



Biliary and pancreatic lithotripsy devices

The ASGE Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of gastrointestinal endoscopy. Evidence-based methodology is employed, using a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported complications of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases data from randomized controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are utilized. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors.

Technology Status Evaluation Reports are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the committee as a whole, and approved by the Governing Board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through January 2007 for articles related to biliary and pancreatic lithotripsy by using the keywords "lithotripsy" and "mechanical" and "electrohydraulic" and "laser" and "shock wave" plus "bile duct" and "choledochus" and "gall-stone" and "gallbladder" and "pancreas" and "choledochoscope" and "cholangioscope" and "pancreatoscope."

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BACKGROUND

Lithotripsy describes a procedure that fragments stones. It is used to decrease the size of large or diffi-

cult-to-remove stones to facilitate their removal or passage from the biliary or pancreatic ducts, or to dislodge impacted stones. Lithotripsy may be performed by using intracorporeal modalities, such as mechanical, electrohydraulic (EHL), or laser devices at the time of endoscopic (via ERCP) or percutaneous access, or via extracorporeal shock wave lithotripsy (ESWL).

TECHNOLOGY UNDER REVIEW

Mechanical lithotripsy

A mechanical lithotripter consists of a wire basket, a metal sheath, and a handle, which provides mechanical retraction of the basket into the metal sheath, directing a crushing force to the stone. There are 2 basic designs of mechanical lithotripters. The integrated devices incorporate all components of the system and are designed for use through the operating channel of the duodenoscope. The salvage devices, consisting of just the metal sheath and the handle, are used when a basket containing a stone becomes impacted in the duct during attempted stone extraction.

Integrated lithotripters function like a standard stone basket until lithotripsy is required. They can be used on stones anywhere within the ducts and can be reapplied until all stones and stone fragments are small enough for extraction. Both single-use and reusable systems are available. Wire-guided baskets are available. Most units require assembly before use. Basket sizes vary within each line.

Salvage devices are designed to be applied over a variety of stone-removal baskets, but not all baskets are lithotripter compatible. Basket designs must include failure points that break safely and allow basket removal from around the stone and the duct when an application of maximum force fails to achieve stone fragmentation. When lithotripsy is required, the basket handle is cut off, the metal lithotripter sheath is passed over the plastic sheath and the wires of the impacted basket, and the lithotripsy handle is attached to the metal sheath and the basket wires. Under fluoroscopic guidance, rotation of the handle retracts the basket and the stone against the sheath, breaking the stone or the basket, and allowing the basket to be removed. Some models can be passed through the endoscope, whereas others require removal of the endoscope before positioning of the metal sheath. Specifications of

commercially available mechanical lithotripters are shown in Table 1.

EHL

EHL systems consist of a bipolar probe and a charge generator. When a charge is transmitted across the electrodes at the tip of the probe, a spark is created. This induces expansion of the surrounding fluid and an oscillating spherical shock wave of adequate pressure to fragment the stone. Continuous saline solution irrigation is required to provide a media for shock wave energy transmission, to assure visualization and to flush away debris. The procedure is usually done under direct choledochoscopic or pancreatoscopic guidance to avoid errant application of shock waves that can cause ductal trauma and perforation. However, lithotripsy probes have been targeted by using centering balloons or basket catheters with fluoroscopic guidance only. The probe is aimed directly at the stone and is optimally positioned ≥ 5 mm from the tip of the endoscope and 1 to 2 mm from the stone.¹ Activation is by a foot switch. According to the manufacturer's recommendations, shock waves are delivered in brief pulses, which range from a single discharge to continuous firing, until the stone is fragmented.² Stone fragments are then removed by standard means.

The Autolith (Nortech, Northgate Technologies Inc, Elgin, Ill) is the only EHL unit that has received FDA clearance for biliary stones. The Nortech biliary probe (Micro II) is 1.9F (0.66 mm) and 250-cm long.

Laser lithotripsy

Several endoscopic laser lithotripsy systems have been used for biliary and pancreatic applications. Focusing laser light of a high-power density on the surface of a stone creates a plasma composed of a gaseous collection of ions and free electrons. This plasma bubble oscillates and induces cavitation with tensile and compressive waves that shatter the stone surface.

