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Initial Evaluation of an Automated ePTFE Suturing and Coaxial Fastener System for Chordae Tendineae Replacement

Candice Y. Lee, MD¹, Jude S. Sauer, MD², Heather R. Gorea², Angelo J. Martellaro², Andy Sifain, MD¹, Peter A. Knight, MD¹.

¹University of Rochester Medical Center/Strong Memorial Hospital, Rochester, NY, USA, ²LSI SOLUTIONS, INC., Victor, NY, USA.

<u>Purpose:</u> Mitral chordae tendineae replacement remains technically challenging. A reliable automated means of remotely securing neochordal suture and setting its length could improve mitral repair surgical outcomes.

Methods: An IACUC-approved sheep cardiopulmonary bypass thoracotomy model was developed to create mitral regurgitation by cutting one or more native chordae tendineae. A customized suturing device placed a pledgeted expanded polytetraflouroethylene (ePTFE) suture loop in a papillary muscle. A second suture loop was then passed through the leaflet edge. Suture ends were extracorporeally threaded through the opposite ends of a titanium fastener delivery device using a coaxial bidirectional snare. With the fastener seated against the papillary muscle and the correct length for the replacement chords determined using an integrated saline infusion technique, the fastener was crimped and suture tails trimmed (Fig. 1). Restoration of mitral valve competency was confirmed visually with pressurized saline.

<u>Results</u>: The feasibility of this study's mitral valve repair model was established in four sacrificed sheep yielding an average knot strength for neochordal sutures of 0.769 kgf. Subsequently, four additional sheep demonstrated successful automated neochordal implantation and were survived. Intraoperative post-repair epicardial echocardiography showed only trace to trivial mitral regurgitation. No device-related complications occurred. At 9 ± 2 weeks post-op, all sheep remain healthy without any clinical signs of mitral insufficiency. Harvest is planned at six months.

Conclusions: The initial success of this automated neochordal suture placement and fastening system to enable easy papillary suturing, real-time suture length adjustment and secure fastening of ePTFE sutures in this survivor ovine model encourages further research.

References:

- 1. Bortolotti U, Milano AD, Frater RWM. Mitral valve repair with artificial chordae: A review of its history, technical details, long-term results, and pathology. Ann Thorac Surg 2012;93:684-91.
- 2. Frater RWM. Chordae: 1959-2009. In: Hetzer R, Rankin JS, Yankah CA, ed. Mitral Valve Repair: The biological solution. Heidelberg, Germany: Springer-Verlag Berlin Heidelberg; 2011: 96-108.

Multiple Choice Questions:

- 1. The chordae tendinae replacement consists of two separate ePTFE suture loops secured with a co-axial titanium fastener. Where is the titanium fastener placed?
 - a. Against the mitral leaflet on the left ventricular side.
 - b. Against the mitral leaflet on the left atrial side.
 - c. Half-way between the papillary muscle and the mitral leaflet.
 - d. Against the tip of the papillary muscle.



Figure 1. Photograph of a neochordal implant with the coaxial titanium fastener seated on the papillary muscle. Placement of the leaflet loop corresponds to the region of the cut chordae.