Renal track creation for percutaneous nephrolithotomy: the history and relevance of single stage dilation

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Introduction: Percutaneous nephrolithotomy (PCNL) was described in the 1980s and revolutionized the treatment of stone disease. The crucial component to this surgery is satisfactory track creation. We examine how the development and production in the 1980s of a single stage dilator (SSD) subsequently modified for pediatric PCNL has become the ideal access tool for mini percutaneous nephrolithotomy (mPCNL) today.

Materials and methods: The conception, production, scientific and clinical development of the original SSD

is described. The pitfalls of track dilation in general according to method of dilation are also discussed and outlined.

Results: This study provides evidence clarifying commonly held misconceptions about the origin of SSD which is the mainstay of the mPCNL technique.

Conclusions: Percutaneous renal surgery continues to evolve. In less than 40 years stone surgery has transformed from a morbid open operation to a number of minimally invasive, routine techniques. The SSD has been an innovation that has played a crucial role in this change.

Key Words: percutaneous, nephrolithotomy, dilator, mini, single, stage, history

Introduction

Over the last 10 years the treatment of smaller intra-renal calculi has moved away from shock wave lithotripsy and back to a surgical approach. Percutaneous nephrolithotomy (PCNL), described in the 1980s revolutionized the treatment of intra-renal

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calculi and still remains an important treatment tool. As changes in digital technology and power sources evolve, so too have modifications to the original technique including supine² and tubeless PCNL³ and concomitant ureterorenoscopy.⁴

Mini percutaneous nephrolithotomy (mPCNL) is the most recent development in percutaneous renal surgery (PRS). As with traditional PRS, this surgery involves entering the renal collecting system with an access needle and guide wire. mPCNL utilizes the technique of single stage dilation to create the track for a fine caliber nephroscope to enter the collecting system. The technique is derived from the

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27830 AA 27830 AB/AC 27830 AA Dilation Cannula, with central channel for guide wires, for Operating Sheath 15/18 Fr., 27830 B 27830 AB Dilation Cannula, with central channel for guide wires and distal curved channel for deflection of guide wires, for Operating Sheath 16.5/19.5 Fr., 27830 C 27830 AC Dilation Cannula, with central channel for guide wires and distal curved channel for deflection of guide wires, for

Figure 1. Mini percutaneous nephrolithotomy (mPCNL) single stage dilators (modified from Storz catalogue Ref 27830AA/AB/AC, Storz (Germany) 2012). These rigid, tapered, metal dilators advance over a guide wire into the collecting system, facilitating the insertion of a miniaturized nephroscope.

Operating Sheath 21/24 Fr., 27830 D

modified PCNL first described in pediatric patients and applied to smaller intra-renal stones in the adult. Of crucial importance is a single stage dilator (SSD) used to rapidly create a suitable track with minimal complications and radiation exposure, see Figure 1. Interest in mPCNL has brought renewed focus on single stage track dilation and with it, increased interest in the development of PRS and nephrocutaneous track creation.

The Webb single-stage dilator, developed in the early years of PRS, was the first commercially available SSD, Figure 2 (Cook Medical, Australia). The SSD offers the surgeon an opportunity to dilate the puncture to an appropriate caliber with one instrument as an



Figure 2. The original Webb Single stage dilator with Amplatz sheath (left) and assembled (right). Note the tapered nose of the grey dilator (facilitating smooth passage across the retroperitoneum) as well as the proximal, circular sheath marker (grey) which safeguards against inadvertent advancement of the Amplatz sheath.

alternative to serial dilation and balloon expansion. In this paper we outline the history of percutaneous surgery, describing the rationale, pitfalls and challenges that led to the development of the SSD, commenting on the relevance of this in the setting of establishing access to the renal collecting system.

Theory for and development of percutaneous renal surgery

Access to the intra-renal collecting system was obtained exclusively via open surgery up until 1955 when Goodwin et al reported a technique for a percutaneous drainage of a large hydronephrosis using x-ray guidance.⁵ It would be more than two decades before the concept of refining this approach to endoscopically treat intra-renal urolithiasis through a percutaneous track would develop.

Alken was among the first to describe the technique.⁶ He emphasized the importance of satisfactory track creation. His paper outlined the importance of the straight, transparenchymal puncture to avoid significant injury to segmental vessels during dilation, thereby allowing rigid instruments and powerful energy sources to enter the kidney and fragment stones. The strategy for planning the ideal track was also described, providing a guide to the planning of PCNL that is still used today. At the time the practice in German hospitals was for the urologist to perform many of their own radiological investigations. It was a logical development for the percutaneous track to be created by the operating surgeon using a telescopic dilator.

