A Novel Single Step Percutaneous Access Sheath: The Initial Human Experience

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Purpose: A novel 1-step percutaneous access sheath NS has been developed that allows the insertion of a dilating balloon and renal access sheath in a single step. We present the initial human experience with this sheath.

Materials and Methods: We performed a retrospective chart and database review of the initial 30 consecutive patients undergoing percutaneous nephrostolithotomy using the NS. Data collected included patient demographics, operative and recovery parameters, and complications.

Results: Mean patient age was 50.4 years (range 11 to 81), mean body mass index was 31.63 kg/m^2 (range 17.1 to 65) and mean preoperative stone area was 6.23 cm^2 (range 1 to 14.6). Six and 3 patients had full and partial staghorn calculi, respectively. Access was achieved via the upper pole in 16 patients, middle pole in 7 and lower pole in 7. Mean operative time was 114.8 minutes (range 61 to 237). Mean estimated blood loss was 145.5 cc (range 10 to 500) and mean postoperative hospital stay was 4.89 days (range 2 to 14). A total of 23 patients (76.7%) had no residual calculi on postoperative computerized tomography, 5 (16.7%) had residual fragments 4 mm or less and 2 (6.7%) had residual stone fragments greater than 4 mm. There were no complications related to the NS.

Conclusions: The NS is safe, easy to use and has potential advantages compared to currently available renal access sheaths.

Key Words: kidney, kidney calculi, nephrostomy, percutaneous, balloon dilatation

There are 2 main dilation methods used in percutaneous renal surgery. The first method requires serial dilation of the tract with increasingly larger semirigid dilators until an adequate size sheath can be placed.[1] The more commonly used technique for renal access involves a 2-step device. A high pressure balloon catheter is first advanced into the collecting system. After balloon inflation a sheath is advanced over the dilated balloon to allow access into the collecting system.

We have developed a novel, 1-step PCNL sheath that allows tract dilation and sheath placement in a single step. We reviewed our initial experience with the first 30 consecutive patients to undergo PCNL with this novel 1-step device.

MATERIALS AND METHODS

A retrospective chart and database review was done of all patients undergoing PCNL using this NS between October 2003 and September 2004. The parameters collected were patient demographics, and stone (size, location and type), operative and recovery parameters. In particular the ability of the NS to allow safe access into the kidney, and the potential strengths and weaknesses of the device were determined.

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BMI was calculated using the formula, weight in kg divided by the square of the height in m.[2] Postoperative stay was rounded to the nearest whole day and calculated from the date of surgery to the date of discharge home. Mean stone area was calculated by measuring the size of the stone on radiological imaging in the left-right and cephalad-caudal planes, and multiplying the 2 values. If multiple stones were present, the area of each stone was added together to determine the total stone area. The stone-free rate was determined by postoperative computerized tomography in 25 patients (83%) and by tomography in 5 (17%). Patients with no residual stone fragments were considered stone-free.

The technique for sheath insertion begins with insertion of an 8Fr nephroureteral stent with the patient under local anesthesia in the interventional radiology suite. The patient is transferred to the operating room and following the induction of general anesthesia a nephrostogram is obtained to delineate caliceal anatomy. A 0.038 extra stiff guidewire is then advanced through the nephroureteral stent into the bladder. A 10Fr dual lumen catheter is advanced over the extra stiff guidewire into the proximal ureter to allow placement of a 0.038 safety guidewire. The NS is advanced over the extra stiff guidewire into the collecting system under fluoroscopic guidance. After it is positioned appropriately half-strength contrast material is injected until the balloon is fully inflated. The balloon is rated to 20 atm. After deflating the balloon the clear PTFE jacket and balloon are removed and the sheath is already positioned for use (fig. 1, *A* to *D*).

