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In vitro evaluation of the Lithoclast Ultra Vario combination lithotrite

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Abstract

Rigid intracorporeal lithotrites can be invaluable in the removal of large stone burdens during percutaneous nephrolithotomy. One such device, the Lithoclast Ultra Vario (LUV) has an outer ultrasound probe and inner pneumatic-ballistic probe. The ballistic probe can be advanced or retracted and run at 1–12 Hz. Since it can be difficult to predict optimal settings with any new device, we asked if in vitro testing could give insight into how best to operate this lithotrite. We tested the LUV under hands-free conditions that simulate treatment of fixed stones and freely movable stones. A fixed-stone test system measured the time to penetrate a gypsum model stone placed atop the probe and a movable-stone system determined time for comminution of a stone within a confined space. In addition, the time to evacuate 2-mm stone particles was measured. For hands-on testing, model stones were placed in a plastic dish submerged in water and the time to comminution was measured. Penetration time of fixed stones was faster with the ballistic probe extended 2.5 mm than when retracted (5.30 ± 0.85 vs. 8.75 ± 1.07 s, $p < 0.0001$). Comminution of free stones was faster with the ballistic probe retracted than when it was extended 1 mm or 2.5 mm (9.7 ± 0.9, 13.8 ± 1.3, 23.7 ± 3.2 s, $p < 0.0001$). In hands-on testing, extending the ballistic probe substantially reduced the efficiency of comminution (36.7 ± 6.4 vs. 131.3 ± 15.3 s, $p < 0.0001$). Clearance of fragments was considerably faster when the pneumatic-ballistic rate was 12 Hz compared to 1 Hz (12.3 ± 1.1 vs. 28.3 ± 2.2 s, $p < 0.0001$). These in vitro findings suggest ways to take advantage of the positive features while minimizing potential limitations of this lithotrite. Extending the ballistic probe is an advantage when the stone is immobile, as would be the case in treating a large stone that can be isolated against the wall of the pelvicalyceal system, but is a

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distinct disadvantage—due to retropulsion—when the stone is free to move. Operation of the LUV at fast ballistic rate significantly improved its ability to aspirate stone fragments.

Keywords

Intracorporeal lithotripsy; Lithotrite; Kidney stones; In vitro testing

Introduction

Intracorporeal lithotrites are a mainstay for removal of large stone burdens during percutaneous nephrostolithotomy (PNL). A variety of devices employing ultrasonic or pneumatic-ballistic probes have proven to be safe and effective. Ultrasonic probes are reported to work particularly well in fragmenting stones that are less dense or that have a rough surface, while pneumatic-ballistic probes are effective in breaking very hard stone material [1, 2]. Whereas ultrasonic probes may not be as effective in breaking harder stones, the ability to aspirate fragments through the hollow probe is considered a distinct advantage. Pneumatic-ballistic probes on the other hand can fragment even the hardest stone types but fragments must subsequently be extracted and the retropulsion of fragments is problematic [3].

The limitations of single mode devices have been addressed by newer dual-probe combination lithotrites [4–6]. One such unit, the Lithoclast Ultra Vario (LUV), has an outer ultrasound probe and inner pneumatic-ballistic probe. The ultrasound mode has a broad range of settings and the pneumatic-ballistic probe can be retracted or advanced beyond the tip of the ultrasound probe and run at rates between 1 and 12 Hz. Since it can be difficult to predict optimal settings with any new device, we asked if in vitro testing could give insight into how best to operate this instrument, particularly as regards the use of the ballistic probe. Hands-free test systems were used to simulate the treatment of freely movable stones and fixed/immobilized stones, and to assess the clearance of small stone fragments. Hands-on tests were also conducted in which volunteers were asked to break freely movable stones in an open dish. The findings indicate that fragmentation and clearance of model stones approximating a 1-cm stone burden is relatively efficient with this device but that performance of the instrument is highly dependent on configuration of the probes, particularly the position of the ballistic probe.

Materials and methods

In vitro test systems

The Lithoclast® Ultra Vario (Electro Medical Systems, Nyon, CH) was evaluated under hands-free in vitro conditions designed to simulate the treatment of stones in fixed or pinned position and stones free to move within a confined space. Tests were also run to assess efficiency in aspirating clusters of 2-mm stone fragments. Additional hands-on tests were conducted in which volunteers were asked to break freely movable stones in an open dish.