Holmium:yttrium aluminum garnet (YAG) lasers are commercially available, and several have FDA clearance for gallbladder and bile-duct stones. They are widely used for urologic indications and are very effective for urinary-tract stones. The laser-light wavelength is in the near-infrared spectrum, at 2100 nm and delivers comparatively high-energy pulses of about 500 to 1000 mJ.³ The laser delivery fibers are up to 4 m long and 200, 365, 550 or 1000 μm in diameter. They fit through the working channels of most choledochoscopes and pancreatoscopes. As with EHL, direct visualization of the stones is generally recommended to prevent ductal trauma. Fibers have also been targeted by using centering balloons with fluoroscopic guidance alone.⁴ Power settings are usually 0.6 to 1.0 J at 6 to 10 Hz for total laser energy of 12 kJ.^{5,6}

These laser lithotripter units are portable; smaller than an endoscope processor tower; weigh 84 to 303 kg; need no special plumbing; and require 110 AC or 220 volt electricity, depending upon the wattage of the unit. Holmium:YAG laser lithotripters are available from several manufacturers.

The frequency-doubled, double-pulse neodymium:YAG (FREDDY) is commercially available and FDA cleared for bile-duct stones. It has been shown to be effective *in vitro* and *in vivo*.³ The FREDDY laser uses wavelengths of 532 and 1064 nm, and generates up to 120 to 160 mJ (approximately 24 mJ at 532 nm). Laser-pulse duration is 1.2 μs at 160 mJ, with single or dual pulse at adjustable rates of 1, 3, 5, or 10 Hz with standard 110 volt AC electricity, or 15 or 20 Hz with 220 volt electricity. However, the latter pulse frequencies are rarely necessary. The recommended settings to start are 120 mJ single pulse and 3 to 5 Hz repetition rate, which can be increased to 160 mJ and 10 Hz. Double pulse at 120 or 160 mJ will cause the fiber to burn back into the buffer more readily than single-pulse settings. The fibers (ThinFlex200Rplus) are 3.5 m long, have an outer diameter of 420 μm , and are marketed for reuse up to 10 times. These fibers can be inserted through the ports of most choledochoscopes and pancreatoscopes. However, the FREDDY laser causes minimal if any ductal injury and has been used through the guide-wire port of a stone-extraction balloon to maintain it in the center of the duct.⁴ This laser is movable, 250 \times 850 \times 600 mm in size, weighs 45 kg, and needs no special plumbing. The FREDDY laser is marketed in the United States as the U100Plus (World of Medicine, Orlando, Fla).

There are also other lasers that have been designed to limit duct injury while recognizing the difference between stone and tissue. Early prototypes of a Q-switched neodymium:YAG never made it to clinical usage because of extreme fragility of the fibers. They are not available for clinical use in the United States. The flashlamp pulse dye laser uses coumarin dye to produce a 504 nm light that is absorbed specifically by pigment in bile-duct stones. The flashlamp pulse dye unit with an automatic stone-recognition system uses rhodamine 6G dye to create a 595-nm wavelength that, by spectroscopic analysis of reflected laser light, delivers energy only to the stone and not to surrounding tissues.⁷

ESWL

ESWL focuses high-pressure shock wave energy at a designated target point while minimizing energy exposure to adjacent tissues. Shock waves can be generated by underwater spark gap (electrohydraulic), piezoelectric crystals, or electromagnetic membrane technologies. The energy can be focused by elliptical reflectors, fixation of piezoelectric crystals to an elliptical dish, or by acoustic lenses, respectively. Spark-gap lithotripters are more powerful and may induce better stone-clearance rates. Shock waves

TABLE 1. Mechanical lithotriptors

Device	Cost: initial/ per use	Assembly required	Contrast injection capability	Working channel, mm	Crush > 1 stone
Integrated*					
Microvasive Endoscopy, Boston Scientific Corp					
Monolith	\$399	No	Yes	3.2	Yes
Trapezoid†	\$779/\$329	Yes‡	Yes	3.2	Yes
Alliance II handle‡	\$450	NA	NA	NA	NA
Olympus America Corp					
BML-3Q§	\$1442/\$0	Yes	Yes	4.2	Yes
BML-4Q§	\$1442/\$0	Yes	No	3.2	Yes
BML-201Q‡	\$879/\$383	Yes	Yes	4.2	Yes
BML-202Q-204Q‡	\$879/\$383	Yes	No	3.2	Yes
Salvage 					
Olympus					
BML-110A-1¶	\$403/\$64	Yes	No	3.2-4.2	No
MAJ-403 (sheath)	\$64	Yes	No	Remove scope	No
Cook Endoscopy					
Conquest TTT					
TTCL-1 (sheath)	\$391/\$140	Yes	No	3.2	No
TTCL-10 (sheath)	\$391/\$140	Yes	No	3.7	No
SLH-1‡	\$251	NA	NA	NA	NA

NA, Not available.