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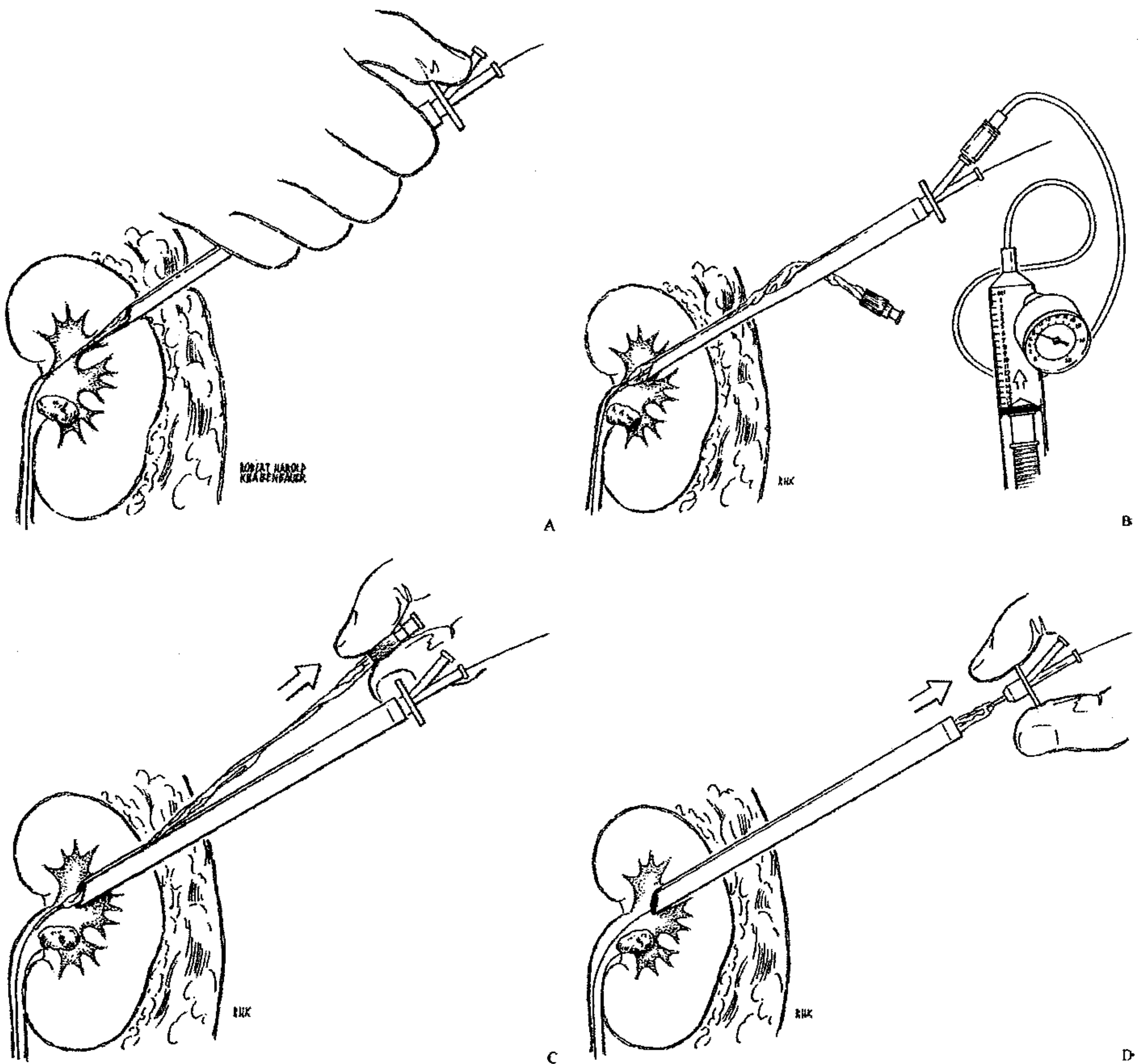


FIG. 1. Placement of novel 1-step device. *A*, uninflated balloon/sheath combination is inserted into kidney over extra stiff guidewire. *B*, inflation device is connected to balloon port and balloon is inflated. *C*, after balloon inflation and deflation clear PTFE jacket that holds sheath in position during insertion is removed (arrow). *D*, balloon is removed (arrow) and sheath is ready for use.