Model stones were prepared from Ultracal-30® gypsum cement [7]. The cement was cast in either 48-well or 96-well plastic dishes to produce cylinders measuring ~12.8 mm × 7.6 mm and ~6.5 mm × 7.5 mm, respectively. The stones were liberated from the plastic with chloroform and stored in tap water prior to use. The larger model stones were used for tests with the “fixed-stone” system and the smaller stones were used with the hands-free “movable-stone” system and in hands-on tests (please see description below).

A “fixed-stone” system described in detail previously was used to assess the ability of this lithotrite to penetrate a fixed, immovable stone [8, 9]. In brief, the lithotrite was mounted in vertical position (probe-up) with the probe extending into a chamber irrigated with tap water by gravity flow (Fig. 1). A U-30 stone was inserted through the top of the chamber and held against the probe tip with a counterweight. This test system measured the time (drop-time or penetration time) for the probe to core through a model stone.

A “movable-stone” system was used to determine the time needed to completely comminute a freely movable stone and evacuate the fragments. The lithotrite was mounted with the probe tip pointing upward and inclined 20° above horizontal (Fig. 2). The tip of the probe was inserted through a hole drilled in the conical end of a 15-ml plastic centrifuge tube (Falcon 2097, Becton–Dickinson, Franklin Lakes, NJ) so that the probe extended 18 mm into the tube. The tube was secured independently of the lithotrite. Tap water was fed through the mouth of the tube at a rate adjusted to match suction through the lithotrite. An extension for the water line was fashioned from a 5-ml polyethylene disposable pipette by cutting off a portion of the bulb. This funnel-like end of this pipette was inserted into the tube to help direct water to the bottom of the tube and to keep the stone near the tip of the probe. Prior to a test, a stone was dropped into the tube, the ‘funnel’ was inserted, irrigation was started, bubbles were allowed to clear, the lithotrite was switched on and the time needed to break up the stone and aspirate all fragments was recorded.

A “fragment-clearance” system tested the ability of the lithotrite to aspirate a mass of stone particles. The lithotrite was mounted with the probe pointing downward at an angle of 50° below horizontal (Fig. 3). The probe tip extended into the open mouth of a 50-ml plastic centrifuge tube (Falcon 2070) to within 4 mm of the conical tip. Irrigation was through the mouth of the tube and soda lime pebbles (Airgas, Inc., Indianapolis, IN) smaller than 2 mm were used as stone fragments. For each test, 3 g of pebbles were added to the tube, irrigation was started, bubbles were allowed to clear, the lithotrite was started and the time to clear all pebbles from the tube was recorded.

A hands-on system tested the ability of an operator to break a freely movable stone and evacuate all particles. A 24-well plastic tissue culture dish (Falcon 3047) was secured inside a 5-in. deep water-filled basin at lab-bench height and a U-30 stone was placed in one of the wells. The operator was instructed to break the stone to completion as fast as possible without pinning the stone against the dish. The time to complete the task was measured and the process repeated 10 times.

Various tests were run to determine the effect of position (extended vs. retracted) of the pneumatic-ballistic probe on stone breakage and the effect of ballistic rate on clearance of fragments. Unless otherwise noted, the 3.8-mm diameter ultrasound probe was used and operated at 100% power, and ballistic rate was set at 12 Hz. Each test condition was repeated at least 10 times.

Statistics

Data were compared using *t* test or analysis of variance (ANOVA) as appropriate, using JMP (SAS Institute, Cary, NC).

Results

Position of ballistic probe

Penetration time of fixed stones was significantly faster when the ballistic probe was extended 2.5 mm compared to when it was flush with the tip of the ultrasound probe (5.30 ± 0.85 vs. 8.75 ± 1.07 s, $p < 0.0001$) (Fig. 4a). However, comminution of stones that were free to move was considerably slower when the probe was extended. Breakage time with the hands-free test system was faster when the inner probe was retracted compared to when it was extended 1 mm or 2.5 mm (9.7 ± 0.9, 13.8 ± 1.3, 23.7 ± 3.2 s, $p < 0.0001$ by ANOVA) (Fig. 4b) and in hands-on testing use of the probe in 2.5 mm extended position was a distinct disadvantage (36.7 ± 6.4 vs. 131.3 ± 15.3 s, $p < 0.0001$) (Fig. 4c).