*Initial cost includes complete system for 1 use, with all reusable components and 1 basket. Per-use cost includes the cost for 1 use of a new disposable component and/or basket.

†Requires Alliance II inflation system, inflation handle, reusable.

‡Reusable handle.

§Reusable handle, metal sheath, and basket.

||Exclusive of the cost of the entrapped basket.

¶Emergency through the scope sheath and handle for use with impacted basket.

must travel through a liquid or tissue medium to minimize energy loss. The interface with the patient is via a water-filled, compressible bag and a gel applied to the skin surface or via submersion in a water basin. When shock waves traverse the stone, cavitation occurs at the surface and changes in acoustic impedance release compressive and tensile forces, resulting in fragmentation. The properties of the stone that determine fragmentation are not the chemical makeup but the size and the microcrystalline structure and architecture. ESWL units are large and require US and/or fluoroscopic guidance.⁸

INDICATIONS

Lithotripsy is used for stones in the intra- and extrahepatic bile ducts and obstructing stones in the pancreatic duct that cannot be removed by conventional methods.

ESWL is used in the same settings and occasionally as adjunctive or primary therapy for gallbladder stones in persons who are unfit for, or who decline, surgery.

EFFICACY AND COMPARATIVE STUDIES

Biliary lithotripsy

The majority of the literature pertaining to bile-duct stone lithotripsy via ERCP addresses extrahepatic stones. Percutaneous approaches may be used for both challenging extra- and intrahepatic stones.

Mechanical lithotripsy leads to complete bile-duct clearance in about 80% to 90% of patients, but 20% to 30% require more than 1 procedure.⁹⁻¹⁹ Mechanical lithotripsy is less likely to be successful with larger and impacted stones.¹⁰⁻¹³

EHL yields clearance of all stones and fragments in about 90% of patients with bile-duct stones that are refractory to standard endoscopic therapy. Repeated procedures and/or other forms of lithotripsy may be required.^{1,2,20-25}

Laser lithotripsy has a potential advantage of relatively precise targeting of stones that reduces the risk of injury to surrounding tissue.²⁶ Based on cumulative results of several small studies, the holmium:YAG laser is reported to result in total clearance of intra- and extrahepatic bile-duct stones in 34 of 35 patients (97%), with minimal morbidity.^{5,6,27-29} Similar results have been achieved with a variety of lasers that are currently unavailable in the United States.^{2,4,30,31} Percutaneous approaches to EHL or laser lithotripsy are frequently used for intrahepatic stones and achieve ductal clearance in 80% to 97% of cases. Multiple (3 to 6) procedures are often required, and percutaneous tubes are usually left in place for several weeks.³²⁻³⁶

ESWL for bile-duct stones refractory to removal by other modalities has yielded complete stone clearance in about 85% of patients.^{7,23,30,37-45} Two or more ESWL procedures were sometimes required, and fragments were typically removed by endoscopic means. It appears that ductal clearance is inversely related to stone size but not necessarily to the number of stones.⁴² Stones recur in about 13% of patients at a mean of 13 months, which may be because of incomplete ductal clearance after ESWL.^{39,41}

Randomized trials have shown laser lithotripsy to be more effective than ESWL at achieving complete bile-duct-stone clearance, at 92% and 66%, respectively, with fewer required procedures.^{7,30} In another study, complete bile-duct clearance occurred in similar proportions of patients randomized to EHL and ESWL at 75% and 79%, respectively.²³ Crossing over to the alternative form of lithotripsy improved the overall clearance rates to 94% to 100%.^{7,23,30} In a nonrandomized series of 108 patients with failed stone extraction by usual methods, success was achieved with mechanical lithotripsy in 33 patients, with EHL in 65 patients, and with ESWL in 7 of 10 patients with intrahepatic stones.²⁴

