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A Usability Comparison of Laser Suction Handpieces for Percutaneous Nephrolithotomy

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Abstract

Introduction: The holmium laser has revolutionized the practice of minimally invasive endoscopy for kidney stones. Recently, a novel, rigid handpiece for use in percutaneous nephrolithotomy (PCNL) that couples the holmium laser with suction has been developed. To date, limited data exist regarding the usability and ergonomics of such treatment systems. We thus sought to compare surgeon-rated usability with three different suction laser handpieces in a porcine model.

Materials and Methods: We performed bilateral reverse PCNL on four female domestic farm pigs. After induction of general anesthesia, percutaneous access was obtained into each kidney by using biplanar fluoroscopy and 8 mm stones (plaster of Paris) were inserted into the calix or renal pelvis for treatment. Four surgeons tested the LASER Suction Tube (Karl Storz®, Germany), LithAssist™ (Cook® Medical), and Suction Handpiece (HP) (Lumenis®, Israel) by using a combination of fragmentation (5 Joules/20 Hertz) and dusting (0.8 Joules/80 Hertz) settings on the Lumenis pulse 120 H laser. The primary outcome assessed was the ease of use of the three devices as measured by a surgeon questionnaire.

Results: A total of 15 stones were treated in 8 renal units. The mean time required for stone fragmentation was 8 min. The mean handling and suction efficiency scores were similar between devices. The Suction HP offered the best laser fiber visibility during lithotripsy.

Conclusion: Suction laser handpieces offer an option to treat renal stones via PCNL, with limited differences noted in most surgeon ratings between devices.

Keywords: kidney stones, laser, PCNL, technology

Introduction

After the initial description of the holmium:yttrium-aluminum-garnet (HoYAG) laser for the treatment of kidney stones in the mid-1990s, 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), both of which procedures 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 on 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 the safety of the three LSHP.

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Materials and Methods

Tested devices

Three LSHP were tested in this study. These included the LASER Suction Tube (Karl Storz®, Germany) and LithAssist™ (Cook® Medical), both of which are currently commercially available, as well as the Suction HP (Lumenis®, Israel), a new device awaiting food and drug administration approval (Fig. 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 40, 38, and 40 cm and the outer diameters 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 four adult, female domestic farm pigs. Pigs were anesthetized and intubated by a certified animal technician by using xylazine (2 mg/kg) and ketamine (10 mg/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 calix. A hydrophilic wire was negotiated down the ureter, and a second safety wire was placed by using an 8F–10F coaxial dilator. The tract was then balloon dilated to 30F, and an Amplatz sheath was positioned in the calix of puncture. Rigid nephroscopy was performed to verify the appropriate sheath position.

Prefabricated Plaster of Paris stones, each measuring 8×8 mm, were inserted into the 30F sheath and positioned into the calix of puncture by using the rigid nephroscope. Lithotripsy was performed by using a 550 μm Slimline™ (Boston Scientific) laser fiber inserted into the LSHP being tested. Laser energy and suction were provided by the Pulse™ 120 H laser system (Lumenis, Israel). Two laser settings were used for stone fragmentation—stone breaking and stone dusting. Stone breaking was performed by using energy settings of 5 J and 20 Hz, whereas stone dusting settings were 0.8 J and 80 Hz. Choice of settings was left to the discretion of the operating surgeon. After 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 by using a lethal injection of Socumb® solution (1 mL/5 kg).

FIG. 1. Photo comparison of the three LSHP (*top* to *bottom*: Lumenis Suction HP, Cook LithAssist, Storz LASER Suction Tube). LSHP = laser suction handpiece.

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, four 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 to 10, with higher scores being more optimal. Mean scores were calculated and compared among LSHP.

Results

Percutaneous renal access was successfully obtained in four 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. The mean lithotripsy time was 8 min (LASER Suction Tube: 7 min; LithAssist: 8.5 min;

Table 1. Postprocedure Questionnaire Rating Each LSHP

Question	*Score*
How easy was laser fiber insertion into LSHP?	1 (hard)–10 (easy)
How easy was LSHP insertion into the 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)

LSHP = laser suction handpiece.

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 the 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

Suction HP: 7.4 min). Stone breaking laser settings were used 70% of the time, whereas the remaining 30% of the time was spent using stone dusting settings.

Mean surgeon-rated LSHP scores are reported in Table 2. Although 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; however, 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 that all three devices were effective for lithotripsy and evacuation of fragments, though no single device scored >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 and Averch.[10] They constructed a hollow, stainless steel tube that could be attached to suction through which they inserted a 365 μm 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.[11] 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 as much as 70 watts of energy to a kidney stone at the time of PCNL is safe.[9] Although use of laser lithotripsy during mini-, ultramini-, and micro-PCNL has been described,[12–14] it is not commonly used at the time of standard PCNL. In one of the few studies on this topic, El-Nahas and colleague, 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, although with a less drop in hemoglobin from preoperative values. Perhaps more importantly, stone-free rates were similar regardless of the energy source used for lithotripsy.[15]

Although 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

FIG. 2. Comparison of suction channel and laser configurations between LSHP.

positions the fiber over the top of the suction tube (Fig. 2). These factors may explain why overall scores among the three devices were similar, although 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 calices that are 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.[16] To address these concerns, further studies are needed, providing a head-to-head comparison of laser suction devices with traditional commercially available lithotrites.

Although 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 were 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 the 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 to 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

On 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 with ultrasonic or ballistic lithotrites are needed to justify their use on a routine basis.

Author Disclosure Statement

No competing financial interests exist.

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Abbreviations Used

HoYAG = holmium:yttrium-aluminum-garnet
LSHP = laser suction handpiece
PCNL = percutaneous nephrolithotomy