Ballistic rate in fragment clearance

The hands-free clearance of stone fragments was more than twice as fast when the ballistic probe, in retracted position, was operated at 12 Hz compared to 1 Hz (12.3 ± 1.1 vs. 28.3 ± 2.2 s, $p < 0.0001$) (Fig. 4d).

Discussion

Extracorporeal lithotrites have become an essential component in the removal of difficult stones during PNL. Both ultrasonic and ballistic-pneumatic devices have proven to be effective and there is little doubt that these instruments are beneficial. Combination lithotrites are relatively new. As there is now only limited clinical experience with these devices, it would be helpful to have a better understanding of their specific advantages and limitations. In vitro studies have proven to be helpful in the assessment of lithotrites and have been particularly useful in comparing different devices [5, 8, 10, 11]. In such work, a hands-free test system can offer the important advantage of eliminating the potential for operator bias [8, 12]. In the current study, we built upon our previous experience with hands-free test systems and devised two new laboratory methods specifically for the purpose of assessing the role of the ballistic-pneumatic probe in the function of the LUV.

The LUV employs both an ultrasound probe and a ballistic probe, both of which can be operated over a range of settings. In addition, the inner ballistic probe can be advanced past the outer ultrasound probe. This feature is intended to enhance the ability to break hard mineral and to aid in de-bulking very large stones. Our in vitro findings suggest that the function and configuration of this probe can have a significant effect on performance. When the ballistic probe was extended, the lithotrite drilled through stationary stones faster than when the probe was retracted. This suggests that working with the probe extended would indeed be beneficial in attacking a staghorn stone or a large stone that can be pinned against the wall of the renal collecting system. However, use of the inner probe in extended position, protruding beyond the outer probe, dramatically reduced the efficiency of the instrument in breaking stones that were free to move. This was particularly evident in hands-on testing in which the operator was called upon to break a stone within a culture dish submerged in water, but was instructed to avoid pinning the stone against the dish. When the ballistic probe was extended 2.5 mm, the operator was forced to chase the stone around the dish, and breakage took roughly nine times longer than when the ballistic probe was retracted. A similar effect was also observed in hands-free tests in which the stone in a confined space of ~2 cm^2 was positioned so that it would fall back against the probe. In this case, the stone could be seen to kick back from the probe on contact. Stone comminution took significantly longer with the ballistic probe at 2.5 mm compared to 1 mm extended and was best with the probe retracted. Both the hands-on and hands-free test systems mimic the retropulsion of stone fragments that is widely appreciated as a significant drawback of ballistic lithotripsy [1, 3, 11, 13]. Thus, these in vitro data clearly suggest that the ballistic probe would be effective in debulking a fixed or very large stone, and that when treating a movable stone the ballistic probe should be in retracted position.

The efficient evacuation and clearance of fragments is one of the big advantages of ultrasonic and combination lithotrites. Our findings suggest that for the LUV the clearance of fragments can be improved by running the unit at fast ballistic rate. To minimize retropulsion, these tests were run with the ballistic probe retracted. Operating the ballistic probe at 12 Hz gave clearance times better than twice as fast as at 1 Hz. This was a somewhat unexpected finding and points to a measure that may offer an advantage in the clinical use of this particular lithotrite.

Conclusions

These in vitro findings suggest ways to take advantage of the positive features of the LUV while minimizing the potential limitations of this lithotrite. Extending the pneumatic probe is an advantage when the stone is immobile, such as when treating a large stone burden or staghorn calculus, but is a distinct disadvantage when the stone is free to move. Stone retropulsion increases with the distance the ballistic probe is extended past the tip of the ultrasound probe. Still, the ballistic probe feature plays an important role in the ability of this lithotrite to aspirate stone fragments and operation at fast ballistic rate with the probe retracted significantly improves fragment clearance.