RESULTS

Mean age in the 30 consecutive patients undergoing PCNL using the NS was 50.4 years (range 11 to 81). Mean BMI was 31.63 kg/m^2 (range 17.1 to 65). Nine patients (30%) had a BMI of less than 25, 6 (20%) had a BMI of between 25 and 30, 8 had a BMI of between 30 and 35 (27%), and 7 had a BMI of greater than 35 (23%), that is 36.9, 38.5, 40.2, 43.7, 45.4, 56 and 65, respectively. The mean American Society of Anesthesiology score was 2.2 (range 2 to 4). The mean stone area was 6.23 cm^2 (range 1 to 14.6).

In 16 patients access was obtained via an upper pole access, while in 7 each access was achieved through a middle or lower pole, respectively. Two patients had horseshoe kidneys, including 1 morbidly obese patient with a BMI of 65. Mean operative time was 114.8 minutes (range 61 to 237). Mean estimated blood loss was relatively low at 145.5 cc (range 10 to 500) and only 1 patient in the series received blood transfusion. The mean hemoglobin decrease was –1.52 gm/dl.

A total of 25 patients were treated with a single procedure, 4 required 2 procedures and 1 required 3 procedures. Of the patients 23 (76.7%) had no residual calculi on postoperative computerized tomography, 5 (16.7%) had residual fragments 4 mm or less and 2 (6.7%) had residual stone fragments greater than 4 mm. When measuring the change in serum creatinine between preoperative evaluation and the postoperative creatinine nadir, creatinine remained sta-

