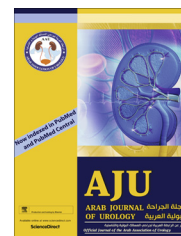




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# A novel percutaneous nephrolithotomy (PCNL) set: The ‘Economical One-shot PCNL Set’ (Ecoset)



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## KEYWORDS

Percutaneous  
nephrolithotomy;  
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Cost;  
One-shot;  
Ecoset, Economical  
One-shot PCNL Set

## ABBREVIATIONS

PCNL, percutaneous  
nephrolithotomy

**Abstract Objectives:** To suggest a novel disposable percutaneous nephrolithotomy (PCNL) set that we named the ‘Economical One-shot PCNL Set’ (Ecoset), which consists of a single 30-F dilator, 30-F sheath, and 8-F polyurethane dilator, as use of a ‘one-shot’ dilatation technique during PCNL is becoming widespread.

**Patient and methods:** The medical records of 42 patients with kidney stones who had undergone ‘one-shot’ PCNL from February 2014 to June 2016 were retrospectively reviewed and analysed. Demographic data, as well as the stone size, radiation exposure time, operation time, hospitalisation duration, rate of treatment success and complications, were recorded.

**Results:** The mean (SD, range) age of the patients was 44.43 (16.54, 11–72) years. The mean (SD) stone size was 35.12 (17.53) mm. The mean (SD) operation time was 54.58 (22.24) min. The mean (SD) fluoroscopic screening time was limited to 154.72 (117.48) s. Treatment success was achieved in 32 (76%) patients. The mean (SD) hospital stay was 3.09 (0.75) days. None of the patients had any major complications. Bleeding requiring blood transfusion was required in three patients. The cost of a disposable dilatation set for a single PCNL operation with a balloon set, a standard Amplatz set, or an Ecoset is ~\$137, \$120, or \$27 (American dollars), respectively.

**Conclusions:** The one-shot dilatation technique using the Ecoset for PCNL can be feasibly, safely, and effectively performed in almost every adult patient. The

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Amplatz dilator set and balloon dilator set have the disadvantage of relatively high cost, whereas the Ecoset is the cheapest 'disposable set' that can be used during PCNL surgery.

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## Introduction

Percutaneous nephrolithotomy (PCNL) is the 'gold standard' procedure for managing particularly large renal stones. The stages of this operation are: obtaining access to the collecting system (guided by ultrasonography or fluoroscopy), dilatation of the tract, placement of the sheath, fragmentation of the calculus, and placement of the nephrostomy catheter. Dilatation of the percutaneous access tract can be achieved by three standard techniques: semi-rigid Amplatz dilatation, metal telescopic dilatation of the Alken type, and balloon dilatation. The novel tract dilatation method 'one-shot' was first introduced by Frattini et al. [1]. In this method, the tract is dilated by a single 30-F Amplatz dilator. After this first study; many studies have been published showing the advantages of this dilatation method [2–8].

No commercial Amplatz dilator set is designed for the 'one-shot' dilatation technique. Therefore; in the present study, we suggest some modifications to the Amplatz dilator set design and present our experience in the use of a novel Amplatz dilator set that we named the '**Economical One-shot PCNL Set**' (Ecoset).

## Patients and methods

Ethics approval for the study was obtained from the local ethics committee of our institution. All patients signed the written informed consent before surgery. The medical records and files of 42 patients with renal stones who had undergone one-shot PCNL from February 2014 to June 2016 were retrospectively reviewed and analysed. These PCNL operations were performed using the novel Ecoset. This set consists of an 8-F polyurethane dilator, a 30-F Amplatz dilator, and a 30-F sheath. All operations were performed in a single centre by surgeons who had similar experience with PCNL surgery. Demographic data, as well as the stone size (largest diameter), radiation exposure time, number of access tracts, operation time, postoperative length of stay, treatment success and complication rates, were recorded.