Acknowledgments

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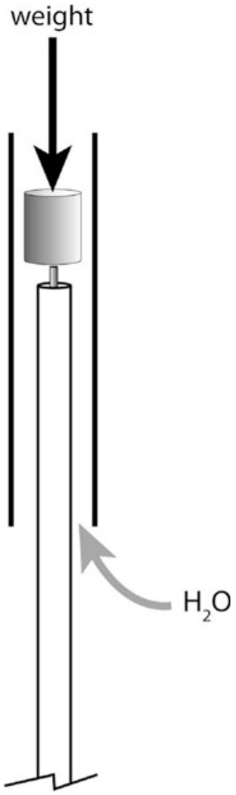

Fig. 1.

“Fixed-stone” system for testing lithotrite, hands-free, in vertical position. Lithotrite is inserted from below, and diagram illustrates the ballistic probe of the Lithoclast Ultra Vario extended past the tip of the outer, ultrasonic probe. Time was measured for the lithotrite to drill through the stone. Illustration simplified from that of Kuo et al. [8]

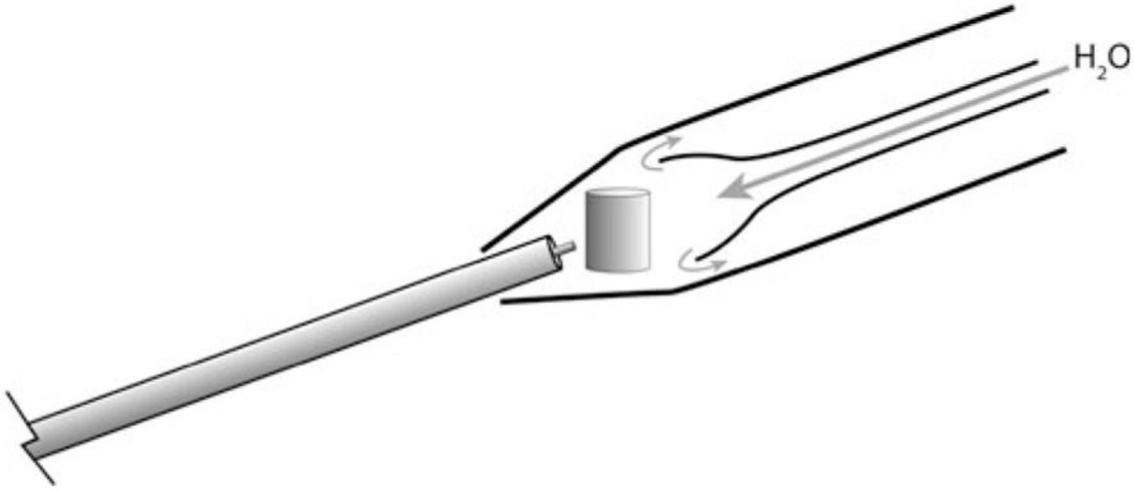

Fig. 2.

“Movable-stone” system for testing lithotrite, hands-free, with the probe angled up, and the test stone resting in contact with the probe by gravity. A plastic funnel-tipped tube directed water toward the probe tip and confined the space occupied by stone fragments to ~3 ml. Time was measured for the lithotrite to break up the test stone and aspirate all fragments

