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External approach to in vivo force measurement on mitral valve traction suture

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ABSTRACT

Background: Force measurements on the mitral valve apparatus have been reported from in vivo and in vitro studies. Recent reparative techniques for ischemic mitral valve insufficiency call for papillary muscle relocation. This study describes a device to measure forces generated on traction sutures utilized for this purpose.

Methods: The transducer design was based on a modified caliper with strain gauges attached. Finite element computer simulation was employed to optimize the signal output. The system was designed to facilitate investigation of the effects of shortening GoreTex traction suture that was extended from near the fibrous trigones of the mitral valve through the papillary muscles. The suture was exteriorized out through the left ventricle in a porcine setup ($n=11$) and attached to the dedicated device for simultaneous papillary muscle relocation and traction suture force measurement.

Results: The transducer demonstrated excellent signal strength, linearity, and durability. Peak force was seen at the onset of the systolic isovolumic contraction ($p<0.001$). Initial results indicated that this external approach can document force magnitudes comparable to previous internally measured forces in the mitral valve apparatus.

Conclusions: It has been proven feasible to measure forces in the mitral valve papillary muscle relocation sutures with an external device. The results from using this equipment will provide insight into the biomechanical requirements of relocation traction sutures and other devices utilized for papillary muscle relocation.

1. Introduction

During the last twenty years, mitral valve (MV) repair has been increasingly preferred over replacement (Reul and Cohn, 1997). Various techniques such as annuloplasty can be accompanied by papillary muscle (PM) relocation as an adjunct procedure due to the reparative and geometry restoring effects (Kron et al., 2002; Langer et al., 2009; Levine and Schwammenthal, 2005; Hung et al., 2002). In addition, PM relocation by itself is also gaining popularity in reparative techniques for mitral valve insufficiency. One of these relocation techniques is utilizing a traction suture that anchors the PMs near the fibrous trigones and hoists them towards the annulus (Kron et al., 2002). To understand the impact on these traction sutures and their strength requirements and to quantify the load on the valvular and subvalvular apparatus as the sutures are shortened to obtain the relocation closer to the annulus, the force applied to them needs to be investigated. In addition, the left ventricular (LV) force balance of the healthy and repaired MV is not yet fully understood, despite many years of experimental measurements and simulations of different parts of the valvular and subvalvular apparatus (Jensen et al., 2001a; Jimenez et al., 2005; Nielsen et al., 2004; Jensen M.O., et al., 2008; Hashim et al., 1997; Hasenkam et al., 1994; Prot et al., 2008). A new approach to measuring these forces is to redirect the tension and externalize the components that are experiencing loading conditions.

The equipment described in this article was originally designed to assist in identifying the point at which the traction suture was no longer slack during the relocation procedure. This was performed by detecting when a cyclic tension in the traction suture was observed and thereby identify a baseline of relocation recorded with millimeter precision (Jensen et al., 2009). Hence, the force transducer described in this article and the attached equipment was designed to detect the onset of load on the traction sutures by measuring these continuously.

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2. Materials and methods

2.1. Force transmission

Traction suture (GoreTex 2-0) was extended on the ventricular side of the MV from the anterior and posterior fibrous trigones through the anterior and posterior papillary muscles, respectively. The suture was then exteriorized out through the left ventricle through a pad placed on the epicardium at the PM location (Fig. 1). The traction suture was guided through a flexible channel to the external transducer through dedicated spherical shaped pearls for proper force transmission and attached to a modified metric caliper device for papillary muscle relocation.

2.2. Force transducers

The transducer design was based on a standard off the shelf mechanical caliper. The modified caliper ensured precise and reliable control of the PM positioning. When a desired relocation was obtained (1 mm precision), the system could lock a spinning wheel and force data could be acquired.

To ensure that sufficient signal was generated to be detected with a strain gauge mounted on the force gauge bracket (Fig. 2a), a Finite Element Model simulation was setup to verify that an applied force in the expected range (Jensen et al., 2001a) created sufficient signal on the brass frame (SolidWorks Simulation/FEA (COSMOS) Version 2008, SolidWorks Corp., Concord, MA). Brass was chosen as material for the force gauge bracket due to its corrosion resistance and material properties with regard to strain gauge applications. The simulation process assisted in identifying the thicknesses of the frame: compromising between signal magnitude and transducer ultimate strength in the recess regions resulted in an optimum thickness of the bracket to be 1.0 mm. The simulation indicated strain values of at least an area average between 50 $\mu\varepsilon$ and 100 $\mu\varepsilon$ at 1.0 N force applied and an area average between 250 $\mu\varepsilon$ and 300 $\mu\varepsilon$ at 5.0 N force applied (Fig. 2b).

