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Automated Suturing For Pacemaker Lead Placement Via Video Guided Minimally Invasive Surgical Access

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Background

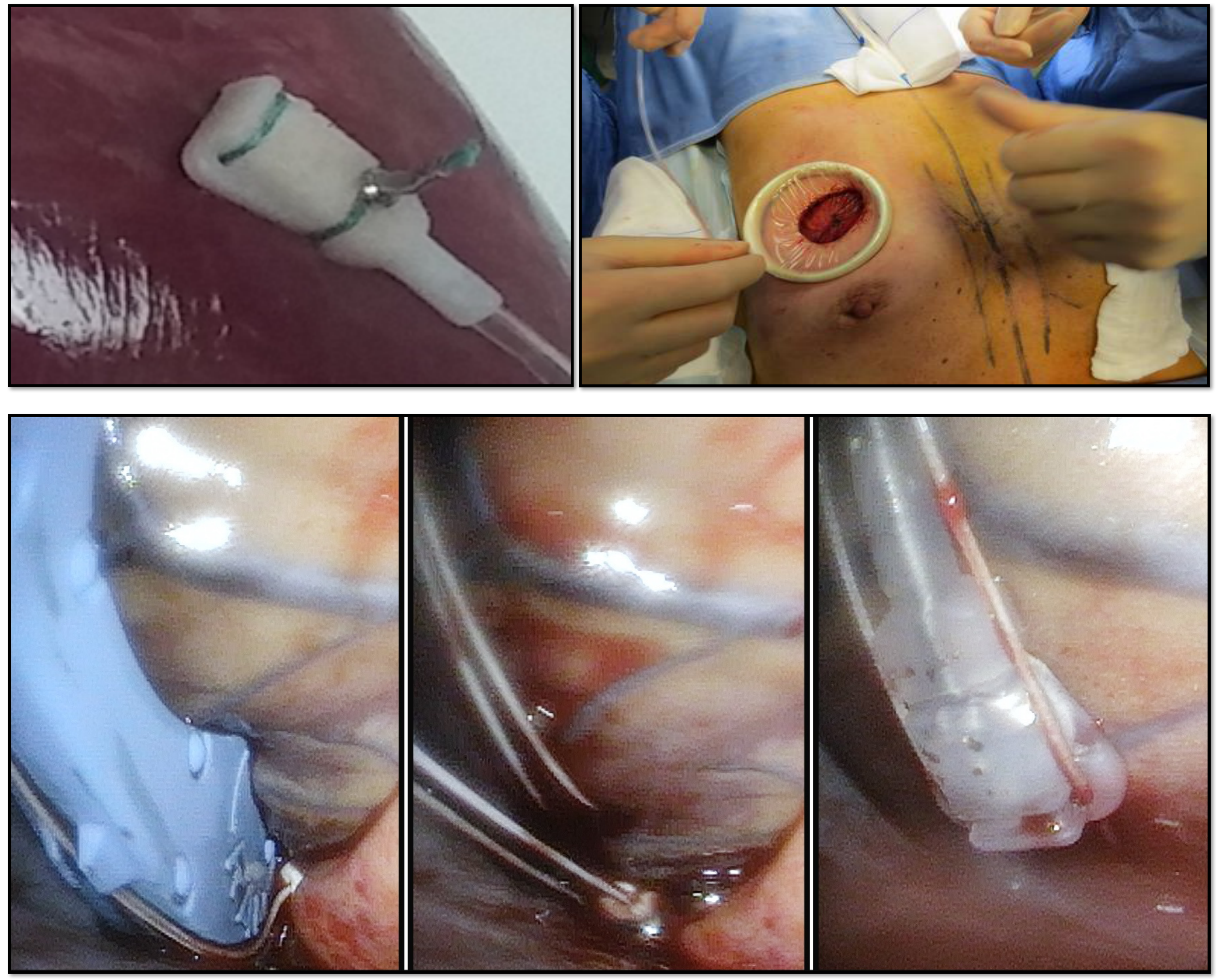
The placement of permanent and temporary cardiac epicardial pacemaker leads through minimally invasive cardiac surgery (MICS) access remains a challenge. A reliable ergonomic approach for remote lead placement requires improved technology. We present a novel means to enable the remote placement of epicardial leads using automated suturing devices and videoscopy.