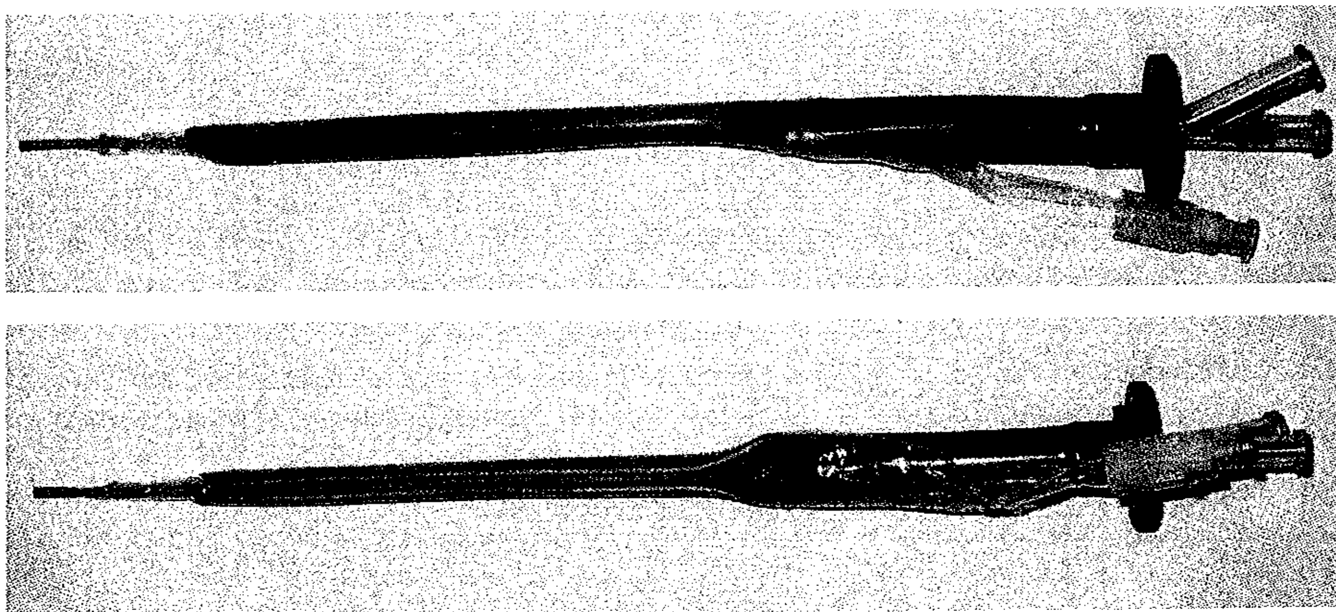


FIG. 2. Novel 1-step access device prior to insertion

ble with a mean increase of 0.05 mg/dl (range −0.4 to 0.4). A rigid nephroscope combined with ultrasonic lithotripsy was used in all except 5 cases and a flexible nephroscope was used to perform renal mapping in 25.

Mean postoperative hospital stay was 4.86 days (range 2 to 14). In the 5 patients requiring more than 1 procedure each mean hospital stay was 8.4 days (range 4 to 14). In the patient requiring 3 operations hospital stay was 14 days. In the 4 patients requiring 2 procedures each hospital stay was 4, 7, 7 and 10 days, respectively.

Chemical analysis of stone composition was available in 21 patients. Chemical analysis revealed pure calcium oxalate in 6 patients, pure calcium phosphate in 2, a mixture of calcium oxalate and calcium phosphate in 5, pure uric acid in 3 and struvite in 2. The remaining 3 patients had various mixtures of stone types.

Complications were observed in 5 patients (17%), including 1 episode of bleeding from a nephrostomy tube placed into a middle pole calix in a horseshoe kidney, which was corrected by changing access into an upper pole calix. This patient did not require transfusion. One patient had bradycardia intraoperatively. Myocardial infarction was ruled out in the intensive care unit overnight and the patient was discharged home on postoperative day 3 without further complication. One patient with chronic renal insufficiency who was not dialysis dependent but who required stone removal prior to kidney transplantation had postoperative ileus. This patient was discharged home on postoperative day 10. Another patient with multiple medical problems, including a history of myocardial infarction, stroke, diabetes and emphysema, had myocardial infarction postoperatively. He was discharged home on postoperative day 10. The final complication consisted of transfusion. This patient had chronic infection and preoperative anemia with a hemoglobin of 9.9 gm/dl. The patient was given 2 U blood intraoperatively and her postoperative hemoglobin was 10.2 gm/dl.

Using the NS access was obtained into the collecting system in all except 1 morbidly obese woman who was 5 feet 10 inches tall (BMI 37). In this case the NS was not used and an extra long Amplatz sheath (Cook Urological, Spencer, Indiana) was placed using the multistep Amplatz dilating system. There were no complications related to the NS in any patient.

DISCUSSION

Although Rupel and Brown extracted a renal calculus with utility forceps via a surgically created nephrostomy tract in 1941,[3] the technique of percutaneous extraction of renal calculi did not gain popularity until the early 1970s.[4–7] Since the early descriptions of PCNL, there have been few

