A USABILITY COMPARISON OF LASER SUCTION HAND-PIECES FOR PERCUTANEOUS NEPHROLITHOTOMY

Casey A. Dauw, Michael S. Borofsky, Nadya York, James E. Lingeman.

Indiana University School of Medicine, Indianapolis, Indiana

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CORRESPONDING AUTHOR: James E. Lingeman
ADDRESS:
1801 N. Senate Blvd, Suite 220
Indianapolis, Indiana 46202
EMAIL: jlingeman@iuhealth.org
PHONE: 317-962-2485 **FAX:** 317-962-2893

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Introduction

Following the initial description of the holmium: yttrium-aluminum-garnet (HoYAG) laser for the treatment of kidney stones in the mid 1990's, endourologic management of kidney stones has seen a renaissance of sorts.[1-3] This is in large part due to the fact that the HoYAG laser has been shown to reliably fragment stones of all compositional varieties while maintaining an appropriate margin of safety.[4] It is not surprising, then, that surgical techniques such as ureteroscopy and percutaneous nephrolithotomy (PCNL), procedures which both commonly utilize the HoYAG laser, are being increasingly performed relative to shockwave lithotripsy for the management of kidney stones.[5,6]

Current practice guidelines advocate PCNL as the preferred treatment for large renal stones.[7,8] Traditional methods of lithotripsy during PCNL have relied upon ultrasonic, ballistic, or a combination of these energy delivery devices. As the power of HoYAG lasers has increased, use of this technology during PCNL as a means to fragment renal stones has been suggested as a safe and effective alternative treatment modality.[9] Recognizing this potential, several urologic device manufacturers have developed novel instruments, known as laser-suction handpieces (LSHP), that couple the HoYAG laser with suction for use during PCNL. Since these devices are fundamentally different than the traditional lithotrites familiar to urologists, ergonomics and ease of use will be important factors impacting their widespread adoption, an area that has not been studied.

Recognizing this, we tested three LSHP at the time of PCNL in a porcine model. In particular, we focused on the ergonomic aspects of these devices and the ease that they can be manipulated by using a questionnaire completed by the operating surgeon. We also assessed the general effectiveness of stone fragmentation and suction as well as safety of the three LSHP.

METHODS

Tested devices

Three LSHP were tested in this study. These included the LASER Suction Tube (Karl Storz®, Germany) and LithAssist™ (Cook® Medical, USA), both of which are currently commercially available, as well as the Suction HP (Lumenis®, Israel), a new device awaiting FDA approval (Figure 1). Each device couples laser energy with suction, allows the surgeon to precisely control the length of exposed fiber, and is introduced through a typical rigid nephroscope working channel. The devices are of comparable length and diameter. The device lengths were 40cm, 38cm, and 40cm and outer diameter of the suction tubes were 12F, 11.6F, and 11.3F for the LASER Suction Tube, LithAssist, and Suction HP, respectively. We tested the Suction HP at a 3:1 frequency relative to the LASER Suction Tube and LithAssist as this device is a prototype.

Reverse PCNL procedure and lithotripsy

After obtaining study approval from the Animal Research Committee at Methodist Hospital (Indianapolis, Indiana), reverse PCNL was performed in 4 adult, female domestic farm pigs. Pigs were anesthetized and intubated by a certified animal technician using xylazine (2mg/kg) and ketamine (10mg/kg). Inhaled 3% isofluorane was used to maintain anesthesia and normal saline was infused at 3%

body weight per hour to maintain intravascular volume. Animals were initially positioned in supine position. Cystoscopy was performed and 5F catheters were inserted into each ureter in retrograde fashion to facilitate delineation of the renal collecting system with contrast. Pigs were then positioned prone for percutaneous access. Using biplanar fluoroscopy and triangulation technique, an 18G diamond tip needle was introduced into a lower pole calyx. A hydrophilic wire was negotiated down the ureter and a second safety wire was placed using an 8F-10F coaxial dilator. The tract was then balloon dilated to 30F and an Amplatz sheath was positioned in the calyx of puncture. Rigid nephroscopy was performed to verify appropriate sheath position.

