Improvements in Intracorporeal Lithotripters for Percutaneous Nephrolithotomy

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Abstract. Percutaneous nephrolithotomy (PNL) is an effective minimally invasive surgical approach for the treatment of large renal stone burden. Intracorporeal lithotripters (ICL) are utilized during PNL to fragment calculi, with some devices capable of concurrently removing fragments as well. Much progress has been made in the design of ICL devices, resulting in potentially more efficient treatment of nephrolithiasis.

Keywords: percutaneous nephrolithotomy, intracorporeal lithotripter.
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INTRODUCTION

Percutaneous nephrolithotomy, a well accepted minimally invasive surgical procedure for the treatment of large volume nephrolithiasis, was first described by Fernstorm and Johannsen in 1976 [1]. This technique involves the establishment of an access tract, or passage, from the flank surface directly into the renal collecting system. The surgeon then inserts a nephroscope into the access tract to allow direct visualization within the kidney. Typically, rigid nephroscopes are utilized for the majority of the treatment process, as they incorporate large caliber working channels enabling insertion of large fragmentation or extraction instruments. In addition, rigid scopes allow delivery of more irrigant and also provide optimal visualization of the collecting system through a rod lens.

Flexible nephroscopes, which incorporate fiber-optic technology, are other important adjunctive instruments for PNL. Visualization with these instruments can be limited at times because of the "honeycomb" effect produced by the fiber-optic bundles. Although the image resolution of fiber-optic endoscopes can be improved by the use of digital filtering technology [2], it does not match that of rigid nephroscopes. The flexibility of these instruments is crucial to allow access to all peripheral calices within the collecting system, but this feature also limits the working channel size such that only smaller, flexible devices such as baskets or laser fibers can be employed. Therefore, flexible nephroscopy is used primarily to treat and extract small residual stones after the main portion has been removed.

Once the stone has been reached percutaneously, ICL devices are utilized in conjunction with nephroscopes to treat the stone burden. A variety of intracorporeal

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devices are available for clinical use. The simplest units provide a means to fragment stones. As technology has advanced, subsequent devices not only comminute stones but also allow for the concurrent removal of fragments. The latest ICLs combine clinically preferred fragmentation modalities while still providing the means for fragment removal. These newer devices have the potential to greatly improve PNL efficiency.

TRADITIONAL INTRACORPOREAL LITHOTRIPTERS

Ultrasonic lithotripter

Ultrasonic lithotripters typically incorporate a handpiece containing a piezoelectric crystal, which is excited by electrical energy. This creates a high frequency vibration of up to 27,000 hertz (Hz) [3]. The vibrational energy is transmitted through a hollow probe which is brought into contact with the stone surface, resulting in fragmentation. Ultrasonic lithotripter handpieces have a central lumen which is contiguous with that of the ultrasonic probe, thus allowing suction to be applied through the device.

The major advantage of the ultrasonic lithotripter lies in its overall clinical efficiency in treating stones. The large caliber probes (ranging from 3.3 to 3.8 Fr), are inserted through rigid nephroscopes. Stones treated with this modality can be simultaneously broken and removed from the collecting system. Ultrasonic probes are also relatively atraumatic, resulting in little effect on the collecting system surface with short periods of direct contact. Because of these favorable characteristics, ultrasonic lithotripsy is often the preferred modality for PNL.

The only clinical disadvantage of this device is its decreased effectiveness when treating very large stones with a hard and dense composition. In these cases, the probe will often “polish” the stone surface without achieving comminution. In these cases, it is often advantageous to initially utilize a separate pneumatic lithotripter to break up the stone into smaller portions which can then be further fragmented and cleared by the ultrasonic unit.

