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## Blunt atrial transseptal puncture using excimer laser in swine

Abdalla A. Elagha, MD, Ann H. Kim, BSc, Ozgur Kocaturk, MSc, and Robert J. Lederman, MD, FSCAI

From the Cardiovascular Branch, Division of Intramural Research, National Heart Lung and Blood Institute, National Institutes of Health, Bethesda, MD, USA

### Abstract

**Objectives**—We describe a new approach that may enhance safety of atrial transseptal puncture, using a commercially available laser catheter that is capable of perforation only when energized. We test this approach in swine.

**Background**—Despite wide application, conventional needle transseptal puncture continues to risk inadvertent non-target perforation and its consequences.

**Methods**—We used a commercial excimer laser catheter (0.9mm Clirpath, Spectranetics). Perforation force was compared *in vitro* with a conventional Brockenbrough needle. Eight swine underwent laser transseptal puncture under X-ray fluoroscopy steered using a variety of delivery catheters.

**Results**—The 0.9mm laser catheter traversed *in vitro* targets with reduced force compared with a Brockenbrough needle. *In vitro*, the laser catheter created holes that were 25–30% larger than the Brockenbrough needle.

Laser puncture of the atrial septum was successful and accurate in all animals, evidenced by oximetry, pressure, angiography, and necropsy. The laser catheter was steered effectively using a modified Mullins introducer sheath and using two different deflectable guiding catheters. The mean procedure time was  $15 \pm 6$  minutes, with an average  $3.0 \pm 0.8$  seconds of laser activation. There were no adverse sequelae after prolonged observation. Necropsy revealed discrete 0.9mm holes in all septae.

**Conclusion**—Laser puncture of the interatrial septum is feasible and safe in swine, using a blunt laser catheter that perforates tissues in a controlled fashion.

### Keywords

Atrial transseptal puncture; Laser angioplasty; Catheterization

### Background

Atrial transseptal puncture is the first step in a variety of procedures such as left atrial rhythm mapping and ablation, percutaneous left ventricular assist device implantation, and balloon mitral valvuloplasty. Unfortunately, atrial transseptal puncture continues to confer a discrete risk of serious complications such as aortic and posterior atrial perforation (1–5). Force accumulates at the tip of needle during conventional puncture and may lead to sudden uncontrolled advancement, contributing to perforation and pericardial tamponade.

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**Address for Correspondence:** Robert J. Lederman, MD, Cardiovascular Branch, Division of Intramural Research, National Heart Lung, and Blood Institute, National Institutes of Health, Building 10, Room 2c713, MSC1538, Bethesda, MD 20892-1538, USA. Telephone: +1 301-402-6769. ledermar@nhlbi.nih.gov.

Commercial excimer laser consoles are widely deployed for applications in angioplasty and pacemaker lead extraction (6,7). The controllable activation of laser angioplasty catheters may have utility during atrial septal puncture, because the perforation capability can instantly be switched off, unlike a needle catheter.

We hypothesize that excimer laser transseptal puncture can be performed easily and safely in swine under X-ray fluoroscopy.

## Methods

### Animal Protocol

Animal procedures were approved by the National Heart Lung and Blood Institute (NHLBI) Animal Care and Use Committee. Eight healthy Yorkshire swine (mean  $57 \pm 19$  kg) underwent anesthesia induction using tiletamine, zolazepam, and xylazine followed by inhaled isoflurane. Femoral or jugular veins and femoral arteries were accessed percutaneously. Heparin 100 units/kg was given after septal puncture. At the conclusion of experiments, animals were euthanized with potassium chloride 4 mEq/kg and necropsy specimens were examined.

### Devices

**Laser catheters and source**—We used off-the-shelf excimer laser catheters (0.9mm Clirpath X-80, Spectranetics, Colorado Springs, CO). These fit inside most catheters rated for 0.038" guidewires. The laser catheter has an inner lumen diameter of 0.0155" that permits pressure transduction, contrast injection, or 0.014" guidewire delivery. We used an unmodified XeCl ultraviolet (308nm) excimer laser source (CVX-300, Spectranetics). All punctures used 25 laser pulses per second at a fluence of 45 mJ/ mm<sup>2</sup>.