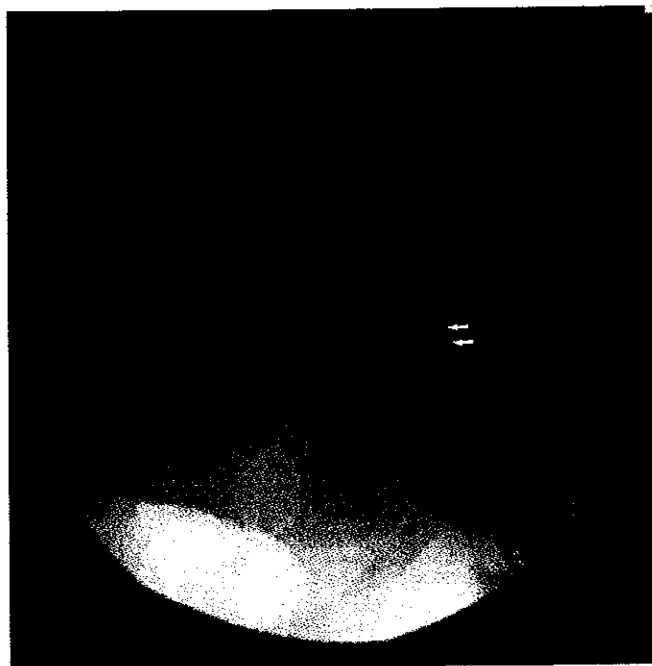


FIG. 3. Fluoroscopic image shows novel device during insertion. Arrows indicate radiopaque markers on distal and proximal portions of beveled distal end of sheath.

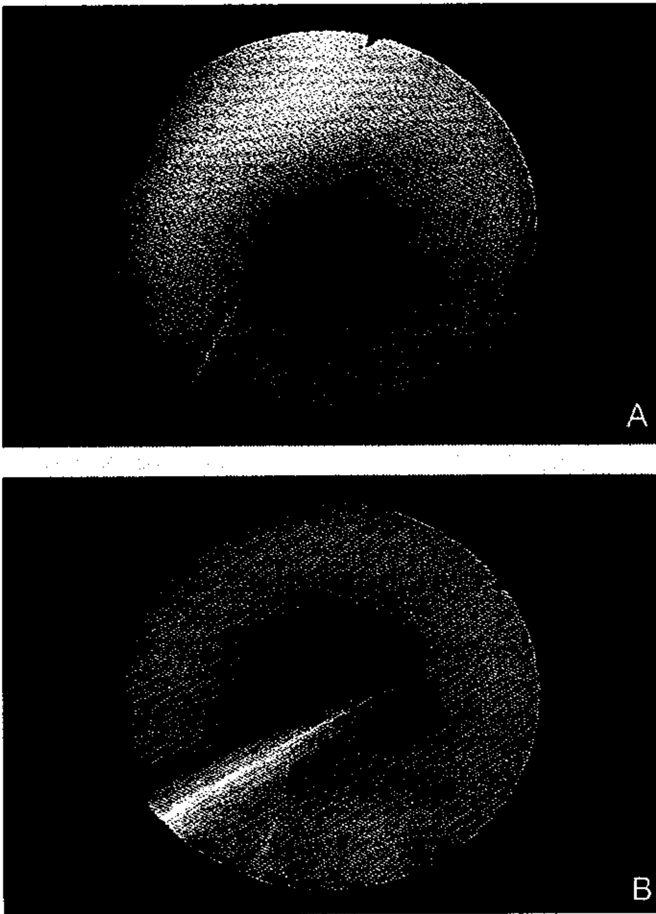
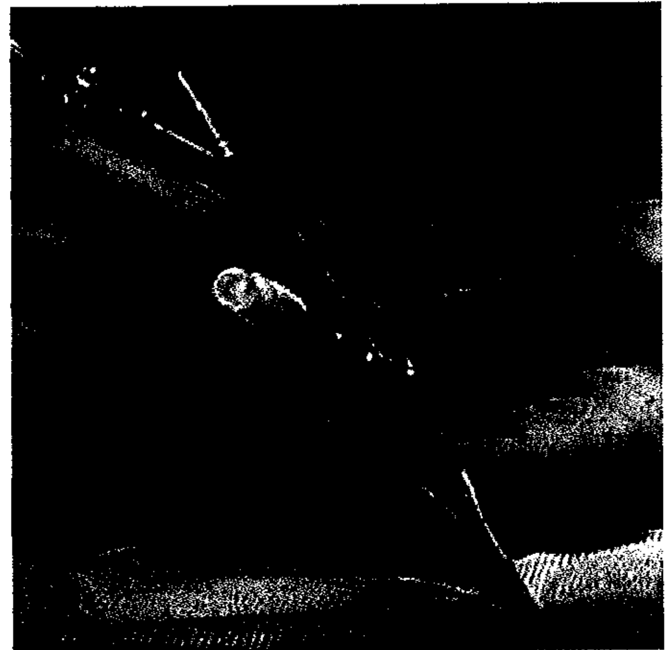


