Miniature ball-tip optical fibers for use in thulium fiber laser ablation of kidney stones

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Abstract. Optical fibers, consisting of 240-μm-core trunk fibers with rounded, 450-μm-diameter ball tips, are currently used during Holmium:YAG laser lithotripsy to reduce mechanical damage to the inner lining of the ureteroscope working channel during fiber insertion and prolong ureteroscope lifetime. Similarly, this study tests a smaller, 100-μm-core fiber with 300-μm-diameter ball tip during thulium fiber laser (TFL) lithotripsy. TFL was operated at a wavelength of 1908 nm, with 35-mJ pulse energy, 500-μs pulse duration, and 300-Hz pulse rate. Calcium oxalate/phosphate stone samples were weighed, laser procedure times were measured, and ablation rates were calculated for ball tip fibers, with comparison to bare tip fibers. Photographs of ball tips were taken before and after each procedure to track ball tip degradation and determine number of procedures completed before need for replacement. A high speed camera also recorded the cavitation bubble dynamics during TFL lithotripsy. Additionally, saline irrigation rates and ureteroscope deflection were measured with and without the presence of TFL fiber. There was no statistical difference (P > 0.05) between stone ablation rates for single-use ball tip fiber (1.3 ± 0.4 mg/s) (n = 10), multiple-use ball tip fiber (1.3 ± 0.5 mg/s) (n = 44), and conventional single-use bare tip fiber (1.3 ± 0.2 mg/s) (n = 10). Ball tip durability varied widely, but fibers averaged greater than four stone procedures before failure, defined by rapid decline in stone ablation rates. Mechanical damage at the front surface of the ball tip was the limiting factor in fiber lifetime. The small fiber diameter did not significantly impact ureteroscope deflection or saline flow rates. The miniature ball tip fiber may provide a cost-effective design for safe fiber insertion through the ureteroscope working channel and into the ureter without risk of instrument damage or tissue perforation, and without compromising stone ablation efficiency during TFL lithotripsy. © 2016 Society of Photo-Optical Instrumentation Engineers (SPIE) [DOI: 10.1117/1.JBO.21.1.018003]

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1 Introduction

1.1 Ball-Tip Fibers in Laser Medicine

Ball-tip optical fibers have been used in laser medicine since the 1990s, first for laser angioplasty and neurosurgery, and more recently for endovenous laser therapy. Laser angioplasty employs the ball tip design by allowing the quartz fiber to taper from a small core to a larger diameter, smooth, rounded ball tip, thus minimizing the probability of mechanical dissection or perforation of the blood vessel wall. Neurosurgical procedures utilize a carbon coated, “hot” ball-tip fiber to absorb light and convert it into heat, thus providing ablative temperatures at low power and increasing safety margins near delicate tissues. Endovenous laser therapy also employs ball-tip fibers to prevent fiber-induced mechanical perforation of veins.

1.2 Holmium: YAG Laser Lithotripsy Using Ball-Tip Fibers

In a similar approach, the use of ball-tip fibers during laser lithotripsy is motivated by the desire to prevent fiber-induced mechanical damage to the inner lining of the ureteroscope working channel and potential perforation of the ureter wall as well. Damage to the working channel is of great concern to patient safety and of further concern to clinicians, since instrument repair is costly, with single ureteroscope average repair costs ranging from $4500 to $13,200.8,9 Damage may occur from both fiber insertion through the working channel during ureteroscope deflection, as well as premature laser activation with the fiber still inside the ureteroscope.