The frame surface was cleaned and prepared with isopropyl alcohol, and strain gauges of model CEA-06-062UW-350 (Vishay Micro Measurements, Basingstoke, United Kingdom) were attached to the frame with cyanoacrylate based glue. The wire connected to the strain gauge at the solder terminals was a 3-conductor vinyl-insulated leadwire (326-DFV, Vishay Micro Measurements). The 3-wire technology eliminates the effects of variable lead wire resistance in a quarter bridge setup. The wire was primed with a nitrile rubber coating (M-Coat-B, Vishay Micro Measurements) to improve bond ability to the final silicone rubber coating (M-Coat-3145, Vishay Micro Measurements). An extra set of strain gauge mounted bracket frames were manufactured to be used as backup equipment if necessary.

2.3. Surgical protocol

Eleven mixed Yorkshire and Danish Landrace pigs with a body weight of 80 kg were used in a study to investigate functionality of the transducer while measuring the impact of PM relocation as adjunct procedure to mitral ring annuloplasty in functional ischemic mitral regurgitation (Jensen et al., 2009). All pigs were bred under standard laboratory animal conditions, and the experiment complied with the guidelines from the Danish Inspectorate of Animal Experimentation. The study was approved by this institution. The details of the surgical preparation of porcine animal experimental protocols at our institution have previously been described (Nielsen et al., 2005).

After establishment of cardiopulmonary bypass and cardioplegic arrest, a PTFE traction suture was attached at each of the left/anterior and right/posterior fibrous trigones and exteriorized through the anterior and posterior PMs, respectively (Fig. 1). Relocation as illustrated in Fig. 3 was performed on beating heart by locking the Gore-Tex suture to point 3 (functionality of the modified caliper) and using the caliper to increase the distance between points 2 and 3. Since the distance between points 1 and 3 is constant, this in turn will decrease the distance between points 1 and 2, resulting in the desired papillary muscle relocation. Asymmetric PM displacement in chronic functional ischemic mitral valve regurgitation dictated the amount of relocation of the individual PMs (Jensen H., et al., 2008). Hence, during the experiments in which the transducer was utilized, the posterior PM was relocated 5 mm, 10 mm, and 15 mm, and the anterior PM was

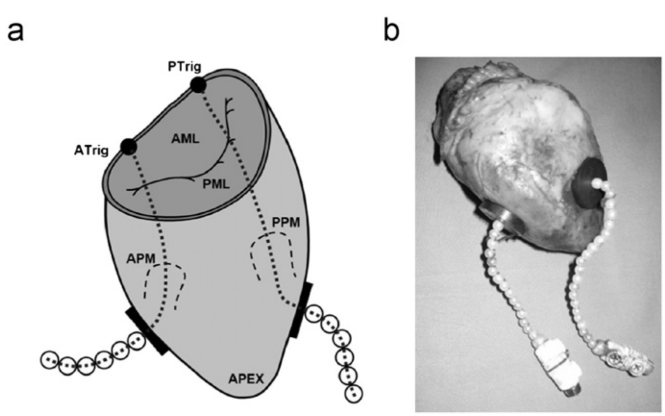

Fig. 1. Papillary muscle relocation and traction suture force transmission system. (a) Schematic displaying the suture attached to the anterior and posterior fibrous trigones and exteriorized though epicardial pads and channeled through a flexible guiding system. ATrig: Anterior Trigone, PTrig: Posterior Trigone, AML: Anterior Mitral Leaflet, PML: Posterior Mitral Leaflet, APM: Anterior Papillary Muscle, PPM: Posterior Papillary Muscle. (b) Picture of a porcine heart with the attached force transmission system.