Prefabricated Plaster of Paris stones each measuring 8 x 8mm were inserted into the 30F sheath and positioned into the calyx of puncture using the rigid nephroscope. Lithotripsy was performed using a 550µm Slimline™ (Boston Scientific, USA) laser fiber inserted into the LSHP being tested. Laser energy and suction were provided by the Pulse™ 120H laser system (Lumenis®, Israel). Two laser settings were used for stone fragmentation - stone breaking and stone dusting. Stone breaking was performed using energy settings of 5 J (Joules) and 20 Hz (Hertz) while stone dusting settings were 0.8 J and 80 Hz. Choice of settings was left to the discretion of the operating surgeon. Following successful stone clearance, if visualization remained adequate, additional stone insertions and treatments were conducted in the same renal unit. Lithotripsy time was measured as the time from initial laser firing to completion of stone fragment clearance.

At the completion of the experiment, animals were euthanized using a lethal injection of Socumb® solution (1ml/5kg).

Measuring usability and safety

A 10-item questionnaire (Table 1) was provided to the operating surgeon at the conclusion of the experiment and was completed for each LSHP. In total, 4 surgeons completed questionnaires for each device. In general, surgeons were asked to rate each LSHP with respect to ease of use, visualization during the procedure, control of laser fiber and suction, effectiveness of lithotripsy and fragment suction, and safety of lithotripsy and suction. Each question was scored on a Likert-type scale from 1-10 with higher scores being more optimal. Mean scores were calculated and compared amongst LSHP.

RESULTS

Percutaneous renal access was successfully obtained in 4 female farm pigs. A bilateral procedure was conducted in all cases. A total of 15 procedures were performed which included 9 using the Suction HP and 3 each using the LASER Suction Tube and LithAssist. Mean lithotripsy time was 8 minutes (LASER Suction Tube: 7 minutes; LithAssist: 8.5 minutes; Suction HP: 7.4 minutes). Stone breaking laser settings were used 70% of the time while the remaining 30% was spent using stone dusting settings.

Mean surgeon-rated LSHP scores are reported in Table 2. While surgeons felt that all three devices were easily introduced into the nephroscope, laser fiber introduction was easier with the LithAssist and Suction HP relative to the LASER

Suction Tube. All three devices allowed for good stone visualization although the Suction HP allowed the best visualization of the laser fiber. Devices were rated similarly by surgeons with regard to effectiveness of lithotripsy and suction to evacuate stone fragments, yet these ratings were lower across all three devices than other domains. The three LSHP were rated similarly with regard to perceived safety of lithotripsy, but respondents felt that the LASER Suction Tube provided the least confidence for suction safety.

DISCUSSION

In our study evaluating the ease of use, effectiveness, and safety of three LSHP in a porcine model, we found that, in general, devices were rated similarly by operating surgeons performing PCNL. Overall, surgeons felt that each device could be inserted without difficulty through a standard nephroscope and provided good stone visualization, though ability to view the laser fiber was markedly better with the Suction HP. Perhaps most importantly, surgeons felt all three devices were effective for lithotripsy and evacuation of fragments, though no single device scored greater than 7 in either category. Safety of lithotripsy was also similar, although the LASER Suction Tube performed more poorly from a suction safety standpoint.

The first reported use of a combination suction and laser device during PCNL comes from Cuellar et al.[10] They constructed a hollow, stainless steel tube that could be attached to suction through which they inserted a 365μm HoYAG laser fiber. They report a stone free rate of 83% in a cohort of 71 patients with a mean stone size of 3.25 centimeters suggesting the effectiveness of this novel approach. This study utilized laser settings commonly used for retrograde intrarenal surgery with a mean energy of 1.3 J and 11 Hz. Only one study has been published regarding newer generation LSHP, in which Okhunov et al showed that the LithAssist device was effective in an *in vitro* model.