Several devices have been introduced to reduce the probability of ureteroscope damage in both situations, such as the endoscope protection system, which employs an optical sensor that shuts off the laser if the distal fiber tip is still inside the ureteroscope working channel, and Flexguard, a protective fiber sheath that insulates the ureteroscope working channel from the fiber. While both of these solutions address laser-induced damage, only the Flexguard sheath additionally prevents mechanical damage. However, the tradeoff for a protected working channel is a decrease in ureteroscope deflection capability and saline irrigation rates needed for visibility and safety, due to the size of the sheath and the additional space that it consumes within the working channel. While laser-induced damage to the inner lining of the ureteroscope working channel constitutes a majority of ureteroscope failures, mechanical damage also contributes to ureteroscope failure and is typically caused by the sharp-edged distal tip of the laser fiber.
A ball-tip fiber for use in Holmium:YAG laser lithotripsy was recently introduced (Flexiva TracTip 200, Boston Scientific, Marlborough, Massachusetts) in the form of a 240-μm-core fiber with a 450-μm-diameter ball tip to address these concerns.16-20 Ball-tip fibers provide an additional safety margin by allowing for simplified advancement through the ureteroscope working channel without unnecessarily bulk up the working channel wall itself through the use of a protective sheath, which would otherwise translate into further loss of ureteroscope deflection and irradiation. The ball tip also prevents chipping of the distal fiber tip during laser lithotripsy, which could otherwise result in angled, side-firing laser irradiation and thermally induced damage to the ureter wall, as previously reported.21

1.3 Thulium Fiber Laser Lithotripsy Using Ball-Tip Fibers

Ball-tip fibers have not yet been tested using small fibers (<200-μm-core) unique to the thulium fiber laser (TFL) for lithotripsy. Their potential advantages are threefold: (1) the ball geometry may provide a beam waist with a higher power density in front of the fiber, increasing stone ablation rates; (2) the rounded surface may reduce fiber tip burn-back by allowing stone fragments to deflect off the tip without causing fiber tip degradation; and (3) the smooth surface may enable atraumatic tracking of the fiber through the ureteroscope, thus preventing damage to the lumen of the working channel during fiber advancement while under ureteroscope deflection. Extensive simulations describing the beam characteristics of ball-tip fibers immersed in both air and water mediums have been previously reported in detail for other applications.22

Conventional bare tip fibers suffer from damage in the form of distal fiber tip “burn-back” during TFL lithotripsy, attributed to excessive temperatures and mechanical stress caused during stone fragmentation, as well as pressures generated during implosion of the cavitation bubble at the fiber tip.23 Such degradation in the clinic may result in the costly disposal of the fiber either during or after the procedure is completed. Previous studies have been conducted to demonstrate the TFL’s ability to spare the proximal fiber tip during lithotripsy.24 Multiple studies have also attempted to reduce distal fiber tip degradation through the use of hollow steel tips,25 tapered fiber tips,26 detachable fiber tips,26 and now ball-tip fibers in this study.

The TFL near-single-mode, Gaussian spatial beam profile also allows higher laser power to couple into smaller fibers (e.g., 50- and 100-μm-core) than those used for Holmium laser lithotripsy. For difficult laser lithotripsy procedures requiring extreme flexion of the ureteroscope (e.g., in the lower pole of the kidney), a smaller fiber permits greater ureteroscope flexibility. The smaller fiber also allows increased irrigation through the small (1.2-mm-ID) ureteroscope working channel, which should translate into improved visibility and safety.25,27,28

The ball tip geometry eliminates the possibility of mechanical damage observed with the use of conventional traumatic flat fiber end faces and allows for unperturbed insertion through the ureteroscope. Therefore, a 100-μm-core silica tube fiber with a 300-μm-diameter distal ball tip is tested, combining the general properties of a ball-tip fiber with a small fiber design for TFL lithotripsy.

2 Methods

2.1 Thulium Fiber Laser Parameters

A 100-W, continuous-wave, TFL (TLR 100-1908, IPG Photonics, Oxford, Massachusetts) with a center wavelength of 1908 nm was used in these studies. A 25-mm-focal-length planoconvex lens was used to focus the 5.5-mm-diameter fiber laser beam from the built-in collimator to a spot diameter of ~25 μm (1/e^2) for coupling into a separate 100-μm-core, low-OH, silica optical fiber with a 300-μm-diameter ball tip (FIPE100140170/2M Ball Lens, PolyMicro, Phoenix, Arizona). The protective jacket at the distal end of the trunk fiber was stripped back, exposing the cladding for a short length of 2 mm near the ball tip. The laser was electronically modulated with a function generator (DS345, Stanford Research Systems, Sunnyvale, California) to produce a pulse energy of 35 mJ, pulse duration of 500 μs, and pulse rate of 300 Hz, selected based on optimal results from previous studies.29

