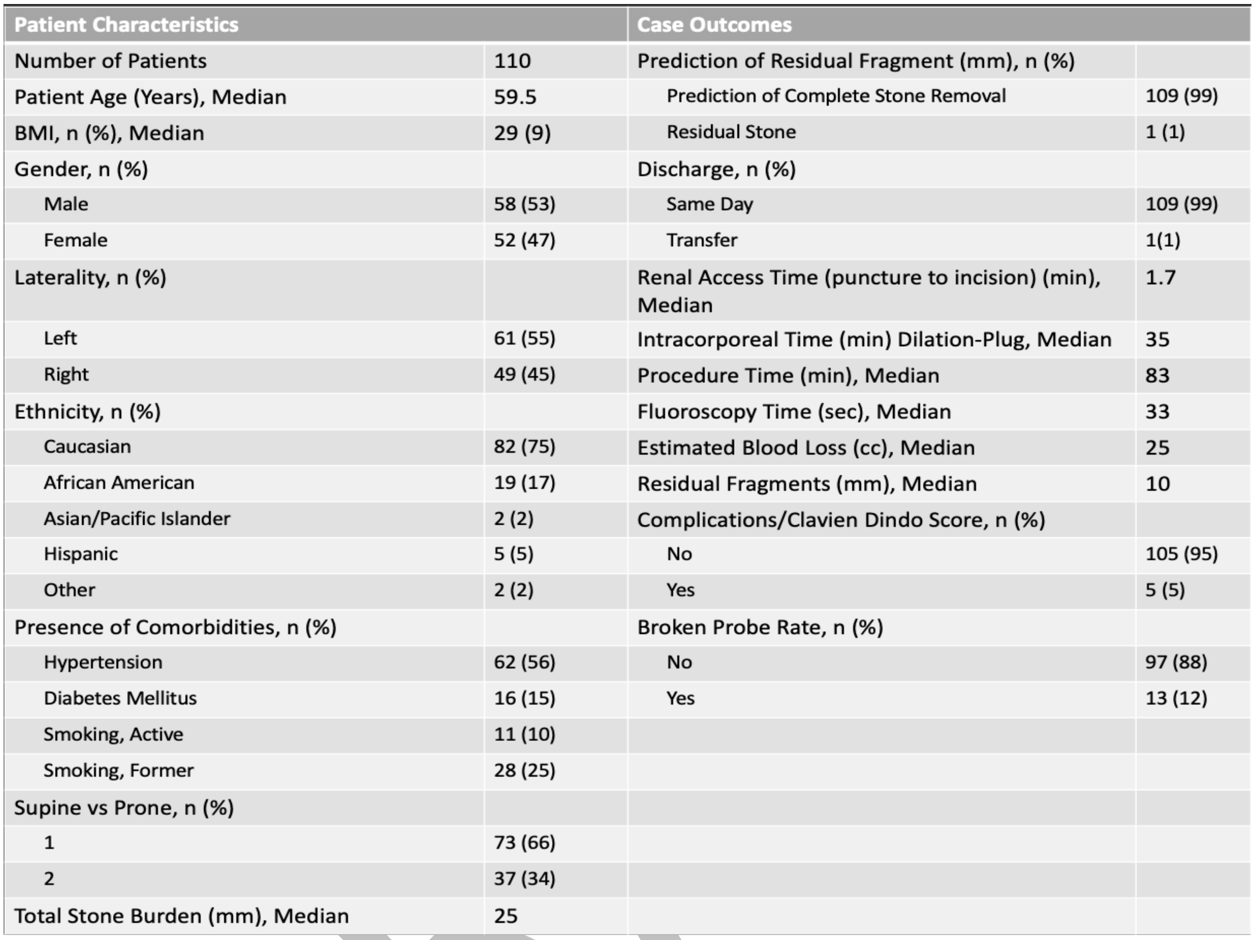
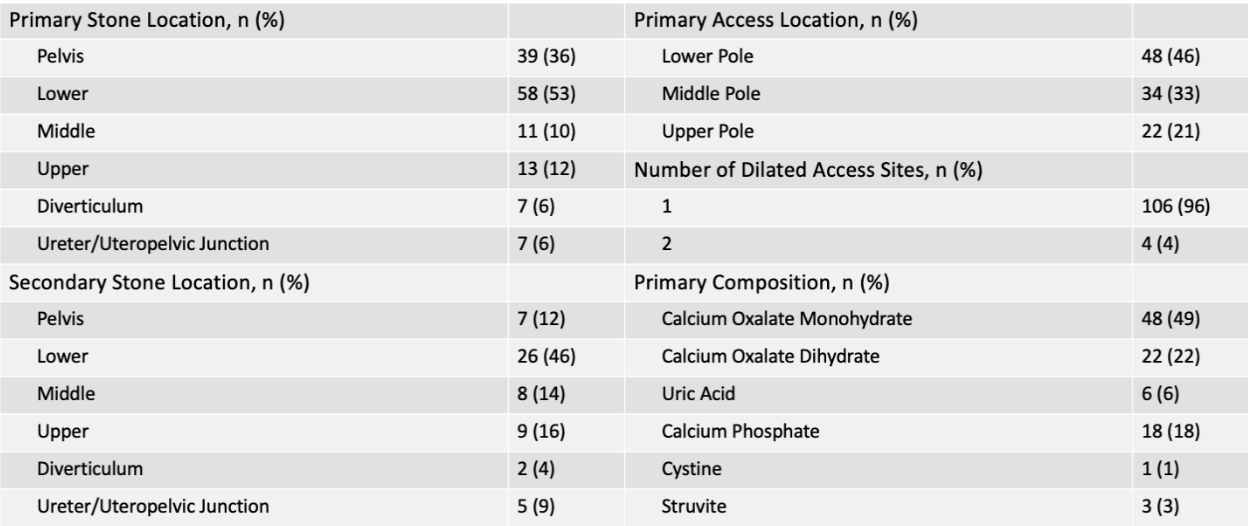