As higher power laser systems have been developed, investigators have determined that delivery of up to 70 watts of energy to a kidney stone at the time of PCNL is safe.[9] While use of laser lithotripsy during mini-, ultramini- and micro-PCNL has been described,[11-13] it is not commonly used at the time of standard PCNL. In one of the few studies on this topic, El-Nahas et al randomized patients undergoing PCNL to high-powered laser lithotripsy versus ultrasonic lithotripsy. They found that operative times were significantly longer when stones were fragmented with laser, albeit with less drop in hemoglobin from preoperative values. Perhaps more importantly, stone free rates were similar regardless of energy source used for lithotripsy.[14]

While our experience in an animal model suggests that stone fragmentation at the time of PCNL using LSHP is feasible, several limitations may impact its widespread acceptance. First, the mechanics of such devices, namely a small bore suction tube (11-12F) limit the ability to evacuate larger stone fragments. In the LASER Suction Tube and LithAssist models, the effective luminal size is even more diminished by laser fiber insertion, a problem avoided by the laser insertion mechanism of the Suction HP device which positions the fiber over the top of the suction tube (Figure 2). These factors may explain why overall scores amongst the three devices were similar, albeit lower than other domains with regard to effectiveness for lithotripsy and evacuation of stone fragments. Due to this small luminal size and limited suction, low pulse energy, high frequency laser settings, commonly referred to as dusting, were frequently employed in our study in an effort to reduce stone into a fine powder amenable to evacuation. Using this approach, it is likely that small fragments are propelled into adjacent calyces not accessible with a rigid nephroscope. Although these fine particles may pass spontaneously, data from retrograde intrarenal surgery studies have raised concerns that outcomes using a dusting technique may be suboptimal.[15] To address these concerns, further studies are needed providing a head-to-head comparison of laser suction devices with traditional commercially available lithotrites.

While we have demonstrated that LSHP are relatively easy to use and can effectively fragment stones, our study must be viewed in the context of some limitations. First, investigators were not blinded to the brand of LSHP being tested, which could have influenced results. Second, the order with which procedures were performed and thus devices used was also not randomized. Since multiple procedures were conducted in some renal units, this could have skewed results. In addition, the questionnaire used to assess usability and safety of each device was not validated. That said, the purpose of this study was to provide proof of concept surrounding use of these instruments, not provide a statistically rigorous comparison. Finally, the stones used to test LSHP effectiveness were Plaster of Paris. The composition of urinary stones can vary widely, impacting their fragmentation and subsequent clearance. Thus, effectiveness may be diminished in cases using stones typically found in humans.

CONCLUSION

Upon testing three LSHP in a porcine model, we found each device to be similarly easy to use and effective for fragmentation of stones. Though two out of three devices are currently approved for human use, further studies are needed to examine their effectiveness across a range of stone compositions. Furthermore, studies comparing their effectiveness to ultrasonic or ballistic lithotrites are needed to justify their use on a routine basis.

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Figure 1 – Photo comparison of the three LSHP (top to bottom: Lumenis® Suction HP, Cook® LithAssist, Storz® LASER Suction Tube)