2.2 Kidney Stone Samples

All kidney stone samples were composed of 60% calcium oxalate monohydrate and 40% calcium phosphate [Fig. 1(b)]. These stones were chosen because calcium oxalate stones comprise about 80% of all stone compositions encountered in the clinic.30 The stone samples were obtained from a single source and had a consistent mass (50 to 80 mg), size (4- to 5-mm diameter), shape, and color. Stone samples were desiccated in an oven at a constant temperature of 70°C for a time of 15 min and then weighed with an analytical balance (Model AB54-S, Mettler-Toledo, Columbus, Ohio) before lithotripsy experiments.
to determine their initial mass. The stone samples were then placed in a wire mesh cradle and immersed in a saline bath. TFL lithotripsy experiments were conducted after a rehydration time of 1 min, using a handheld ball-tip fiber. Stone ablation rate was calculated by dividing stone mass by laser operation time. A minimum of 10 stone samples were used for each study group (bare fiber and ball-tip fiber configurations). For data analysis, “single use” referred to data obtained from the optical fiber during its initial ablation of each stone sample. “Multiple use” referred to data obtained from the same ball-tip fiber used in multiple stone sample studies. The distinction arises because fibers not showing evidence of distal tip damage or degradation during a study were reused to determine their maximum number of uses until fiber failure.

2.3 Experimental Setup

A 1.5-mm mesh sieve was integrated into a 70-mm diameter, 150-mL transparent plastic sample container, and bowed in a concave orientation while remaining level at the conic epicenter [Figs. 1(a) and 1(b)]. Kidney stones were submerged in a saline bath and placed in the center of the sieve curvature. All stone samples were free to move inside the sieve cone during the studies. The fiber was manually held in contact with the stone samples during the entire study and only repositioned to target fragments that were displaced during irradiation. Stone samples were irradiated until all ablated fragments were sufficiently small (<1.5-mm diameter) to pass through the mesh sieve. Laser fragmentation times were recorded for each experiment, which were equivalent to total procedure times since significant stone retropulsion was not observed and repositioning of the fiber to treat individual stone fragments was minimal.

Damage inspection of the ball-tip fiber was conducted using a CCD camera (DCC1645C, Thorlabs, Newton, New Jersey) to record images before and after fiber use (Fig. 2). Undamaged fibers were reused for another stone sample ablation study. Degraded fibers had their ball tip clipped and the fiber repolished for direct comparison as bare tip fiber control studies.

2.4 Ureteroscope Irrigation Rate Studies

Saline irrigation rates were measured by introducing gravitational flow from a saline bag (at a fixed height of 100 cm) through the 3.6 Fr (1.2 mm) working channel of a flexible ureteroscope (Uretero-Reno Videoscope URF-V, Olympus, Southborough, Massachusetts). Saline flowed freely through the ureteroscope for 2 min for each experiment. Studies were conducted using the same 100-μm-core fiber with a 300-μm-diameter ball tip inserted through the working channel. Saline irrigation volume was then measured with a graduated cylinder. A sample size of \( n = 4 \) was performed with the mean ± standard deviation recorded. Percent flow rate was calculated by dividing flow with a fiber inserted by flow through the empty working channel (control) without a fiber present.

<table>
<thead>
<tr>
<th></th>
<th>100-μm ball-tip fiber</th>
<th>100-μm bare tip fiber</th>
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<tbody>
<tr>
<td>Single use</td>
<td>Ablation rate (mg/s):</td>
<td>1.3 ± 0.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.3 ± 0.5</td>
</tr>
<tr>
<td></td>
<td>Operation time (s):</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>55 ± 24</td>
</tr>
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<td></td>
<td>Stone mass (mg):</td>
<td>73 ± 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>66 ± 13</td>
</tr>
<tr>
<td>Number of samples (N):</td>
<td>10</td>
<td>44</td>
</tr>
</tbody>
</table>