Treatment success was defined as the absence of any residual stones or the presence of clinically insignificant residual fragments. Radiation exposure time was defined as the number of seconds of radiation exposure that had elapsed, based on the dose summary of the fluoroscopy machine at the end of each procedure. Operation time

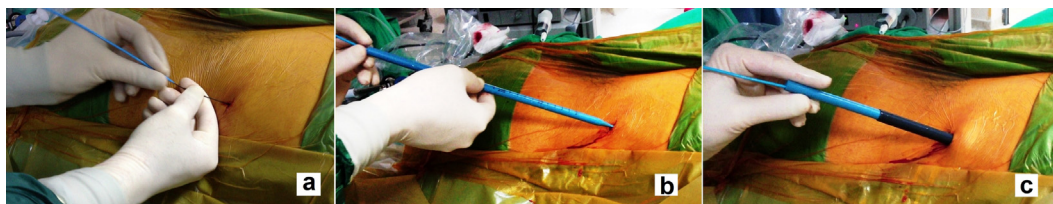
was defined as the time spent on surgery from the moment the nephrostomy needle punctured the pyelocalyceal system to the moment when the nephrostomy site was closed or the nephrostomy tube was secured [9]. Complications were classified using the Clavien–Dindo classification score system standardised for PCNL [10]. Haemoglobin drop was defined as the change in haemoglobin from before the surgical procedure to 6–24 h after surgery. Stone size was defined as the largest diameter of the stone on ultrasonography or radiography.

In this technique, after administration of general anaesthesia, a 6-F ureteric catheter was advanced to the renal pelvis, under direct vision with the cystoscope, in the lithotomy position. The ureteric catheter was fixed to the transurethral Foley catheter, the patient was repositioned to the prone position, and the renal collecting system anatomy was outlined by retrograde injection of diluted contrast via the ureteric catheter. The targeted calyx was then punctured with an 18-G access needle under fluoroscopic guidance. After a guidewire was passed into the calyx, the 8-F polyurethane dilator was advanced over the guidewire. Tract dilatation was then performed in our patients by directly advancing a single 30-F Amplatz dilator over the 8-F polyurethane dilator and a 30-F sheath was placed in the collecting system. In this way, the tract is created in a single step. This tract dilatation and sheath placement were performed under fluoroscopic guidance in all patients (Fig. 1).

Patient enrolment had no specific exclusion criteria, so all patients who underwent one-shot standard PCNL with a 30-F tract size for kidney stone indications during the study period were eligible for inclusion. Patients whose PCNL tract size was < 30 F were excluded from the study.

## Results

The one-shot dilatation technique using the Ecoset was successfully applied in 45 patients, and the tract was dilated in 42 patients. The mean (SD, range) age of the patients was 44.43 (16.54, 11–72) years. The mean (SD, range) stone size was calculated as 35.12 (17.53, 17–65) mm. In all, 12 patients had staghorn renal stones. The mean (SD, range) operation time was 54.58 (22.24, 20–10) min. The mean (SD, range) fluoroscopic screening time was limited to 154.72 (117.48, 30–420) s. For all patients a second tract was not required. Treatment success was achieved in 32 (76%) patients. The mean



**Fig. 1** The steps of the one-shot dilatation technique during PCNL surgery. (a) Advancing of the 8-F polyurethane dilator over the guidewire. (b) Advancing of the 30-F Amplatz dilator over the 8-F polyurethane dilator. (c) Advancing of the 30-F Amplatz sheath over the dilator.

**Table 1** The demographic characteristics and perioperative findings.

Characteristic	Value
Age, years	
Mean (SD)	44.43 (16.54)
Median (range)	45 (11–72)
Male/female, <i>n</i>	25/17
Side, right/left, <i>n</i>	25/17
Stone size, mm	
Mean (SD)	35.12 (17.53)
Median (range)	26.5 (15–80)
History of renal surgery, <i>n</i> (open/PCNL)	12 (5/7)
Operation time, min	
Mean (SD)	54.58 (22.24)
Median (range)	50 (20–100)
Haemoglobin drop, mg/dL	
Mean (SD)	1.37 (1.11)
Median (range)	1.1 (0–3.7)
Postoperative length of stay, days	
Mean (SD)	3.09 (0.75)
Median (range)	3 (2–5)
Radiation exposure, s	
Mean (SD)	154.72 (117.48)
Median (range)	125 (30–420)
Treatment success rate, <i>n</i> (%)	32 (76)
Complication rate, <i>n</i> (%)	5 (11.9)
Clavien–Dindo classification grade	
I (fever)	1 (2.4)
II (blood transfusion)	3 (7.1)
IIIa (failed ureteric stenting)	1 (2.4)

(SD, range) hospital stay was 3.09 (0.75, 2–5) days. The demographic characteristics and perioperative findings of the patients are summarised in [Table 1](#).

A PCNL tract was created in 12 patients who had a history of previous renal surgery. However, in three patients (with previous renal surgery), the tract could not be dilatated by a one-shot technique. These failed attempts were managed successfully using Amplatz renal dilators in two steps (20-F and 30-F dilators), which we called the ‘double-shot’, or in three steps (using 14-F, 20-F, and 30-F dilators), which we called the ‘triple-shot’.