Simultaneously in the United Kingdom a team approach comprised of urologist and radiologist was developed by Wickham and Kellett.⁷ Using their technique, the patient had a percutaneous nephrostomy (PCN) inserted under local anesthesia by the radiologist. Over the period of a week the nephrostomy tube was serially upsized until the fistulous track was 24FG-26FG and granulating. At this time the second stage was performed under general anesthesia in the operating theatre by the urologist. A 21FG cystoscope was passed directly through the track (without a sheath) to the stone. Stone manipulation was carried out by basket extraction only. This early series described the learning curve of this new operation, in particular the technical difficulties encountered negotiating tortuous tracks and engaging stones in a basket. Even in its infancy, the authors correctly predicted that this new technique would soon become standard of care.

The scientific basis of PCNL and proof of the safety and efficacy of this surgery was first reported by Webb and Fitzpatrick, following their involvement with Wickham's

early pioneering work.⁸ Pathological assessment of canine kidneys harvested 6 weeks following creation of a 22FG track and endoscopic lithotripsy of an implanted human calculus showed small scars only along track sites. Normal function (compared to the contralateral kidney) was also demonstrated as was excellent stone clearance at 6 weeks.

To avoid confusion it is worth defining the nomenclature associated with "stage" and PCNL. PCNL was described by Wickham as a "two-stage procedure", the initial stage being establishment of the PCNL track in the radiology department and the second stage at a later date comprising endoscopic stone manipulation in theatre. When referring to track dilation, a SSD is one that creates a nephrocutaneous track with only a single passage of the dilator in comparison to the alternative dilation techniques that involve multiple dilations or balloon dilations. It has also been referred to as "Single Increment", "Target" and "One Shot" dilation.

Creation of a percutaneous track for stone manipulation

As the popularity of PCNL grew, the principles of access became more uniform. Under radiological guidance, a puncture needle was introduced through the skin and a guide wire passed through the retroperitoneum and outer border of the kidney to enter the collecting system. Once established, the track is dilated to approximately 1 cm (24FG-30FG) in diameter. After dilation, a tubular Amplatz sheath was inserted over the dilator from skin to kidney creating a nephrocutaneous conduit for irrigation and endoscopic visualization within the collecting system.

Initially the three instrument systems used to dilate the track were graduated Amplatz dilators (tapered, polymer based dilators), a pneumatic balloon expander and metal serial telescoping dilators. The former required the initial passage of an internal "long grey" dilator over the guide wire. Serial interchange of dilators proceeded over the "long grey". Once the desired caliber of track was created, a hollow Amplatz sheath was inserted over the last dilator, which was removed. Using a balloon expander, a fascial dilator was initially passed over the guide wire. This was followed by insertion of the balloon. After adequate position was confirmed radiologically the balloon was inflated and track created. Then an Amplatz sheath was inserted over the balloon or a second dilator. Metal telescopic dilators, designed with each component of the dilator snugly fitting inside the next, larger dilator (similar to a traditional car aerial) also involve the passage of ever enlarging dilators to create a suitable track.

Concept and production of the single-stage dilator

As PCNL progressed from stones that could be simply extracted to more complex calculi such as staghorns and those in calyceal diverticuli, the stability of track during dilation became increasingly important. Access was severely compromised should the operator be unable to establish an adequate length of guide wire in the collecting system. In these instances, multi stage dilation resulted in loss of the wire and track. Having to exchange multiple instruments over the wire was time consuming, predisposed to bleeding and risked kinking or displacement of the wire and also prolonged use of fluoroscopy.

Wickham and Kellett were joined by Webb at the Devonshire Hospital and Institute of Urology, London in 1984 where they continued to develop and expand the applications PCNL in the United Kingdom. Amplatz dilators were routinely employed to create the track. On occasion when the Amplatz set failed to gain access such as stones in calyceal diverticulum, a radiological vascular dilator was used by Kellett. This dilator was not otherwise used routinely as it was long, cumbersome, liable to displace the kidney and prone to bending during dilation.

On returning to Australia in 1985, Webb decided to explore the potential of designing and developing a purpose built, single stage renal dilator for general use. This was done in conjunction with Cook Australia who conveniently had a small factory in Melbourne at this time.