Fig. 2 (a) Ball-tip fiber prior to thulium fiber laser (TFL) lithotripsy. (b) Degraded ball-tip fiber after TFL lithotripsy, with ~100 μm of burn-back (35 mJ, 500 μs, 300 Hz, ~16,500 pulses, \( t = 55 \) s). (c) Control fiber prior to TFL lithotripsy. (d) Degraded control fiber tip after TFL lithotripsy, measuring ~1 mm of burn-back, represented by the dotted line (35 mJ, 500 μs, 300 Hz, ~12,000 pulses, \( t = 40 \) s).
2.5 Ureteroscope Deflection Tests

The same flexible ureteroscope described above was also used to perform primary (forward) and secondary (backward) deflection tests both with and without the ball-tip fiber inserted through the working channel. The maximally flexed ureteroscope configurations were then photographed and a protractor was used to measure the maximum deflection angle.

2.6 Cavitation Bubble Studies

The TFL operating at 1908 nm with 35-mJ pulse energy, 500-μs pulse duration, and 300-Hz pulse rate delivered laser energy through the 100-μm-core, silica ball-tip fiber. The fiber tip was submerged in a saline bath, either by itself or in contact with a kidney stone sample. Cavitation bubble dynamics using both bare and ball-tip fibers were recorded. Imaging was performed using a high speed camera (SA5, Photron, Tokyo, Japan) at 105,000 frames per second and with 10-μm spatial resolution.

3 Results

3.1 Stone Ablation Rates

Stone samples were irradiated until all ablated fragments were sufficiently small (<1.5 mm diameter) to pass through the mesh sieve, in accordance with acceptable clinical criteria for stone fragment size. Figure 1(c) shows a stone prior to TFL lithotripsy and stone debris after experiments. Ball-tip fibers produced a sizeable amount of residual dust in addition to traditional larger fragments.

Measured laser operation times and calculated stone ablation rates during TFL lithotripsy experiments using ball tip and bare tip fibers (control) are summarized in Table 1. Initial stone mass was similar for all datasets and measured 73 ± 13, 66 ± 13, and 71 ± 6 mg for single-use ball tip, multiple-use ball tip, and bare tip fiber control studies, respectively (P > 0.05). Operation times were recorded and measured 61 ± 21, 55 ± 24, and 54 ± 9 s for each group (P > 0.05). There was no statistical difference (P > 0.05) between stone ablation rates for single-use ball-tip fiber (1.3 ± 0.4 mg/s), multiple-use ball-tip fiber (1.3 ± 0.5 mg/s), and conventional single-use bare tip fibers (1.3 ± 0.2 mg/s). The TFL with a low pulse energy and high pulse rate produced a vibrational effect, which led to the stone oscillating in the same relative position, only requiring local pursuit of the stone within a few millimeters of the initial stone location. It should be noted, however, that the presence of

<table>
<thead>
<tr>
<th>Fiber #</th>
<th># Samples treated</th>
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<td>1</td>
<td>1</td>
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<tr>
<td>2</td>
<td>3</td>
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<td>10</td>
<td>4</td>
</tr>
<tr>
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<tr>
<td>S.D.</td>
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</table>

Table 2 Number of samples successfully fragmented by each ball-tip fiber.

Fig. 3 Ureteroscope deflection studies conducted with a flexible digital ureteroscope (URF-V, Olympus, Southborough, Massachusetts). (a and b) Maximum primary and secondary deflection of flexible ureteroscope with empty working channel (without ball-tip fiber inserted through ureteroscope). (c and d) Maximum primary and secondary deflection of flexible ureteroscope with ball-tip fiber inserted through ureterscope. Note that ureteroscope deflection is not significantly affected by the presence of the fiber.
the sieve may have distorted the normal retropulsion movement typically encountered in the clinic to some degree.

Ball-tip fibers found to be undamaged after single use were reused for ablation of multiple samples. This process continued for each ball tip until it showed significant degradation and diminished energy output, evidenced by a sharp increase in operation time and a corresponding sharp decrease in stone ablation rate. Only then the ball tips were clipped and the bare fiber tip was repolished for use in control studies. First time use of samples was noted for each fiber as well as number of succeeding samples tested (Table 2).