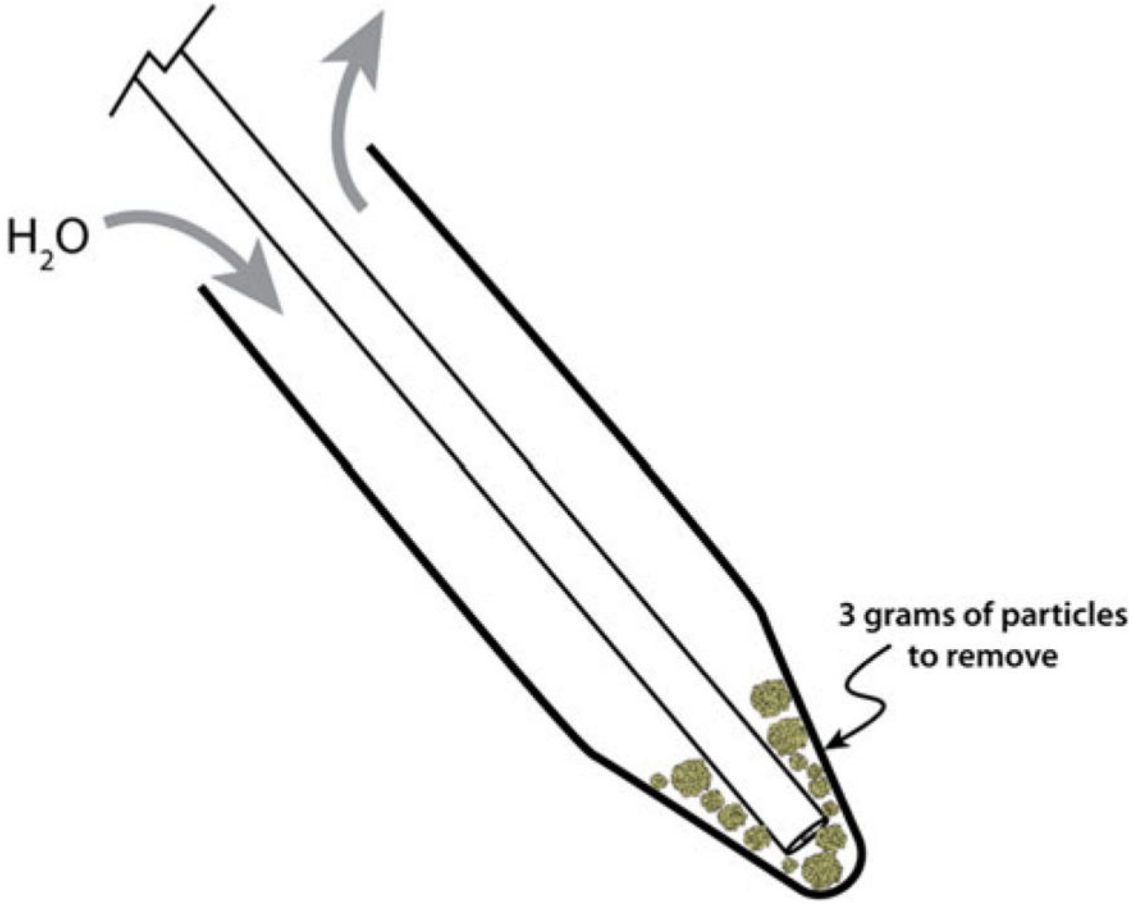

Fig. 3.

“Fragment-clearance” system for testing the lithotrite, hands-free, with the probe angled downward. Time was measured for complete removal of ~2 mm test pellets

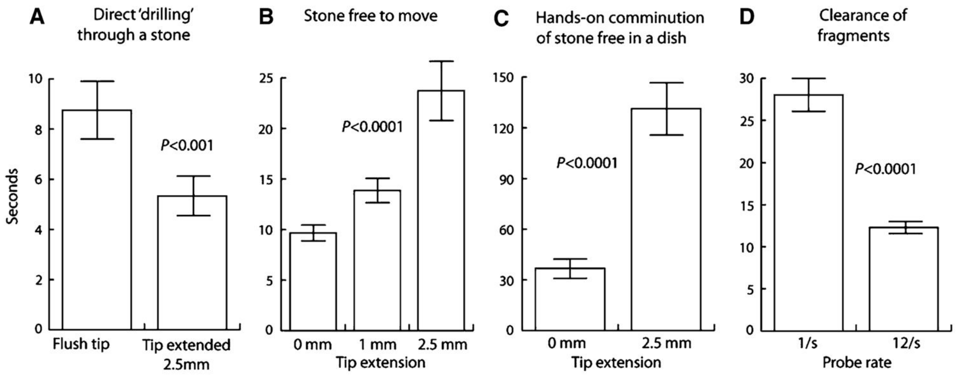

Fig. 4.

Effect of ballistic probe settings on lithotrite performance in vitro. Time needed to drill through a stone held in fixed position (as in Fig. 1) was faster when the inner probe was extended (**a**), but having the tip project beyond the outer probe reduced the efficiency of complete comminution when the stone was free to move in hands-free testing (as in Fig. 2) (**b**) and when the operator worked to eliminate a stone within an open dish (**c**). The clearance of stone fragments in hands-free tests (as in Fig. 3) was faster at fast ballistic rate (**d**)