None of the patients had any major complications during the postoperative period. The modified Clavien–Dindo grading system indicated complications in five patients. The mean (SD, range) decrease in haemoglobin level was 1.37 (1.11, 0–3.7) mg/dL. Transfusion was required in three patients (Grade II complication). There was postoperative fever in one patient (Grade I complication). Prolonged urine leakage occurred in one patient and ureteric stenting without general anaesthesia was attempted, but this failed due to ureteric orifice oedema (Grade IIIa complication). Urine leakage resolved spontaneously in the following days.

## Discussion

Dilatation of the percutaneous tract for PCNL is an important step and is performed using four techniques: semi-rigid Amplatz dilatation, metal telescopic dilatation of the Alken type, balloon dilatation, and the one-shot dilatation described recently. The tract dilatation technique may affect the cost of the surgery, fluoroscopy time, haemoglobin decrease, surgery duration, and success rate of dilatation in patients with a history of previous renal surgery. A recent meta-analysis that compared the four tract dilatation methods for PCNL showed that a one-shot dilatation can significantly decrease tract fluoroscopy time and lower the haemoglobin decrease when compared with metal telescopic dilatation, especially in patients with a history of previous open nephrolithotomy. There were no significant differences in stone-free and blood transfusion rates between the one-shot dilatation and metal telescopic dilatation methods [11]. Frattini et al. [1], who evaluated the costs of disposable dilatation methods, argued that balloon dilatation has the disadvantage of a relatively high cost, Amplatz dilatation has intermediate cost, and one-shot dilatation is the cheapest.

Dilatation of the tract can be performed quickly and safely in a single step over the guidewire with a balloon dilator, but is relatively expensive. Dilatation of the tract by Alken telescoping dilators and semi-rigid Amplatz dilators is performed by serial dilatation, which is time consuming and results in longer fluoroscopic exposure when compared with balloon dilator usage [8]. Moreover, a standard Amplatz dilator set contains a

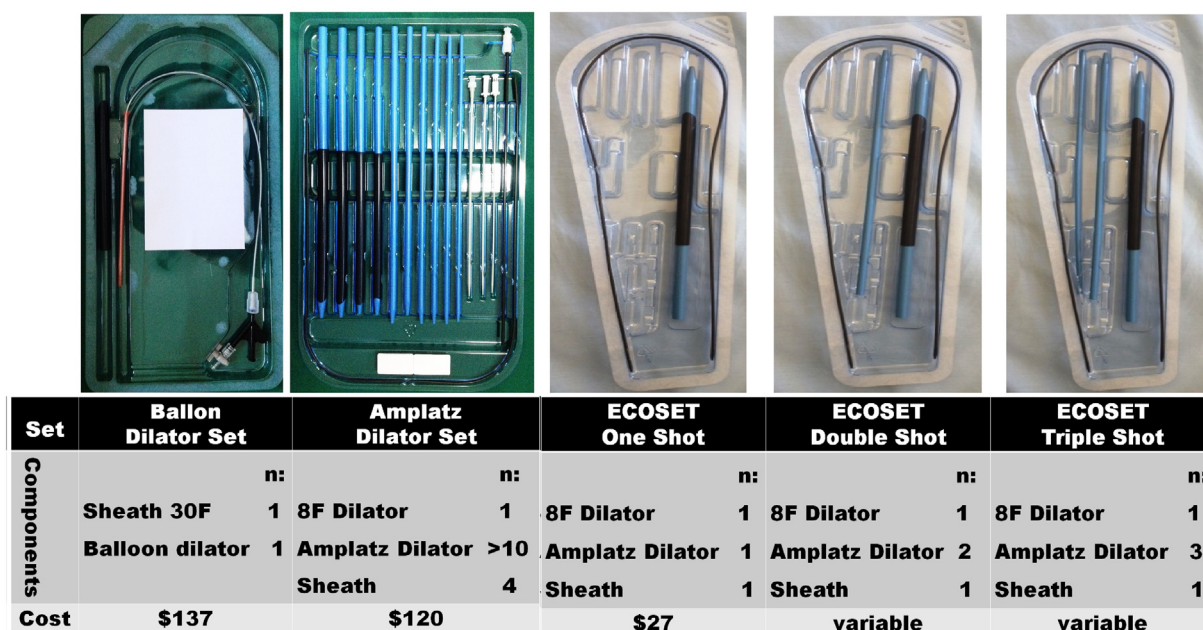


Fig. 2 Components and costs of the disposable sets used for standard PCNL surgery.