The initial Webb SSD model differed from vascular dilators as it was solid (to facilitate smooth dilation) rather than hollow and had a tapered end. The SSD was produced by Cook Australia in 1986 (Catalogue Ref JCD24.0-38-30-WEBB). The inner core was a narrow channel allowing the dilator to run snugly over a 0.038 inch guide wire. It was immediately apparent that for a SSD to be effective, the taper and length of the nose were crucial. Too short, and the kidney was displaced. Too long and the Amplatz sheath could not be safely inserted into the collecting system. Through trial and error, 2.2 cm was found to be the optimal length for the tapered end.

The single stage dilator set comprises a 17 cm bevelled Amplatz sheath and a 30 cm dilator made of stiffened PVC, Figure 2. At 19 cm the tapered dilator has a circular mark, informing the surgeon leading edge of the Amplatz sheath was just short of the shoulder of the dilator bevel so that the sheath would not advance independently of the shoulder of the dilator and traumatize the kidney.

The ideal SSD should traverse the retroperitoneum in a smooth, controlled fashion and enter the collecting system atraumatically. In practice this was difficult to achieve due to differing degrees of resistance arising in the various layers of the puncture. This impedance was overcome by polishing the taper with glass to create a frictionless tip.

Production was via an extrusion machine, which allowed PVC tubing to be divided into accurate lengths and for the hydrophilic PVC tips to undergo a tapering and polishing process.

Following relocation of Cook Australia, production of the dilator was transferred and now continues to its original specifications with Surgitek, Australia (Catalogue Ref BUWD0226030).

Application of single stage dilation and comparison to other forms of track creation

The established methods of track creation include serial Amplatz dilators, balloon dilation and metal telescoping dilators (see descriptions in "creation of a percutaneous track for stone manipulation"). All of these techniques have advantages and disadvantages.

A number of studies describe the successful use of the SSD in conventional PCNL. Frattini et al⁹ [reported on 78 consecutive patients undergoing PCNL who had tracks created by Amplatz (serial) dilation, balloon dilation or metal telescoping dilators. They reported equivocal stone clearance between all groups with faster operative times, reduced cost and less radiation exposure for the SSD group. Furthermore there was significantly less blood loss in the SSD cohort compared to the balloon dilation group.

A meta-analysis examining all four techniques of track creation was published in 2013. In total four randomized controlled trials (RCT) and eight clinical controlled trials were included involving nearly 7000 patients. The authors concluded that the stone free rates were comparable for each technique. However the SSD was again associated with shorter fluoroscopic times, smaller hemoglobin drops (when compared to metal telescopes) and shown to be safe in kidneys that have been previously operated on.

A further RCT published a year later¹¹ again showed SSD to be a quicker procedure associated with significantly less radiation exposure and with a lower overall complication rate.

A series focusing on stones within calyceal diverticuli exclusively used SSD for track creation, ¹²

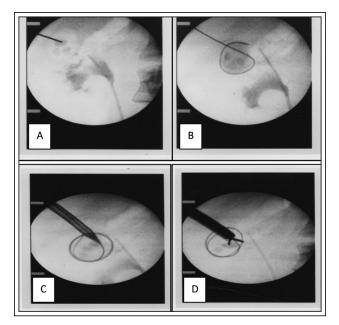


Figure 3. Fluoroscopic appearance of stone in an upper pole calyceal diverticulum undergoing an SSD assisted PCNL demonstrating **(A)** direct needle puncture **(B)** placement of guide wire into the diverticulum **(C)** single stage dilation and **(D)** endoscopic clearance.

see Figure 3. This series demonstrated excellent stone clearance with minimal morbidity and commented in particular on the advantage on SSD in reducing the incidence of stone and guide wire displacement and facilitating access to and dilation of the diverticular neck. In one case a pneumothorax was recognized during a supra-costal puncture. The authors commented that where serial dilation could let air into the chest between dilations and increase the risk of developing a significant pneumothorax, the SSD and sheath maintained tamponade throughout the remainder of the case and on removal of the Amplatz, the deficit was easily closed with a purse-string suture without requirement of a chest tube.