**Delivery catheters**—We used a range of steering devices. We modified a conventional 8Fr Mullins sheath (Medtronic) to reverse the distal taper of the inner diameter, which is presumably implemented to smooth the transition to the Brockenbrough needle. We performed this modification at the bedside using a 0.040" parylene coated mandrel (New England Precision Grinding, MA) and a heat gun (Beahm Designs Model 210-A) set at 190° C for 40 seconds.

We also tested two off-the-shelf deflectable guiding catheters. The Morph catheter (Biocardia, South San Francisco, CA) is available with a 6Fr outer diameter, 76cm working length, and is available with a 3 cm "reach" or lateral deflection. The Naviport catheter (Cardima, Fremont, CA) is available with an 8Fr outer diameter and 90cm working length, but to accommodate shorter dilator catheters we employed the 11Fr version with a 73cm working length and 4 cm reach.

### Ex Vivo Perforation Force and Pressure Waveform Analysis

We measured the forward force required for transseptal puncture using both needle and laser. Both a Spectranetics X80 laser and a Brockenbrough needle (Cook Medical) devices were attached to a digital force meter (Model ZPH, Imada, IL) and positioned against freshly explanted interatrial and interventricular septum from a 90kg pig. The average maximum force was recorded while the catheter was advanced across the septum using the force gauge.

Residual holes were compared using fresh atrial septal tissue, examined at rest and under tension sufficient to "flatten" it for measurement using calibrated images.

Pressure waveform damping was compared among three catheter devices: a 0.038" guidewire-compatible 6Fr × 100cm multipurpose catheter (Boston Scientific), a Brockenbrough needle

guidewire port, and the 0.9mm laser catheter, all filled with heparinized normal saline. *In vivo* arterial and venous waveforms were sampled from the analog output of clinical recording hardware (*Cathcor*, Siemens) at 100Hz using an analog-to-digital convertor (*Powerlab*, ADInstruments). Output spectral analysis was performed (*MacLab*, ADInstruments) after Fast Fourier Transformation to obtain the first six harmonics, which were normalized to the catheter waveform spectrum.

### Transseptal Laser Catheterization

Baseline cardiac MRI (breath-held, ECG-gated, segmented, steady state free precession, 1.5T Sonata, Siemens using standard torso phased-array coils) verified there was no pre-existing patent foramen ovale or atrial septal defect.

In the first set of experiments, the modified Mullins sheath and dilator were introduced percutaneously into the femoral vein and advanced in the superior vena cava over a guidewire and then withdrawn into the fossa ovalis, using a rigid mandril. A transfemoral pigtail catheter was positioned in the aortic root. The laser catheter was then apposed to the fossa under X-ray guidance. Contrast could be injected, and distal pressure could be measured through the guidewire lumen of the laser catheter. Continuous pressure was applied to the Mullins sheath to maintain apposition between the laser and the target tissue. The laser was activated while applying gentle pressure for 2–4 seconds until it advanced across the septum. At this point, the operator immediately terminated laser activation. Finally, the Mullins dilator and sheath were delivered across the septum using the laser catheter as a rail. In other experiments, the deflectable catheters substituted for both the Mullins sheath and dilator.

### Statistics

Continuous parameters were reported as mean  $\pm$  standard deviation, and compared using a two-tailed Student *t* test.

## Results

### Ex vivo findings

Representative force-time curves are shown for the needle and laser catheters (Figure 1). The maximum force required to perforate fresh interatrial septum *ex vivo* was  $2.2 \pm 0.28$  N using a Brockenbrough needle versus  $0.21 \pm 0.07$  N using the X-80 laser catheter,  $p < 0.001$ . The curves show a linear accumulation of forward force using the needle before sudden “give” as the needle perforates. By contrast the laser force-time curves are less dramatic. The findings were similar using ventricular myocardium as a test medium ( $0.27 \pm 0.04$  N using the laser vs  $2.7 \pm 0.13$  N using the needle).

The guidewire lumen of the laser damped pressure recordings more than the guidewire lumen of the needle (Figure 2). The laser created holes that were 25–30% larger than the Brockenbrough needle measured unstretched (laser  $1.04 \pm 0.08$ mm; needle  $0.82 \pm 0.08$ mm,  $p = 0.02$  vs laser; 8Fr sheath  $2.63 \pm 0.53$ mm) and under distending tension (laser  $0.81 \pm 0.08$ mm; needle  $0.63 \pm 0.16$ mm,  $p = 0.04$  vs laser; sheath  $2.17 \pm 0.62$ mm).

