Initial clinical evaluation of a new pneumatic intracorporeal lithotripter

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OBJECTIVE

To test the clinical efficacy of the StoneBreaker™ (LMA Urology, Gland, Switzerland), a novel device which is much more compact and ergonomic than other current intracorporeal pneumatic lithotripters, and more powerful, generating contact pressures of up to 2.9 MPa, thereby enabling better pneumatic fragmentation and removal of stones during percutaneous nephrostolithotomy (PCNL), ureteroscopic stone fragmentation (USF) and vesical stone lithotripsy (VL).

INTRODUCTION

There are several methods available for intracorporeal lithotripsy, and these have either laser, ballistic or electrohydraulic energy sources. Some drawbacks of existing systems, besides cost, are that they require external electrical power or access to compressed air pipelines, are large and are not portable. The StoneBreaker™ (LMA Urology, Gland, Switzerland) addresses some of these issues, and in the present study our aim was to evaluate the efficacy of this novel lithotripter.

PATIENTS AND METHODS

We prospectively evaluated 102 patients, comprising 49 PCNLs, 48 USFs and 5 VLs, treated using the StoneBreaker. The stone size, position, number of shocks required to fragment the stone to effect complete clearance, and degree of retropulsion were documented in each case; any evidence of urothelial trauma was noted.

RESULTS

All stones were satisfactorily fragmented and all patients rendered stone-free. Very few shocks were required, and documented retropulsion was minor. There was no evidence of consequential urothelial trauma at the end of any procedure.

CONCLUSION

The StoneBreaker appears to be a safe, effective, robust and compact device for intracorporeal lithotripsy.

KEYWORDS

pneumatic, lithotripter, intracorporeal, stone, calculus, lithotripsy
stone lithotripsy (VL) using the StoneBreaker. All stones were satisfactorily fragmented and all the patients were rendered stone-free.

For PCNL, of the 33 staghorn/partial staghorn and 16 renal pelvic stones, the mean (range) stone size was 2.8 (1.8–4.8) cm (staghorn or partial staghorn in 33, renal pelvic in 16); 43 were successfully cleared with a single puncture and six required multiple punctures. The mean (range) number of shocks for fragmentation with subsequent successful clearance was 34 (2–76) (Figs 2 & 3).

For USF, there were six upper, 19 mid and 23 lower ureteric calculi (48) for which the stone size was 1.1 (0.8–3.1) cm and the number of shocks for fragmentation with subsequent successful clearance was 9 (4–24) (Figs 2 & 3).

Finally, for VL the stone size was 4.9 (2.8–7) cm and the number of shocks required for successful clearance was 48 (25–60). The best results were for USF requiring a mean of nine shocks for mean stone size of 1.1 cm, followed by PCNL (34 shocks per 2.8 cm) and VL (48 shocks per 4.9 cm). This translates to a mean of 10 shocks/cm for disintegrating stones. For the overall group therefore, the mean stone size was 2.9 (0.8–7.0) cm and the mean number of shocks to render the patients stone-free was 30 (Figs 2 & 3).

There were no direct complications attributable to the lithotripsy and there was no demonstrable evidence of tissue trauma.

**DISCUSSION**

The ideal lithotripter appears to be one that optimizes size and portability, is deflectable, effective irrespective of the type of stone, reusable, and should cause minimal collateral tissue damage. There are currently several energy sources available for intracorporeal lithotripsy, i.e. ultrasonic, electrohydraulic, laser and pneumatic (summarized in Table 1). However, none of the currently available intracorporeal lithotripters meet all of the ideal standards.

### TABLE 1 A comparison of energy sources available for intracorporeal lithotripsy

<table>
<thead>
<tr>
<th>Type of lithotripter</th>
<th>Mechanism of action</th>
<th>Access</th>
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<tbody>
<tr>
<td>Electrohydraulic</td>
<td>Shock waves generated electrohydraulically (microexplosions)</td>
<td>Coaxial cable probe</td>
</tr>
<tr>
<td>Ballistic/pneumatic</td>
<td>Impact of projectile projected onto metallic rod using air under pressure</td>
<td>Probe</td>
</tr>
<tr>
<td>Ultrasonic</td>
<td>Vibration at high frequency imparted via a metallic transducer</td>
<td>Probe</td>
</tr>
<tr>
<td>Electrokinetic</td>
<td>Projectile (magnetic core) impacted onto metallic rod by electromagnetic acceleration</td>
<td>Probe</td>
</tr>
<tr>
<td>Lasers (Ho, Nd:YAG, Ho: YAG, pulsed-dye, Alexandrite)</td>
<td>Holmium: YAG lithotripter - most effective at present; uses principle of photothermal stone decomposition</td>
<td>Probe</td>
</tr>
</tbody>
</table>