In spinal cord patients, supracostal and multiple punctures are frequently required to treat infected stones. In a study looking at 54 of these patients treated using a SSD,¹³ complete clearance was seen in 84%, with all complications encountered treated conservatively (including fever, bleeding and two pneumothoraxes). Again the authors noted the advantage of the SSD when it came to suspected pneumothorax and commented on reduced blood loss with multiple punctures using this technique and excellent access to the kidney despite significant skeletal deformities in many patients.

Adoption of the SSD for the pediatric population

When pediatric PCNL was proposed in Melbourne's Royal Children's Hospital, a theoretical objection was made. Although the technique was proven clinically in the adult population, there were concerns the smaller pediatric kidney might bleed more significantly when dilated with instruments designed for larger adult organs. Further concerns related to the volume of irrigating fluid the child might absorb and the risk of hypothermia.

Before embarking on pediatric PCNL a laboratory study of the SSD was performed in vivo, in the canine model.¹⁴ The effect of single increment versus multi incremental and metal telescoping of the canine kidney was assessed. Under general anesthesia, a subcostal incision was made and the kidney delivered. A 6FG fascial dilator was passed through the convexity of the kidney into the collecting system to introduce a guide wire, and the dilating systems (SSD, multistage Amplatz, telescopic and balloon) were used to dilate to 24FG. A 25FG Amplatz was passed and the kidney observed for a few minutes. Kidneys were harvested either immediately, at 48 hours or 6 weeks. This study showed single-stage dilation to have less associated bleeding compared to serial dilation at the time of track creation and no evidence of significant parenchymal or functional renal damage immediately or at 6 weeks.

For pediatric PCNL a narrower track and access sheath was required. These dilators and Amplatz sheaths were manufactured to a caliber of 14FG-16FG, fitting over a 0.032 inch guide wire (Cook Medical, Australia). Reporting on the first 60 children treated with this modified PCNL technique,¹⁵ it was shown that excellent stone clearance with minimal morbidity was achievable. The same technique was adapted for endopyelotomy in children with PUJ obstruction¹⁶ giving excellent access to the collecting system in all cases and satisfactory outcomes in the majority of the 17 patients who underwent surgery.

Development of mPCNL

The principles of mPCNL were established by pediatric PCNL, which employed a small version of the adult SSD. Experience with pediatric PCNL showed that smaller stones could be cleared with finer instruments - the smaller caliber of access into the kidney minimizing the risk of bleeding and other morbidities. The first series of mPCNL in the adult population was published in 1998¹⁷ for stones less than 2 cm and demonstrated equivalent stone clearance rates to conventional PCNL. Whilst the original authors credit a series of 11 children reported

the previous year treated by modified "miniature" PCNL and single stage dilation to obtain renal access¹⁸ as inspiration for the idea to developing mPCNL in adults, it is clear the initial series of 60 patients treated for stone¹⁵ and 17 for endopyelotomy¹⁶ reported 5 years before appears to have been overlooked. Larger series in adult patients have subsequently shown advantages for mPCNL compared to PCNL for length of stay in hospital, transfusion rate and overall complication rates with comparable stone clearance rates.¹⁹ Furthermore mPCNL has been proven to be equally efficacious as flexible ureterorenoscopy for small intra-renal calculi.²⁰ As with the original pediatric population^{15,16} SSD was found to be optimal in many series due to its reduced instances of bleeding and radiation exposure, and the lesser likelihood of wire dislodgement.

Summary

The Webb SSD arose in the dawn of PRS as a concept to overcome anticipated difficult access in complex stone surgeries. Its genesis can be traced to an established radiological instrument which was adapted for use in the kidney. Custom designed for adults, the initial model was re-examined in vivo in the laboratory setting before being remodified for the pediatric patient. As the Seldinger vascular dilator was adapted and used as the inspiration for percutaneous renal track creation, so too has the concept of renal tract dilation been applied to other fields, including the creation of the percutaneous tracheostomy dilator.²¹

The development of the mPCNL, utilizing modern, available technologies such as laser and digital optics combined with established instruments such as the SSD, has produced a cost effective, clinically safe and reproducible technique that is becoming a reliable option for the treatment of small to medium sized intrarenal calculi. Surgical methods, ideas, technologies and instruments continue to evolve on the bedrock of established surgeries. As available technologies progress, undoubtedly more powerful fragmentation sources will be able to access renal stones via smaller instruments suggesting the future of PCNL may lie with finer caliber tracks. In this scenario, creation of a safe, stable track will continue to remain crucial suggesting the SSD will continue to play an important role in this surgery.

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