Pneumatic lithotripter

The pneumatic, or ballistic, lithotripter is perhaps the simplest ICL currently available. The main component of this device, which is powered by an external compressed air source, consists of a hollow handpiece containing a metal pellet. A solid blunt probe, with a diameter typically ranging from 2 to 3.2 mm, is secured to the handpiece and the probe tip brought into direct contact with the stone surface. When the handpiece is activated, the pellet in the handpiece is driven forcibly against the solid probe. This “jackhammer” effect enables breakage of the stone into smaller fragments. Denstedt *et al* reported on the initial use of this device and found that it was effective in fragmenting 94% of treated calculi [4].

There are many advantages of the pneumatic lithotripter. First, it is very effective in breaking apart stones. From a clinical standpoint, it is most useful for quickly fragmenting very large stone burden or hard calculi, such as those comprised of calcium oxalate monohydrate or brushite (calcium hydrogen phosphate). This device is also very safe, as the blunt tip of the solid probe will not damage the urothelium of the collecting system. The minimal tissue effects of pneumatic lithotripsy have been demonstrated in a swine model where no pathologic change was seen in areas of the urinary tract treated directly with pneumatic probes after 6 weeks of follow-up [5].

The main disadvantage of the pneumatic lithotripter is that one cannot simultaneously remove stone fragments from the collecting system during treatment. For removal, the surgeon must insert separate grasping forceps or an extraction basket through the nephroscope to extract fragments piecemeal. This can be a cumbersome process when dealing with a large stone.

Holmium laser

The holmium laser has been available since the mid 1990s and presently is widely utilized for the treatment of nephrolithiasis. This laser produces a wavelength of 2140 nm and works through a photothermal mechanism [6]. Laser energy is delivered with flexible quartz fibers ranging from 200 to 1000 microns in diameter. Unlike the older Candela laser, which would only treat pigmented calculi, the holmium laser is effective for fragmenting calculi of all compositions [7]. Because the photothermal effect of the holmium laser results in a vaporization of stone material, it tends to produce smaller fragments during lithotripsy than the pneumatic lithotripter. This has been shown in an *in vitro* experiment utilizing calculi of varying compositions obtained from a stone laboratory[8].

Despite the fact that the holmium laser is commonly used for ureteroscopic lithotripsy, most urologists do not use this device as a first-line ICL during PNL. This is mainly because of the inefficiency of the laser with large stones. Although investigators have utilized the holmium laser during PNL and found it to be an effective lithotrite, its inefficiency in treating large stones has been noted [9].

In addition, concurrent fragment removal when utilizing the holmium laser remains an issue. Cuellar and Averch have reported on the use of a suction probe device through which a holmium laser fiber can be inserted. This adjunctive device facilitates fragment removal during holmium laser PNL, but has not been widely adopted [10].

Lastly, the holmium laser's unique properties also allow it to cut tissue cleanly while maintaining superior hemostasis. As such, this laser can also be utilized for applications such as treating benign prostatic hyperplasia [11]. When treating stones, however, the laser fiber must be in contact with the stone surface at all times to prevent injury or perforation to adjacent urothelial tissue. The potential for tissue injury during stone treatment was demonstrated by Santz-Cruz *et al* in an *ex vivo* porcine ureter experiment, where the holmium laser produced the fastest perforation time of any tested energy modality when activated within 0.5 mm of the ureteral wall [12]. However, the laser was not able to produce acute perforation when the fiber was held 2 mm away from the wall.

Electrohydraulic lithotripter

The electrohydraulic lithotripter (EHL) produces stone fragmentation through acoustic shockwave and cavitation effects generated by a spark at the end of a probe which is typically placed in near contact with the stone surface. Although it is effective in stone fragmentation, EHL can be a traumatic energy modality which may lead to mucosal soft tissue injury. Like the holmium laser and pneumatic lithotripters, EHL lacks a reliable method of concurrent stone fragment removal during PNL. This modality has been superseded by the aforementioned devices.