In the late 1980s the advent of ultrasonic devices and pneumatic lithotripters facilitated the destruction and clearance of urinary calculi [1–5]. Ultrasound-based lithotripters used through rigid endoscopes provide high fragmentation rates (97–100%) and stone-free rates (94%); however, they can take a long time to disintegrate hard or dense stones [6].

The Swiss Lithoclast™ was introduced in the 1990s as a ballistic lithotripter and uses clean pressurized carbon dioxide as an energy source to fire a projectile onto a metal rod in contact with the stone; it is effective in the kidney, ureter and bladder. Denstedt et al. [5] first reported their experience with the Lithoclast in 31 cases, with successful fragmentation of 94% of calculi. There were no intraoperative or long-term complications directly related to the use of this device, and they concluded that it was a safe, effective and inexpensive means of intracorporeal
lithotripsy for calculi throughout the urinary tract. Several others have since assessed the efficacy of this device and reported similar conclusions [5, 7–10]. In a study of complications of pneumatic ureterolithotripsy soon after treatment Aridogan et al. [11], in a series of 979 patients, found that 86.5% of the stones were removed successfully. However, there was a wide array of complications, including stone migration into the kidney (7.2%), mucosal damage (3.5%), ureteric perforation (1.7%), ureteric avulsion (0.4%), and conversion to open surgery (0.2%). During the period after treatment, flank pain (18.4%), pelvic discomfort (5.5%), macroscopic haematuria (7.3%), and UTI (5%) were recorded.

Pietrow et al. [12] conducted a prospective study to evaluate the combination of a pneumatic/ultrasonic lithotrite in a clinical environment. They found that although the two devices successfully managed stones of various compositions, stone-free and complication rates were only slightly better with the combined unit than using ultrasound alone.

The use of the holmium laser has been well documented, especially for small ureteric or renal stones [13,14]. It appears to be the intracorporeal energy source of choice for retrograde intrarenal surgery [15].

Many groups have assessed the efficacy of combined approaches vs one method (i.e. ultrasonic, electrohydraulic laser or pneumatic alone); none have conclusively found that any combination is significantly better over the others. In a study of 349 procedures using holmium-YAG laser lithotripsy for PCNL, Jou et al. [16] found that although it is an effective and safe lithotripter, patients with a very large stone burden required a combination of this technology with another, more powerful, intracorporeal lithotripter.

Animal studies were used to evaluate the safety of the StoneBreaker in a model of acute ureteric perforation; whilst this is the subject of another report, there was no evidence of perforation even at artificially high pressure settings of up to 5.0 MP. In the same paper we compared the fragmentation efficiency with the Swiss Lithoclast; the number of ‘hits’ required to break 10 large, 10 medium and 10 small stone phantoms to fragments of <7 mm (large) or <3 mm (medium and small) was recorded for both the StoneBreaker and the Swiss Lithoclast. Using a t-test to compare the results, for large stone phantoms (mean 7.4 g), the Lithoclast required a mean of 307 firings, vs 77 for the StoneBreaker (P < 0.001); for medium stones (mean 3.2 g), the respective values were 221 and 46, and (P < 0.001) and for small stones (mean 0.5 g), 72 and 26 (P < 0.01).

We acknowledge the limitations of the present study; after treatment most patients were deemed to be stone-free on plain radiography. Ideally this finding should have been correlated with either CT or ultrasonography, but this was unfortunately not economically feasible. For the same reason, the stone composition could not be quantified either.

In conclusion, the StoneBreaker appears to be an effective, compact and portable intracorporeal lithotripter. More studies, including comparative analyses, are needed to objectively quantify its place among endourological options for lithotripsy.

CONFLICT OF INTEREST
Abhay Rané is a funded study investigator. Source of funding: LMA Urology.

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Abbreviations: PCNL, percutaneous nephrostolithotomy; USF, ureteroscopic stone fragmentation; VL, vesical lithotripsy.