ESWL for gallbladder stones yields clearance rates of 77% to 100% among patients with solitary radiolucent gallbladder stones smaller than 20 mm, a functioning gallbladder, and a patent cystic duct. However, only about 20% of gallstone patients meet these criteria, and only half of patients with multiple and/or larger stones will be cleared.⁴⁶⁻⁴⁸ Calcified stones respond at about half of these rates.⁴⁹ Adjuvant dissolution therapy with ursodeoxycholic acid helps with clearance and reduces complications.⁴⁶ Stone recurrence and the need for subsequent intervention are common.⁵⁰⁻⁵³

Pancreatic lithotripsy

Preliminary reports describe successful stone extraction with mechanical lithotripsy⁵⁴ and with intraoperative or endoscopically guided EHL.^{22,55-57} There are no reports

on holmium:YAG laser lithotripsy in the pancreas. There are limited small series describing the use of other lasers for pancreatic stones.^{58,59}

ESWL leads to successful drainage in 80% of selected patients with obstructing pancreatic-duct stones, with or without endoscopic therapy.^{45,55,60-65} Most patients have significant improvement in pain, decreased narcotic use and hospital visits, and have avoided surgery, with a mean follow-up of about 6 months to 14 years. It appears that a younger age, shorter duration of disease, and a single stone are associated with better outcomes. There are no comparative trials dealing strictly with lithotripsy vs other therapies for obstructing stones.

EASE OF USE

Mechanical lithotripsy

Relative ease of use makes mechanical lithotripsy the first-line approach to difficult bile-duct stones and appropriate for use in routine clinical practice. Choledochoscopy is not required for mechanical lithotripsy. Some integrated lithotripters require assembly and greater knowledge of their function. Both integrated and salvage devices are stiff, somewhat unwieldy, and require more time than standard stone extraction.

EHL and laser lithotripsy

The EHL is compact; easily mobile; and requires no special electricity, plumbing, or protective wear. The holmium:YAG and FREDDY lasers are medium sized, portable units that require no special plumbing but may require 220 volt electrical power. Personnel who use medical lasers need formal training in laser function and safety. Special protective eyewear must be used.⁶⁶ Before starting endoscopy, the laser must be warmed up and calibrated. Both EHL and laser fibers may be difficult to manipulate through the working channel of a choledochoscope or a pancreatoscope. Prolonged application of energy and repeated procedures are often required to achieve complete stone fragmentation and clearance with either EHL or lasers.

EHL and laser lithotripsy are usually performed with the probes under direct visualization via a choledochoscope or a pancreatoscope passed through the duodenoscope.⁶⁷ Two light sources and image processors are required. This technique typically requires 2 operators. These instruments are fragile, and care must be taken to avoid damage during insertion through the duodenoscope. A limitation is the lack of 4-way tip deflection. During lithotripsy, stone fragments frequently obscure visualization, and continuous irrigation is required.^{1,4}

Percutaneous transhepatic or T-tube access for cholangioscopy and antegrade application of the EHL or laser lithotripsy is another option. Advantages that result from the more direct access of this approach include the

opportunity to use shorter, more maneuverable, less angulated instruments and a reduced need for sedation. Disadvantages include the need for establishing large-caliber percutaneous access, logistical coordination of serial procedures with a radiologist, and requirement for a sterile field.

ESWL

ESWL is usually performed by urologists. This technique may require prior placement of a stent, or a nasobiliary or nasopancreatic drain for stone localization. Stone debris is usually removed during subsequent endoscopic or percutaneous extraction procedures. Pancreatic-stone fragments may pass spontaneously, without endoscopic intervention. If adequate fragmentation has not occurred, ESWL may need to be repeated.