### 3.2 Saline Irrigation Rates

Saline irrigation flow rates through the ureteroscope working channel with and without the insertion of the 100-μm-core/140-μm-cladding/170-μm-buffer trunk fiber and 300-μm-diameter ball-tip fiber yielded values of 23.0 ± 0.8 and 27.7 ± 1.0 ml/min, respectively. This translated into an 83% flow rate with the ball-tip fiber present. These values are consistent with measurements reported during previous studies, testing a wider range of both smaller and larger fibers, and the 83% flow rate with the ball-tip fiber is significantly higher than the 43% flow rate using a standard 270-μm-core Holmium fiber.25,28,31

### 3.3 Ureteroscope Bending Studies

Figure 3 shows the influence of the ball-tip fiber on deflection of a flexible ureteroscope. Primary (forward) deflection with and without fiber inserted measured 267 and 268 deg, respectively. Secondary (backward) deflection with and without fiber inserted measured 169 and 170 deg, respectively. These values are within the error for measurement and show that the ball-tip fiber did not significantly impede ureteroscope deflection. Previous studies have reported that maximum deflection of this specific

Fig. 4 Images taken every ~50 μs with a high speed camera (105,000 frames per second) of the cavitation bubble dynamics near the distal end of the ball-tip fiber during a single 500-μs long TFL pulse. (a) t = 0 μs, (b) t = 47 μs, (c) t = 95 μs, (d) t = 143 μs, (e) t = 191 μs, (f) t = 238 μs, (g) t = 286 μs, (h) t = 333 μs, (i) t = 381 μs, (j) t = 429 μs, (k) t = 476 μs, and (l) t = 524 μs.
ureteroscope is decreased from 275 to 217 deg (primary) and 180 to 161 deg (secondary) simply with prolonged clinical use, so the small changes in deflection angles measured in this study are insignificant.

3.4 Cavitation Bubble Studies

A stream of cavitation bubbles was observed during delivery of a single 500-μs long TFL pulse at 35 mJ (Fig. 4). Representative images for the ball-tip fiber with and without a stone sample are shown in Figs. 5(a) and 5(b). The maximum bubble diameter of 600 μm was observed 900 μm from the ball tip, and the bubble stream extended for 2400 μm, at t = 440 μs. However, as expected, the presence of the stone altered the geometry of the cavitation bubble. The stone not only impeded cavitation bubble expansion in the forward direction, but also ejected stone material which most likely contributed to pressure variations as well. Representative cavitation bubble images near the bare fiber tip both with and without stone sample are also shown for comparison [Figs. 5(c) and 5(d)]. For bare tip fiber with similar laser settings, a maximum bubble diameter of 440 μm was observed 460 μm from the fiber tip, and the bubble stream extended for 1080 μm at t = 280 μs. The cavitation bubble stream length at the bare fiber tip was shorter possibly due to the divergent laser beam exiting the fiber, as compared with the focused beam from the ball-tip fiber.

4 Discussion

TFL procedure times for each dataset were comparable to previously reported in vitro ureter model results, conducted with similar laser parameters (35 mJ, 500 μs, and 300 Hz) and a bare tip fiber, which reported an operation time of 54 ± 22 s.29 TFL procedure times are also shorter than the procedure time of 167 ± 41 s previously reported using the conventional Holmium:YAG laser with a separate set of standard clinical parameters of 600 mJ, 350 μs, 6 Hz, and a 270-μm-core optical fiber.29 It should be noted that Holmium laser lithotripsy using higher pulse energies during preliminary studies did not result in shorter procedure times due to an observed increase in stone retropulsion. The stone particles or dust created during TFL lithotripsy [Fig. 1(c)] also appear to be smaller than the stone fragments typically produced during conventional Holmium laser lithotripsy, which may potentially translate into lower stone retreatment rates in the clinic. Initial saline irrigation rate measurements and ureteroscope deflection tests also indicate minimal losses due to the presence of the small ball-tip fiber diameter. These results, coupled with stone ablation rate results comparable to bare fiber tips, suggest that ball-tip fibers may serve as a viable replacement for traditional bare tip fibers for TFL lithotripsy.