Table 1. Patient characteristics and case outcomes



Patient Characteristics		Case Outcomes	
Number of Patients	110	Prediction of Residual Fragment (mm), n (%)	
Patient Age (Years), Median	59.5	Prediction of Complete Stone Removal	109 (99)
BMI, n (%), Median	29 (9)	Residual Stone	1 (1)
Gender, n (%)		Discharge, n (%)	
Male	58 (53)	Same Day	109 (99)
Female	52 (47)	Transfer	1(1)
Laterality, n (%)		Renal Access Time (puncture to incision) (min), Median	1.7
Left	61 (55)	Intracorporeal Time (min) Dilation-Plug, Median	35
Right	49 (45)	Procedure Time (min), Median	83
Ethnicity, n (%)		Fluoroscopy Time (sec), Median	33
Caucasian	82 (75)	Estimated Blood Loss (cc), Median	25
African American	19 (17)	Residual Fragments (mm), Median	10
Asian/Pacific Islander	2 (2)	Complications/Clavien Dindo Score, n (%)	
Hispanic	5 (5)	No	105 (95)
Other	2 (2)	Yes	5 (5)
Presence of Comorbidities, n (%)		Broken Probe Rate, n (%)	
Hypertension	62 (56)	No	97 (88)
Diabetes Mellitus	16 (15)	Yes	13 (12)
Smoking, Active	11 (10)		
Smoking, Former	28 (25)		
Supine vs Prone, n (%)			
1	73 (66)		
2	37 (34)		
Total Stone Burden (mm), Median	25		

Table 2. Stone type and location



Stone Type and Location			
Primary Stone Location, n (%)		Primary Access Location, n (%)	
Pelvis	39 (36)	Lower Pole	48 (46)
Lower	58 (53)	Middle Pole	34 (33)
Middle	11 (10)	Upper Pole	22 (21)
Upper	13 (12)	Number of Dilated Access Sites, n (%)	
Diverticulum	7 (6)	1	106 (96)
Ureter/Uteropelvic Junction	7 (6)	2	4 (4)
Secondary Stone Location, n (%)		Primary Composition, n (%)	
Pelvis	7 (12)	Calcium Oxalate Monohydrate	48 (49)
Lower	26 (46)	Calcium Oxalate Dihydrate	22 (22)
Middle	8 (14)	Uric Acid	6 (6)
Upper	9 (16)	Calcium Phosphate	18 (18)
Diverticulum	2 (4)	Cystine	1 (1)
Ureter/Uteropelvic Junction	5 (9)	Struvite	3 (3)