In summary, most urologists performing PNL with traditional ICLs will use either the ultrasonic or pneumatic lithotripters, as these devices are simple to utilize, effective, and are inserted through rigid nephroscopes that optimize stone visualization. When dealing with very large and hard stones, these devices can be used sequentially, employing the pneumatic unit initially to quickly break up the stone into smaller chunks and then using the ultrasonic unit to finish fragmenting and concurrently removing the smaller pieces. Although effective, the sequential use of these devices, with removal and reinsertion of the respective instruments, can be tedious and time consuming.

EVALUATION OF ICL EFFICIENCY

In the past, with ultrasonic lithotripters becoming the preferred modality for stone fragmentation during PNL, many manufacturers introduced units for clinical use. From the urologist's standpoint, it was difficult to ascertain which units were truly the most efficient. As such, many groups devised testing methods to compare and contrast commercially available ultrasonic ICL devices.

Liatsikos *et al* tested four ultrasonic lithotripter units utilizing Plaster of Paris stone phantoms [13]. In this study, the stone phantoms were placed into a container with water. The probes of each ultrasonic unit were positioned into a rigid nephroscope and continuous irrigation applied through the scope. The stone phantoms were then treated with each ultrasonic device, with the end point being complete fragmentation of each phantom. The inherent weakness of this study is that stone fragmentation was performed by hand. As a result, operator bias could have significantly affected the results of this study.

Haupt designed an *in vitro* system to test ultrasonic lithotripter devices which fixed the handpieces and probes such that the probes pointed downward and were positioned within a water basin [14]. An elaborate weight and fulcrum system then brought a stone phantom, which had been placed within the basin, against the probe tip with a constant force. While eliminating potential operator bias, this complex system would hinder reproducibility of results.

Our group devised another novel *in vitro* hands-free testing system in which the ultrasonic handpieces and probes were secured upright [15]. This system (Fig. 1) utilized an irrigation sheath through which probes were inserted and allowed for continuous tap water irrigation to surround the probes to prevent overheating. An acrylic sheath was then fashioned to fit over the irrigation sheath such that the tip of the probe could be seen.

An Ultracal-30 (U-30) gypsum stone model, which had been shown to provide reproducible fragmentation outcomes in prior *in vitro* shock wave lithotripsy experiments, was chosen for this study [16]. A U-30 stone was placed atop the probe tip once it had been secured within the irrigation and acrylic sheaths, and finally a weighted rod was positioned over the stone to provide a constant pressure keeping the stone in contact with the probe. The advantages of this system included the elimination of user variability, production of reproducible results, and also the simple mechanism of maintaining a constant force against the probe tip/stone interface.

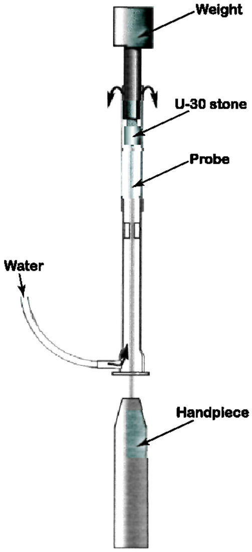

FIGURE 1. Hands-free testing apparatus for the evaluation of ultrasonic lithotripter units [15]. The handpiece and probe combination is secured in an upright fashion, with the probe placed through the irrigation sheath. Irrigant is then run through the irrigation sheath during testing. A test stone is placed atop the probe tip, which is visible through an acrylic cylinder fitted on the end of the irrigation sheath. The weighted rod is then placed atop the test stone, providing a constant force against the test stone.

This system was first utilized to evaluate the efficiency of 5 pure ultrasonic lithotripter devices. These units were the Olympus LUS-1 and LUS-2 (Olympus, Melville, NY), the Circon-ACMI USL-2000 (Circon-ACMI, Southborough, MA), the Karl Storz Calcuson (Karl Storz, Culver City, CA), and Richard Wolf model 2271.004 (Richard Wolf, Vernon Hills, IL). The endpoint of this study was to determine the mean penetration times achieved by each ultrasonic unit in treating groups of U-30 stones.