While the stone ablation rates reported with ball-tip fibers are promising, the ball-tip fiber additionally serves to prevent fiber-induced mechanical damage to the inner lining of the ureteroscope working channel and potential perforation of the ureter wall during initial fiber insertion. However, eventual degradation of the ball tips [Fig. 2(b) and Table 2] with repeated fiber use in contact with multiple stone samples suggests that the current ball-tip fiber design dimensions may not be optimal for reducing distal fiber tip degradation. Several specifications could be altered, including ball tip size and/or shape, as discussed below.

In this study, the ratio of ball tip to fiber (300-μm ball diameter/140-μm fiber core + cladding diameter) was 2.1. While it may be possible to increase this ratio to about 2.5, there are fundamental limits to the maximum ratio due to several factors. If the ratio is too high, there will be insufficient core and cladding glass material to draw the ball tip during fabrication. The neck or interface between the trunk fiber and ball tip may also become too fragile and susceptible to fracture. It may also be possible to slightly increase both fiber trunk and ball tip diameters (keeping ratio fixed) to yield a more robust fiber optic system resistant to degradation, without completely sacrificing the small fiber dimensions that are advantageous in providing both maximum saline irrigation rates and ureteroscope deflection during TFL laser lithotripsy.

Furthermore, ball tip designs used during Holmium laser lithotripsy actually employ a tapered teardrop geometry as opposed to the more spherical experimental design used in our experiments. This teardrop shape may potentially improve its mechanical properties, making the neck or interface between trunk fiber and ball tip more robust for handling, however, it is unclear whether the design aids in increased stone ablation rates as well. Future studies will focus on the dependence of stone ablation and ball tip degradation rates on ball tip diameter and shape.
It should be noted that these preliminary studies were performed with fixed laser parameters (35 mJ, 500 μs, and 300 Hz) based on the optimal stone ablation rates reported during previous studies.\(^\text{26}\) However, ball tip degradation rates may potentially be reduced through exploration of a wider range of laser parameters (including pulse energy, pulse duration, and pulse rate), so that high stone ablation rates are also balanced with fiber longevity.

Exploration of stone ablation rates with the ball-tip fiber in noncontact mode is also warranted. Previous studies suggest that potentially be reduced through exploration of a wider range of the cavitation bubble stream observed in this study [Fig. 5(c)].\(^\text{33}\) The longer cavitation bubble stream observed using the ball-tip fiber [Fig. 5(a)] may potentially translate into noncontact TFL lithotripsy at even longer working distances than 1 mm, but this remains to be studied in more detail.

The in vitro experimental setup in this study provided realistic manual manipulation of the fiber and imaging of the distal fiber tip after each study. However, this setup did not allow for constant saline irrigation, continuous imaging, or operation through an ureteroscope. A more robust experimental setup may be advantageous for imaging ball-tip fiber degradation in real time during lithotripsy and to better understand the physical mechanism for ball-tip fiber degradation. Also, stone samples were chosen, in part, for consistency in composition, mass, and diameter, to provide reproducible ablation results. Future studies will utilize a wider range of stone sample sizes and variety of stone compositions to demonstrate clinical viability.

5 Conclusions
The 100-μm-core, 300-μm-diameter, ball-tip fibers used for TFL lithotripsy rapidly fragmented kidney stones at rates comparable to conventional 100-μm-core bare tip fibers, using laser parameters of 35 mJ, 500 μs, and 300 Hz. While the ball-tip fibers did not demonstrate resistance to degradation with repeated use, the spherical geometry provides an additional safety feature for initial fiber insertion through the ureteroscope working channel and into the ureter as well. Additionally, the ball-tip fibers used during this preliminary study are also smaller than 240-μm-core, 450-μm-diameter ball-tip fibers used during Holmium:YAG laser lithotripsy, which should translate into improved saline irrigation rates and ureteroscope deflection. In summary, the miniature ball-tip fiber may provide a cost-effective design for safe fiber insertion through the ureteroscope working channel and into the ureter without risk of instrument damage or tissue perforation, and without compromising stone ablation efficiency during TFL lithotripsy.

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