FIG. 4. Endoscopic view of internal sheath surface after expansion. *A*, proximal part of previously folded portion. *B*, distal portion.

modifications in the technique of renal access. Originally renal access involved sequential insertion of graduated semirigid dilators until the desired sheath size could be inserted.[1,8] The use of multiple dilators was time-consuming and with each sequential dilation the potential existed for injury to the collecting system.[9] In the early 1980s a high pressure balloon catheter was developed to dilate the nephrostomy tract but this technique still required insertion of a sheath over the inflated balloon.[10,11] The 2-step process of balloon dilation followed by sheath placement represented a simplification of the original multistep procedure and it has been viewed as a safer technique for performing tract dilation.[12] Won and Eshghi reported their experience using a high pressure balloon catheter, followed by advancement of the sheath over the balloon in 320 patients during a 5-year period.[13] They found that this technique was more advantageous than the traditional Amplatz dilators due to less trauma, shorter dilation time and decreased blood loss.

The 1-step percutaneous sheath tested in this report represents a further simplification in percutaneous access technology compared with prior renal access techniques. It allows simultaneous insertion of a dilating balloon and an access sheath in a single step.

The device consists of a PTFE sheath that is compressed, folded and wrapped around a high pressure balloon catheter (fig. 2). A clear PTFE jacket holds the sheath in position during insertion (fig. 1, *B*). The uninflated sheath is 6Fr at the tip and it tapers to 20Fr in its mid portion. The balloon has 2 radiopaque markers that identify the proximal and distal bevels of the sheath to allow appropriate positioning of the device inside the collecting system prior to inflation (fig. 3). Expansion of a high pressure balloon catheter inside the sheath allows expansion of the sheath in the collecting system (figs. 4 and 5). The inner diameter of the inflated sheath is 30Fr, which is identical in size to standard renal access sheaths on the market. The outer diameter is smaller than conventional percutaneous access sheaths (33Fr vs 34Fr).



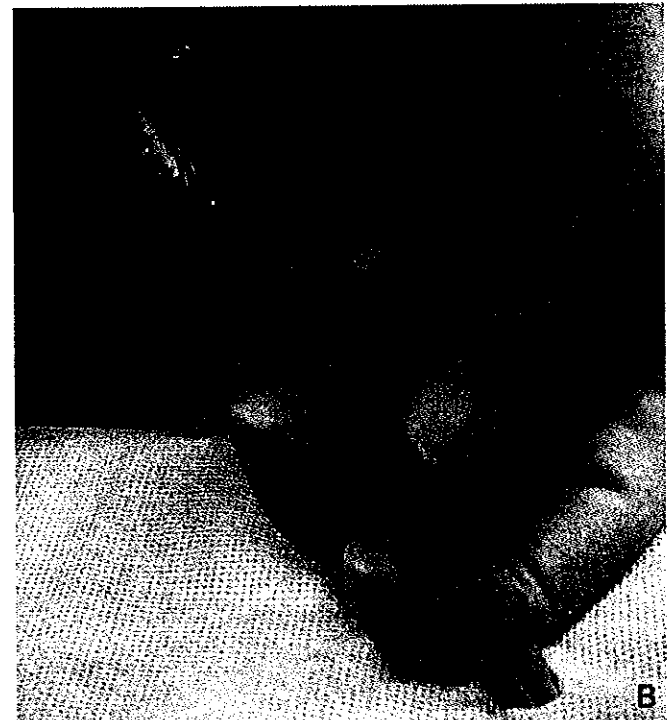


FIG. 5. External view of balloon/sheath combination. *A*, prior to balloon expansion. *B*, after balloon expansion.