TABLE 1. Summary of Ultrasonic Lithotripter efficiency ratios

Ultrasonic lithotripter	Efficiency ratio (Mean ± SD)*
Olympus LUS-2	1.0 ± 0.1
Circon-ACMI USL-2000	1.1 ± 0.3
Karl Storz Calcuson	1.4 ± 0.3
Olympus LUS-1	2.1 ± 0.5
Richard Wolf 2271.004	3.6 ± 0.8

* Lower numbers translate to higher efficiency. Data from reference 15.

In this study, all units were utilized at 100% output (power). The Olympus LUS-2 produced the fastest overall mean penetration time of 28.8 ± 2.7 seconds. When this value was used to normalize all other mean penetration times into efficiency ratios, the results are summarized in Table 1.

The results showed that the Olympus LUS-2 and Circon-ACMI USL-2000 units performed at an essentially equivalent efficiency, with all other differences statistically significant by ANOVA using the Tukey-Kramer HSD test.

THE DEVELOPMENT OF NEW COMBINATION ICL DEVICES

To overcome the aforementioned disadvantages of traditional ultrasonic and pneumatic devices, newer ICL devices have attempted to combine these modalities to provide better efficiency of stone treatment. The first of these devices is termed the Lithoclast Ultra (Boston Scientific Corporation, Natick, MA). The other device is called the Cyberwand (Gyrus/ACMI, Southborough, MA).

Lithoclast Ultra

This device combines both pneumatic and ultrasonic lithotripsy through the use of a combination handpiece, which is actually two separate handpieces connected together. The first portion of this combination handpiece is a traditionally designed pneumatic handle with a smaller diameter solid probe which is 1 mm in diameter. The ultrasonic handle, while still driven by a piezoelectric mechanism, is modified to allow insertion of the pneumatic probe through it and then subsequent anchoring of the pneumatic handle. As such, the pneumatic probe is positioned within the hollow ultrasonic probe lumen. Each energy modality can be activated either separately or concurrently during stone treatment, which theoretically allows the quick ballistic fragmentation of a large bulk of stone and then treatment completion with concurrent removal of fragments with the ultrasonic probe.

Because of the wide variety of ultrasonic power and pneumatic frequency settings available with the Lithoclast Ultra device, the testing apparatus designed and utilized by our group for the evaluation of ultrasonic lithotripters was used to assess the efficiency of various setting combinations [17]. Ultrasonic output (power) settings of 40, 70, and 100% were used in concert with pneumatic frequency settings of 1, 4, 8, and 12 Hz. Again, the endpoint used was the mean penetration time achieved using each setting combination with groups of U-30 stones. The pneumatic probe was positioned flush with the end of the ultrasound probe for this study.

The results showed that the setting combination with both the highest ultrasonic output and pneumatic frequency (100% and 12 Hz) produced the fastest mean penetration time of 8.9 ± 1.1 seconds. Notably, the mean penetration times achieved with any combination setting was still faster than the most efficient pure ultrasonic lithotripter, the Olympus LUS-2. Mean penetration times were also compared with ANOVA. As shown in Fig. 2, the analysis revealed that incremental increases in ultrasonic output as well as pneumatic frequency resulted in statistically significant reductions in penetration times (p=0.001 and p<0.001, respectively). However, the pneumatic modality produced the greatest reductions in penetration times.

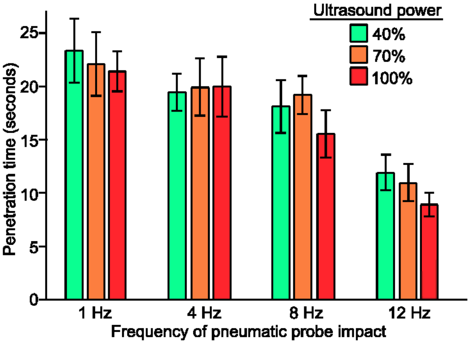

FIGURE 2. Summary of mean penetration times (seconds) achieved with Lithoclast Ultra unit on *y axis* with pneumatic frequency settings on *x axis* and ultrasonic output settings of 40% in green, 70% in orange, and 100% in red. Using ANOVA, increases in pneumatic frequency settings had a much greater proportional effect on decreasing mean penetration times compared to increases in ultrasound output, though each modality produced statistically significant effects.