Methods

Automated technology was developed for epicardial lead placements. For permanent lead placement, an adjustable shaft dual needle suturing device simultaneously placed both bites of a horizontal mattress suture into the targeted tissue. Leads were advanced into position using specialized introducers. Each lead was secured with two titanium fasteners. Placement was examined on *ex vivo* porcine hearts for attachment tensile strength. Automated lead suturing was performed via a subxiphoid approach on a cadaver model, a video assisted thoracoscopic surgery (VATS) approach in an ex vivo porcine thorax and a left lateral non rib-spreading mini-thoracotomy approach in a clinical setting. For non-permanent leads, a customized connector was developed to attach to the end of a commercially available temporary pacemaker wire (after removal of its needle) to enable the suturing device needle to pull the pacemaker wire through the targeted tissue.

Results

Permanent epicardial leads were successfully secured in all models and in the initial MICS clinical experience. Lead suture placement required less than 3 seconds to complete once the automated device tip was positioned. Lead holding force testing on porcine hearts demonstrated that the suture and titanium fasteners always remained intact, while the ventricular and atrial tissue yielded at mean holding forces of 2.0kgf and 1.5kgf, respectively. The automated suturing device consistently drew connectors and their attached temporary epicardial pacemaker lead wires through ex vivo porcine tissue. Secured epicardial pacemaker leads were placed successfully in 3 patients with no intraoperative or postoperative complications with minimal pain.

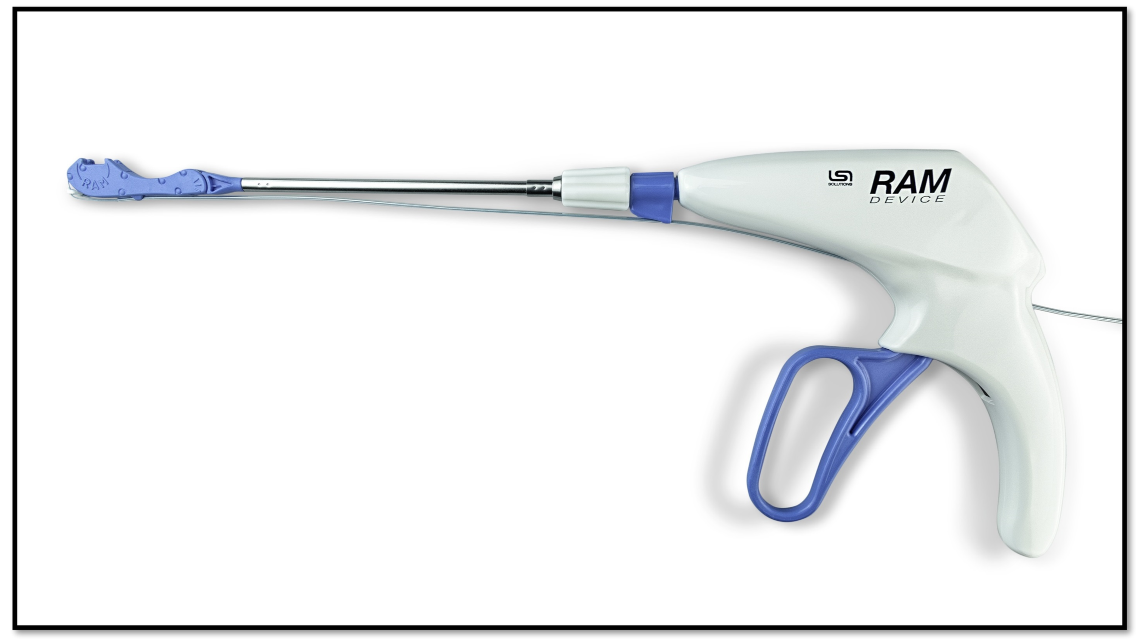


Top Left: Close-up of placement of epicardial leads.

Top Right: Placement is performed via mini-thoracotomy with allows for a 2-4 cm incision on lateral chest, preferred over a sternotomy.

Bottom: Video guided placement of leads shown in sequential order.

Technology



This shafted device has a rotational knob, articulating tip, and dual curved needles that are pre-loaded with epicardial leads. A single squeeze places a horizontal mattress suture that is secured with a titanium fastener.

Conclusions

Automated suturing technology and videoscopy enabled MICS permanent and temporary epicardial pacemaker lead placement. Experimental models demonstrated rapid deployment and excellent fixation strength. The success of this automated epicardial lead placement research study and initial clinical use encourages further exploration towards improving adult and pediatric patient outcomes.

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