minimum of 10 dilators and four sheaths. The number of these dilators used during a standard PCNL operation performed with gradual dilatation is unclear. All the dilators are used serially or used by skipping some of the sizes. For example, if the aim of the surgeon is to create a 30-F tract using standard Amplatz dilator set, this tract can be obtained in three ways: by serial use of all dilators; by using some dilators and skipping some of the sizes (i.e., the 16-F, 24-F, and 30-F dilators); and by a one-step 30-F dilator. In the literature, this issue is unclear and most authors do not provide any details of how many dilators are used during a standard PCNL performed using the Amplatz dilator set. Therefore, if a surgeon performs a standard PCNL operation using some of the dilators or a one-step technique, most of the dilators and sheaths in an Amplatz dilator set are redundant.

This kind of design pattern increases the cost of an Amplatz set, as well as the cost of the operation. Therefore, we first designed a novel Amplatz dilator set for the one-shot dilatation technique. In the present study, we present our experience using this novel Amplatz dilator set, which we have named the *Ecoset*. If a surgeon prefers to use two dilators during PCNL, we suggested another novel Amplatz dilator set that we called the ‘*Ecoset double-shot*’. For the surgeon that uses three dilators, we suggest the ‘*Ecoset triple-shot*’ (Fig. 2). These designs can be varied according to the surgeon’s practise. Clearly, the total cost of the set will decrease due to the reduction in the number of dilators and sheaths.

In the present study, radiation exposure time, operation time, rate of stone clearance, complication rate, treatment success, and haemoglobin drop were similar to previously reported data obtained using the one-shot technique [1,3–8]. We can also perform this tech-

nique successfully in patients who have undergone previous renal surgery (open or PCNL), as mentioned in the literature [4]. This confirms that the one-shot dilatation technique is feasible, safe, and well-tolerated in most patients. Significant advantages of this technique are its greater cost effectiveness and the reduction in time required during the dilatation steps. This less time-consuming dilatation results in less radiation exposure and a reduced operation time. Our present patients had high stone burdens, and yet the total operation time was consistent with that reported in recently published studies by Amirhassani et al. [3] and Nour et al. [7]. The mean (SD) operation time reported by Amirhassani et al. [3] was 51.14 (40.85) s and was 54.58 s in the present study. The median operation time reported by Nour et al. [7] was 85 s and was 50 s in the present study. Frattini et al. [1] noted that the one-shot dilatation technique had a shorter median radiation exposure time when compared to gradual dilatation using Alken telescoping dilators (264 vs 227 s, respectively) and our present results are consistent with this (154.7 s).

The one-shot dilatation technique did not lead to more haemorrhagic events or other complications when compared with multiple incremental techniques [3,4,6–8]. A reduction in the complication rate has been reported by some authors, but the differences were not statistically significant [1,3]. Recent studies report complication rates of 8–34%, and this rate was 11.9% in our present study. Frattini et al. [1] were the first to describe the one-shot dilatation technique, and they estimated the cost of the Alken dilator set, balloon dilator set, and one-shot dilator set at ~\$500, \$300, and \$60 (American dollars), respectively. They underlined that, for a single procedure, the Alken dilator set is the least

expensive, even if the initial cost is the highest, because the set is reusable. The cost for a single PCNL procedure therefore is low, as many procedures are performed with the same set.

The most important difference in our present study was when comparing the costs of disposable sets used during PCNL surgery. The cost for a single PCNL operation with a disposable balloon set, a disposable standard Amplatz set, and a disposable Ecoset is ~\$137, \$120, and \$27 (American dollars), respectively (Fig. 2). Additionally, the Ecoset double-shot and Ecoset triple-shot are clearly less expensive than a standard Amplatz dilator set.

The present study has several limitations, as it included relatively few patients and did not include a control group. Also, the study was retrospective in design with the attendant disadvantages of such studies.

### Conclusions

The use of a one-shot dilatation technique during PCNL surgery is increasing over time. This technique is usually performed using Amplatz renal dilators, but a commercial product specifically for this technique is lacking. We suggest a novel Amplatz dilator set for the one-shot dilatation technique – the Ecoset. Additionally, the contents of this Amplatz dilator set can be designed according to the needs of surgeons (i.e., one-shot, double-shot, triple-shot). Undoubtedly the production of these sets will reduce the costs of PCNL surgery.

### Conflict of interest

None

### Source of funding

None

### Ethical approval

Ethical approval for the study was obtained from the local ethics committee of our institution.

### Informed consent

Informed consent was obtained from all individual participants included in the study.

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