### In vivo findings

The laser transseptal technique is illustrated in Figure 3. Panel A shows the Mullins sheath (arrowhead) positioned using standard technique against the fossa ovalis. For reference, we positioned a pigtail catheter in the aortic root (white arrow). The laser catheter is advanced to the distal tip of the Mullins dilator and is identified by its distal radiopaque marker (black arrow). After a brief application of laser energy, the laser catheter advances easily into the left atrium (Panel B, black arrow). Contrast injection (panel C), pressure waveforms, and oximetry

confirm position. A guidewire can be introduced through the laser catheter lumen into the desired left sided chamber. The laser catheter serves as a rail to introduce a dilator into the left atrium (panel D). When using a Mullins dilator, we found it helpful to apply continuous forward pressure to maintain apposition to the fossa ovalis before perforation; when using deflectable guiding catheters this proved less important.

Laser transseptal puncture was successful in all eight animals. The total procedure time was  $15 \pm 6$  minutes. When using a deflectable guiding catheter, the procedure time was  $10 \pm 1$  minutes. The laser was activated for  $3.0 \pm 0.8$  seconds. The force applied to laser catheter during the procedure was minimal compared with conventional needle puncture. The laser induced no arrhythmia.

Correct left atrial position was confirmed by pressure waveforms (right atrial mean  $4.0 \pm 1.2$ , left atrial pressure  $7.6 \pm 2.4$  mmHg,  $p < 0.05$ ), hemoglobin oximetry (right atrial 74%, left atrial 96%,  $p < 0.05$ ), and radiocontrast.

After transseptal puncture, animals were observed for  $5.9 \pm 2.3$  hours without sequelae. Necropsy confirmed the desired position of the puncture at the fossa ovalis (Figure 4). There was no hemopericardium in any animal. Holes created *in vivo* using the laser catheter measured 0.9mm. Holes created *ex vivo* using the laser were the same size but had a smooth contour compared with holes created using a Brockenbrough needle, which had a “torn” morphology..

## Discussion

Using commercially-available catheters, we have successfully performed excimer laser transseptal puncture in healthy swine. The laser requires ten-fold less forward force to cross cardiac tissue compared with a conventional needle. Because the laser catheter is blunt and does not perforate tissue except when activated, laser puncture may be an attractive alternative to conventional needle puncture.

Despite widespread application and decades of experience, needle transseptal puncture still risks pericardial tamponade and aortic communication. The procedure is more challenging in patients with abnormal atrial septal morphology, distorted septal contour, thickened atrial septum especially in elderly patients, atrial baffles, or prior valve surgery (8). Because puncture force may drive the needle forward across both the target septum and the contralateral free atrial wall, the incidence of complications is higher in patients with small left atria (9). Repeat transseptal puncture may fail using conventional Brockenbrough needle or radiofrequency ablation system due to thickened atrial septum (10).

Like the needle, the laser contains a central guidewire lumen which can be used for pressure measurement, contrast injection, or guidewire delivery. Unlike the needle, the laser catheter requires minimal forward force during activation, has adjustable energy and pulse rate, and is sufficiently rigid to serve as a “rail” to advance larger catheter devices into a suitable left sided target. Though untested, the laser may offer a “rescue” alternative in cases of thickened or distorted atrial septa.

The tested 0.9mm laser creates slightly larger holes than the Brockenbrough needle, and damps pressure waveforms comparatively more than the Brockenbrough needle. We were still able to distinguish right and left atrial pressure waveforms in healthy swine.

Nevertheless, the excimer laser remains capable of perforating non-target tissue if improperly directed. For example, posterior left atrial perforation remains possible if laser energy is not immediately discontinued after successful traversal of the interatrial septum. The consequences

of inadvertent puncture may be comparably more severe, since perforation with the laser is equivalent to delivering the entire Brockenbrough needle, not just the tip, across a target.

## Limitations

These experiments were conducted in healthy swine which do not model the challenges of complex atrial transseptal puncture in humans with distorted, scarred, calcified, or patched septal anatomy. The comparative healing characteristics of laser and needle holes are not characterized here.