The balloon inside the NS is rated to 20 atm. Due to the balloon design the device is intended for a single use only.

The simplicity of insertion with the NS and the avoidance of the most difficult step of insertion noted with the standard 2-step balloon/sheath system, that is sheath insertion over the balloon, should translate into increased safety, although this study is not a comparison study between access sheaths and we did not directly address this issue. In an animal study we observed that the 2-step sheath required 147 seconds for insertion compared with 97 seconds for the 1-step sheath, which is a 50% decrease in insertion time.[14]

This initial human experience with the NS included various patients with various renal access locations. In each patient the NS was able to provide collecting system visualization and stone treatment. This experience includes morbidly obese patients with a BMI as high as 65, 2 with horseshoe kidneys and 5 with full staghorn calculi. The device was simple to use, safe and effective. Our initial transfusion rate with the NS device was 3%, which compares favorably to the 7% to 25% transfusion rate reported in the literature for the traditional 2-step balloon device.[9,15,16]

There are potential advantages of this novel device compared to standard techniques for percutaneous access. In a comparison study perforation of the collecting system was noted in 11.6% of cases using the traditional 2-step balloon dilator and in 16.6% when Amplatz dilators were used.[16] Stoller[15] and Goharderakhshan[17] et al also suggested that advancement of the working sheath over the balloon is potentially traumatic and could result in renal laceration. The NS is placed inside the collecting system using fluoroscopy prior to balloon inflation. After the balloon is inflated the sheath is already in position and ready for use. There were no instances of collecting system injuries in this study.

The NS is also thinner and is more expandable than the standard Amplatz sheath and it may allow more irregular sized stones and larger stones to be pulled through the sheath intact. Despite increased deformability we have not witnessed sheath injury during intact extraction. Another potential advantage of the NS device is its use during upper pole access above the 12th rib. The standard 2-step balloon inserted over the rib often results in a fully inflated balloon that is angled over the 12th rib. Insertion of the rigid sheath over the angled balloon may be difficult and potentially impossible because the rigid sheath catches on the rib and requires significant force for placement. This difficulty of placing the sheath over the angled balloon is avoided using the NS since even moderate angulation of the balloon does not interfere with sheath deployment. This is due to the flexibility of the sheath and the fact that the sheath is already in position when the balloon is inflated. This increased flexibility also may require care during insertion of the rigid scope but did not impair the ability to pass the rigid scope into the collecting system in any case.

As with all novel technologies, it is important to use the device correctly. The uninflated 20Fr diameter at the mid portion of the NS is larger than the 7Fr of the balloon portion of the 2-step balloon/sheath system. In these 30 consecutive cases there was no instance in which the NS could not be advanced through the fascia or renal capsule. An extra stiff guidewire was used in all cases to provide increased rigidity to allow the passage of the uninflated NS into the collecting system.[18]

It is also important to ensure that the device is fully advanced into the collecting system before balloon inflation. If the device is inflated with the sheath outside of the collecting system, it can be advanced into the collecting system over the rigid nephroscope or the balloon can be re-inflated, and the balloon and sheath can be advanced together as a unit into the collecting system. In 2 patients in this series this maneuver was performed without complication. The folded nature of the uninflated sheath results in an inflated configuration that sometimes may not appear perfectly round. This was not found to hamper vision or the ability to treat the stone in any patient.

CONCLUSIONS

This initial human experience with the NS demonstrates that it is safe and effective for use during percutaneous nephrostolithotomy. This new device offers a potential alternative to the standard devices currently used to treat large renal calculi. One-step insertion makes this an attractive new option for percutaneous renal access.

ACKNOWLEDGMENT

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Abbreviations and Acronyms

BMI	=	body mass index
NS	=	novel 1-step percutaneous access sheath
PCNL	=	percutaneous nephrostolithotomy
PTFE	=	polytetrafluororethylene

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