Pietrow, *et al* have evaluated the efficacy of the Lithoclast Ultra device in a clinical setting in a prospective, randomized trial in 20 consecutive PNL patients comparing treatment and clearance times achieved with the Ultra to those using the Olympus LUS-2 ultrasonic lithotripter [18]. In this trial, the mean stone areas and locations were similar in both patient groups, with the Ultra patients having a mean stone area of 809.2 mm^2 and the LUS-2 patients an area of 795.5 mm^2. The mean stone clearance times were 21.1 minutes for the Ultra, compared to 43.7 minutes for the LUS-2. This translated to a stone clearance rate of 39.5 mm^2/min for the Ultra and 16.8 mm^2/min for the LUS-2. Clearance differences were statistically significant.

Despite the apparent clinical advantages provided by the Lithoclast Ultra, a number of characteristics can detract from the clinical experience with this device. First of all, the combination handpiece can be quite heavy and cumbersome to use. In addition, with the pneumatic probe within the lumen of the ultrasonic probe, fragments can sometimes clog the unit. In addition, the ballistic effect of the pneumatic probe can propel stone fragments away, counteracting the suction of the ultrasonic probe. A new, modified combination handle is in development and may address some of these issues.

Cyberwand

The Cyberwand is a unique device which utilizes a dual probe configuration to deliver both vibrational and ballistic energy to treat stones. This unit has been recently evaluated *in vitro* by Kim *et al* [19]. Unlike the Lithoclast Ultra, this unit utilizes a single handpiece powered through a piezoelectric mechanism. Vibrational energy at approximately 21,000 Hz from the handpiece is transmitted directly through the inner probe in the same manner as a traditional ultrasonic lithotripter. However, the vibrational energy conveyed to the outer probe is dampened through the use of a free mass and spring loaded mechanism which essentially reduces the vibrational frequency to 1,000 Hz and allows limited excursion of the outer probe tip to produce the ballistic "jackhammer" effect on a stone's surface.

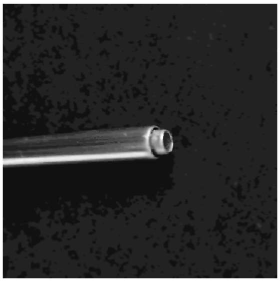

FIGURE 3. Image of the tip of the Cyberwand device. Note the dual probe configuration. The inner, high-frequency probe extends approximately 1 mm beyond the outer, low-frequency probe, at rest.

Our group's *in vitro* ICL testing system has been used to compared penetration efficiency of the Cyberwand with the Lithoclast Ultra device [19]. In this study, which again used groups of U-30 stones, mean stone penetration times with both devices were determined and then compared with unpaired Student t-tests. The mean penetration time achieved by the Cyberwand was 4.8±0.6 seconds, compared to 8.1±0.6 seconds (p<0.0001) for the Lithoclast Ultra.

From a clinical standpoint, a multi-center, randomized, prospective trial is currently underway to compare the treatment efficiency of the Cyberwand device to the Olympus LUS-2 device during PNL.

CONCLUSIONS

Intracorporeal lithotripters are important devices utilized for the treatment of stones during PNL. Improvements in ICL design are ongoing and have resulted in new and potentially more efficient devices. The *in vitro* testing system utilized by our group has provided objective, reproducible results which have been useful in evaluating the efficiency of ICL devices. Prospective, randomized clinical trials continue to be important to confirm the findings from *in vitro* experiments.

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