Transseptal puncture procedures are guided both by visual and tactile cues. Other adjuncts or alternatives are available to enhance safety of septal puncture. Functionally-positioned electrophysiologic catheters, such as His bundle and coronary sinus recording catheters, provide useful landmarks for identifying the fossa ovalis (11). Extending a guidewire through a conventional needle may reduce the incidence of posterior wall perforation (12), but only after safe septal needle traversal. Right atrial angiography may enhance procedural safety in patients with distorted anatomy (13). A radiofrequency perforation catheter (14–16) provides an alternative to the laser technique described here.

## Conclusions

We describe percutaneous laser transseptal puncture accurately and safety in swine using commercially available laser catheters. The blunt-tip laser catheter does not risk perforation except when activated. Since it requires minimal forward force, it may be less likely to “jump” inadvertently across the left atrial free wall. It may provide a valuable alternative to needle transseptal puncture. Clinical testing is warranted, especially in patients with abnormal atrial geometry.

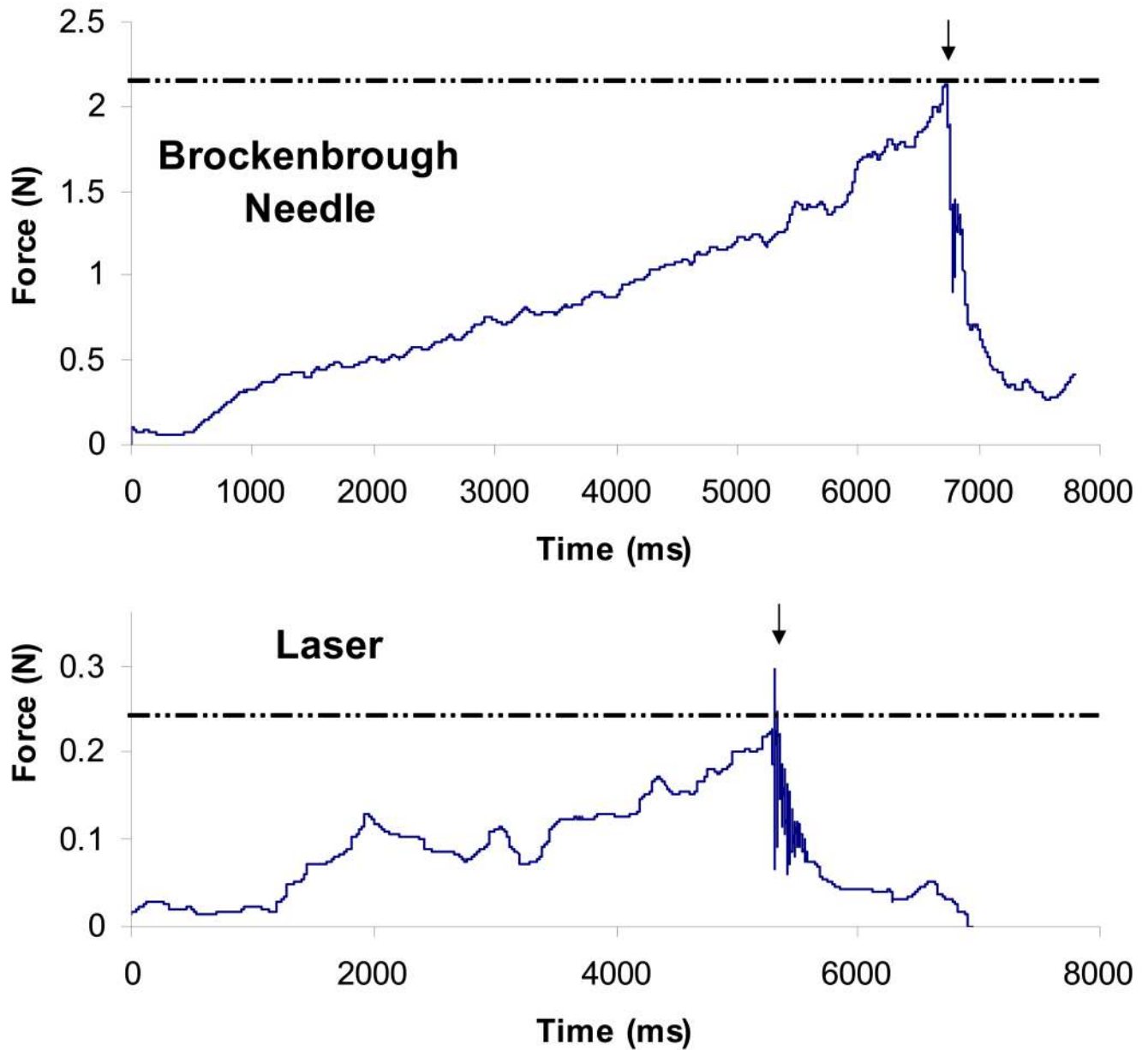
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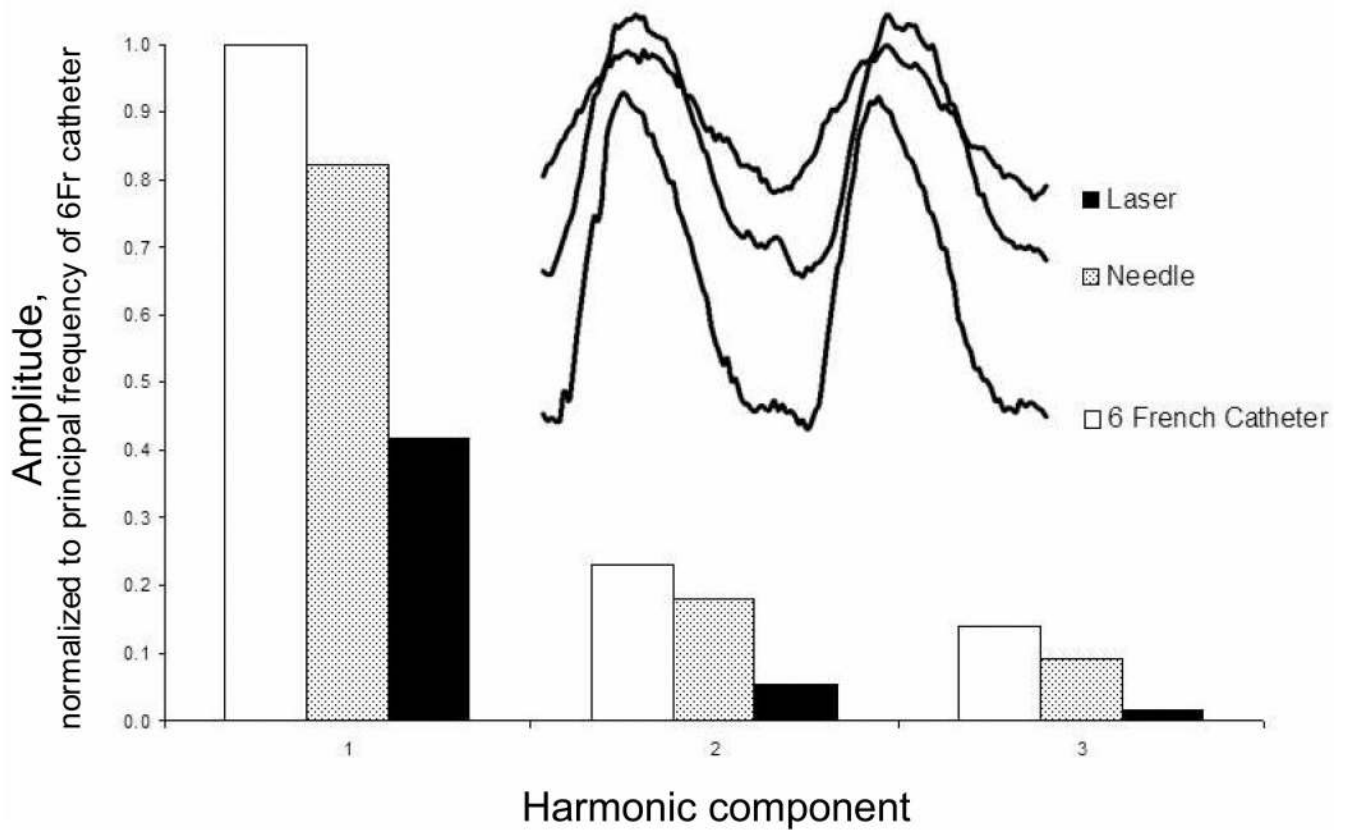
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**Figure 1.** Representative force-time curves while traversing interatrial septum *ex vivo*. Perforation pressure is applied through a force meter. Note the different force scales. The force peaks (dotted line) immediately before traversal (arrow) with both devices but is reduced approximately ten-fold using the laser catheter compared with the Brockenbrough needle.