SAFETY

The majority of complications related to intracorporeal lithotripsy are associated with gaining pancreaticobiliary access (eg, ERCP or percutaneous transhepatic access) and include pancreatitis, hemorrhage, perforation, and sepsis.^{32-36,68} Basket impaction is a potential complication unique to mechanical lithotripsy. Both EHL and laser lithotripsy have an overall complication rate of 7% to 9%, the most common being hemobilia, cholangitis, and, rarely, ductal perforation.^{2,3,20} There are no reported complications from the holmium:YAG or FREDDY lasers. However, the published experience is limited and biliary epithelial damage has been noted in vitro with the holmium:YAG device.^{5,6,27-29,69}

Complications with ESWL for cholelithiasis develop in 30% to 40% of patients; the most common is biliary colic. About 5% of patients develop biliary obstruction or pancreatitis.⁴⁶⁻⁴⁸ ESWL for choledocholithiasis is associated with short-term morbidity in about 14% of patients and includes pain, hemobilia, cholangitis, sepsis, hematomas, pancreatitis, hematuria, ileus, and anesthesia problems. Mortality is reported in less than 1% of patients and developed in the setting of advanced age, serious comorbidities, and concomitant cholangitis.⁴⁴

There have been no serious complications reported after pancreatic lithotripsy, but rates similar to those of biliary lithotripsy should be expected. Mild pancreatitis, cholangitis, abdominal abscess, transient jaundice, vomiting, bradycardia, and dysrhythmias may be expected to occur.^{44,55,61-63,65}

FINANCIAL CONSIDERATIONS

Mechanical lithotripters are relatively inexpensive (Table 1). The Autolith EHL generator has a list price of \$12,900 and the Micro II probes are \$262 each. There are several holmium:YAG laser units available, with a price range from \$40,000 to \$133,000. The manufacturer's list

price for the U100*plus* FREDDY laser is \$54,000. The cost of the laser fibers ranges from about \$250 to more than \$1000. Some fibers may be reused up to 10 times, with reprocessing costs to consider. Laser units may be available on a fee-per-use basis, which may be \$1600 to \$2400 per case, with up to a \$300 charge for fiber reprocessing. Costs for choledochoscopes and repairs also need to be considered.⁶⁷ Holmium:YAG and FREDDY lasers are frequently used in urology and may be a shared resource. ESWL lithotripters cost about \$450,000 to \$800,000 and are usually part of a urologic service program for management of nephrolithiasis. These units may also be mobile and brought to hospitals, on a scheduled basis, with lease or fee-for-service arrangements.

Endoscopic lithotripsy has a dedicated current procedural terminology (CPT) code: 43265 (ERCP with endoscopic retrograde destruction, lithotripsy of calculus/calculi, any method). There is currently no specific code for ERCP-assisted choledochoscopy or pancreatoscopy but various methods of coding may be used, depending upon local payers.⁶⁷ One approach is to use CPT codes 47999 (unlisted procedure, biliary tract) or 48999 (unlisted procedure, pancreas) and add an amendment stating that the unlisted procedure is similar to CPT 47554 (biliary endoscopy, percutaneous via T-tube or other tract with removal of calculus/calculi). The ERCP may be coded as 43264 (ERCP with endoscopic removal of calculus/calculi from biliary and/or pancreatic ducts), because stone fragments are almost always removed by balloons or baskets after intracorporeal lithotripsy. The choledochoscopy or pancreatoscopy can be attached as a second procedure with the unlisted procedure codes noted to be similar to CPT 47554. If there are 2 endoscopists involved, one may code 43264 and the other may use the unlisted procedure code as outlined above. Alternatively, CPT 43265 may be used with a 22 modifier for unusual procedural services for the primary endoscopist. The second endoscopist may use the same codes with an 80 modifier. ESWL for gallbladder or bile-duct stones may be coded as CPT 43265 with a letter of explanation, or as CPT 47999 or CPT 48999 with annotation that it is similar to CPT 50590 (Renal lithotripsy, extracorporeal shock wave). There is a HCPCS (Healthcare Common Procedure Coding System) code S9034 (ESWL for gallstones or bile duct), but this is not accepted by Medicare and many other providers.

CONCLUSION

Lithotripsy is a relatively safe and effective treatment for selected difficult bile-duct and pancreatic-duct stones. Most refractory stones can be removed with mechanical lithotripsy. Other forms of lithotripsy are used much less frequently and are generally limited to referral centers. EHL is effective and relatively inexpensive. Published

experience with holmium:YAG laser and FREDDY lithotripsy is limited. EHL and laser lithotripsy usually require direct visualization, which is technically difficult. ESWL is effective but expensive, often requires marking the stone with internal drains or stents, and relies on subsequent procedures for extraction of stone fragments.

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