Figure 2 – Comparison of suction channel and laser configurations between LSHP

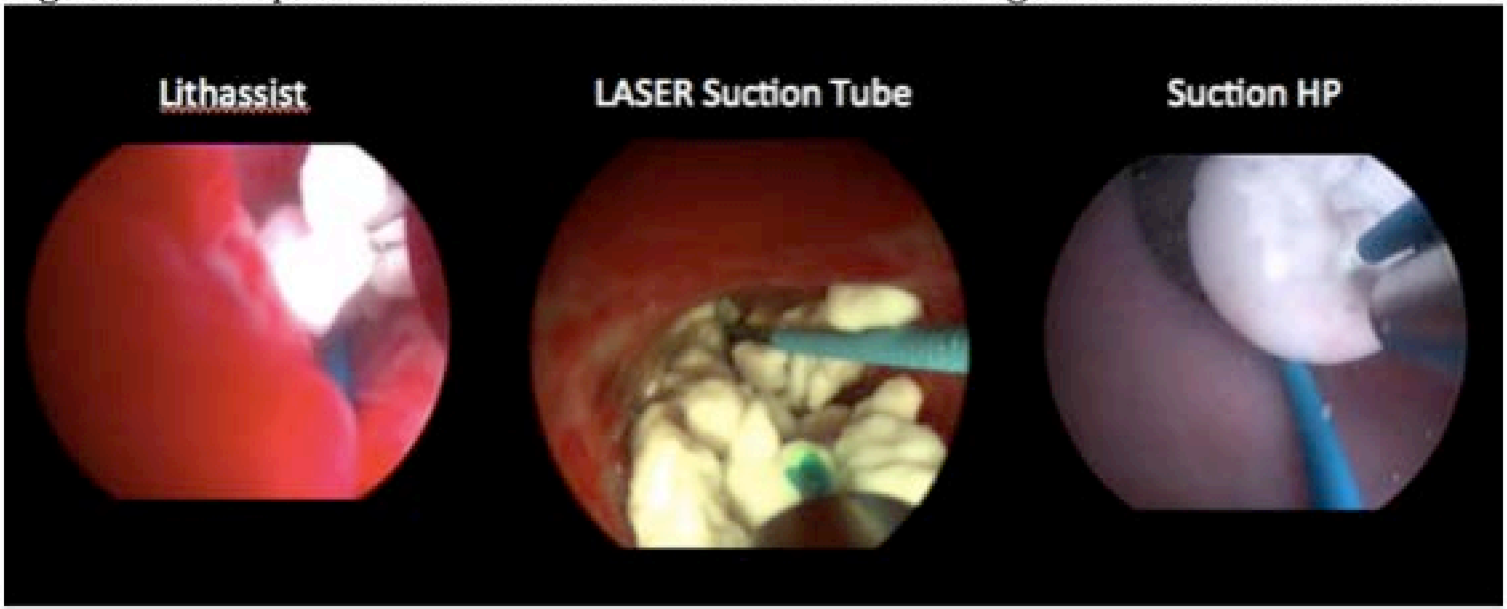

Table 1 – Post-procedure questionnaire rating each LSHP

Question	**Score**
How easy was laser fiber insertion into LSHP?	1 (hard) – 10 (easy)
How easy was LSHP insertion into nephroscope?	1 (hard) – 10 (easy)
How good was visualization of the stone with the LSHP employed?	1 (poor) – 10 (good)
How good was visualization of the laser fiber with the LSHP employed?	1 (poor) – 10 (good)
How good was your ability to control the laser fiber length?	1 (poor) – 10 (good)
How good was your ability to control the suction intensity?	1 (poor) – 10 (good)
How effective was lithotripsy using the LSHP?	1 (ineffective) – 10 (very effective)
How effective was fragment evacuation (suction) using LSHP?	1 (ineffective) – 10 (very effective)
How confident were you with lithotripsy safety?	1 (not confident) – 10 (very confident)
How confident were you with suction safety?	1 (not confident) – 10 (very confident)

Table 2 – mean LSHP scores by question

Question	LASER Suction Tube	LithAssist	Suction HP
How easy was laser fiber insertion into LSHP?	5.0	8.0	9.0
How easy was LSHP insertion into nephroscope?	8.5	8.7	9.0
How good was visualization of the stone with the LSHP employed?	8.7	7.3	9.7
How good was visualization of the laser fiber with the LSHP employed?	5.5	4.3	10
How good was your ability to control the laser fiber length?	5.5	3.7	10
How good was your ability to control the suction intensity?	4.0	7.3	8.7
How effective was lithotripsy using the LSHP?	6.0	6.7	6.3
How effective was fragment evacuation (suction) using LSHP?	6.5	5.0	7.0
How confident were you with lithotripsy safety?	5.0	6.7	7.0
How confident were you with suction safety?	5.5	9.0	9.7