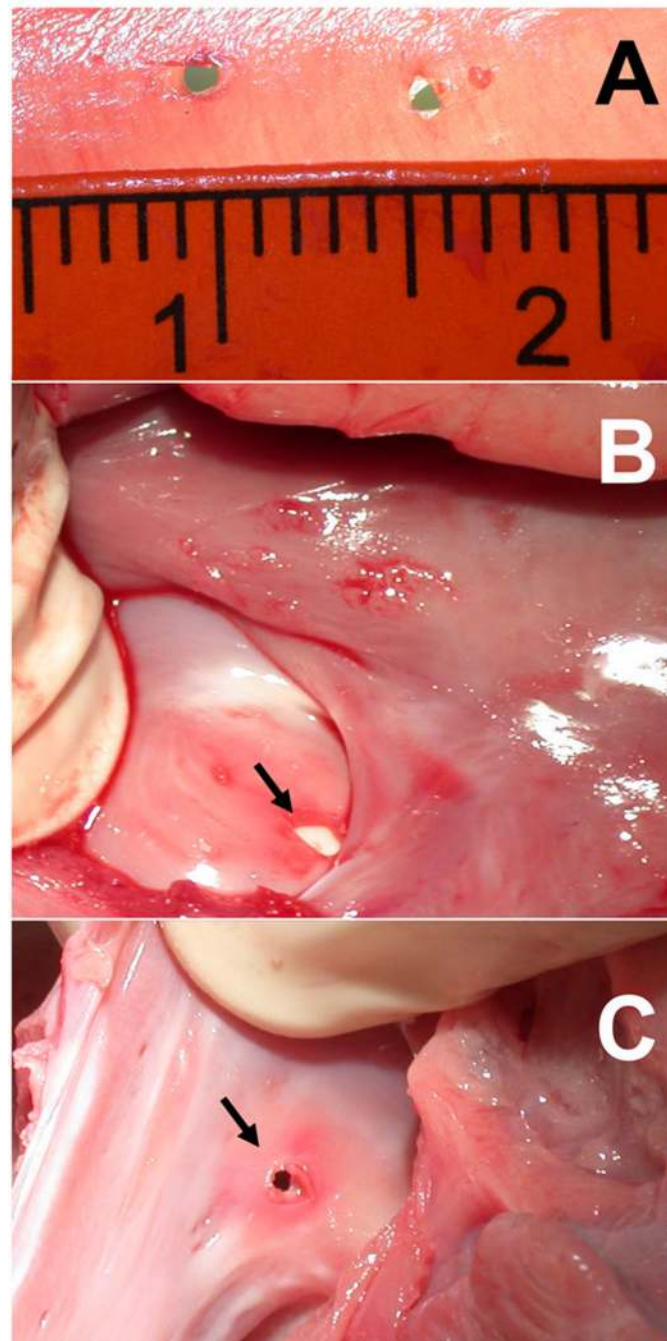
**Figure 2.**

Spectral analysis of arterial pressure waveforms obtained using a 6Fr 0.038" guidewire-compatible arteriography catheter, a Brockenbrough needle, and the 0.9mm laser catheter central lumens. Representative waveforms are superimposed on the upper right side. The first three harmonic components of each are normalized to the amplitude of the principal frequency of the 6Fr catheter. The needle and the laser catheters are progressively overdamped compared to the 6Fr catheter.





**Figure 3.** Illustration of laser transseptal technique. (A) The Mullins sheath (arrowhead) is positioned against the fossa ovalis, and a pigtail catheter (white arrow) positioned in the aortic root. The radiopaque tip of the laser catheter is visible at the tip of the Mullins dilator (black arrow). (B) The activated laser catheter traverses the septum. (C) Radiocontrast is injected through the laser catheter. (D) The sheath is advanced using the laser catheter as a rail. In this case a guidewire is in position also.



**Figure 4.** Representative necropsy findings. (A) Representative holes created in atrial septal tissue *ex vivo* using the laser catheter (left) and Brockenbrough needle (right). They have the same size but different morphology. Holes created *in vivo* viewed from the right atrial (B) and left atrial (C) sides while the tissue is stretched.