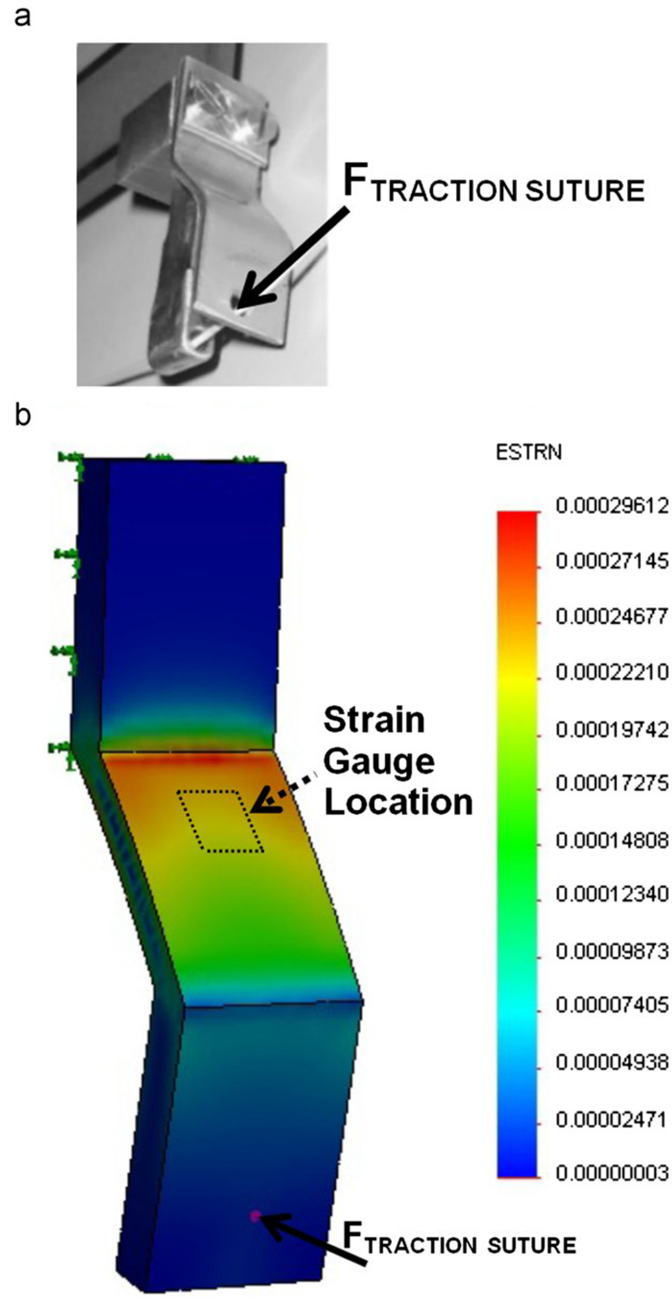

Fig. 2. Strain gauge application optimization. (a) Image of the force gauge bracket brass frame. (b) FEM model of the brass frame displaying that the highest strain values at $F_{\text{TRACTION SUTURE}}=5$ N are close to 300 $\mu\varepsilon$ and are located at the recess region just below the part of the frame that is fixed to the modified caliper (see Fig. 2a), where the largest momentum load of the frame is located. Strain gauge location (grid size of 3 mm × 2 mm) is indicated with dotted lines, reaching approximately 200 $\mu\varepsilon$ at $F_{\text{TRACTION SUTURE}}=5$ N.

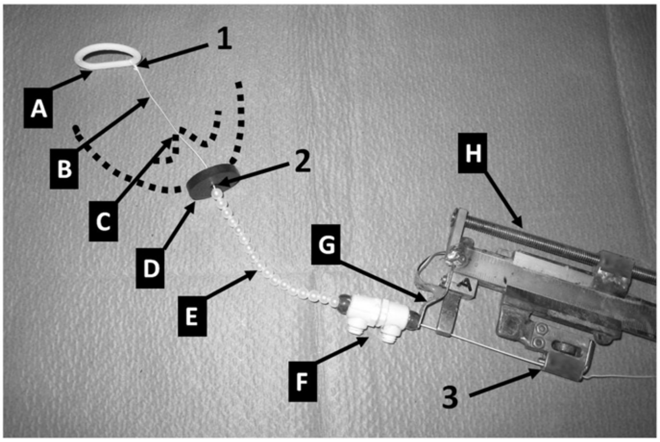

Fig. 3. Annuloplasty and papillary muscle relocation setup including suture locking device for chronic experimentation. A, Annuloplasty Ring; B, Gore-Tex suture; C, papillary muscle outline; D, epicardial pad; E, string of pearls; F, suture locking device; G, strain gauge; H, sliding caliper. Posterior papillary muscle stitch is displayed; an identical setup was utilized for the anterior papillary muscle. Relocation works by changing the distance between points 1 and 2 (see text). Image reproduced with permission from Wolters Kluwer Health, and the American Heart Association License Number 2766640760474.

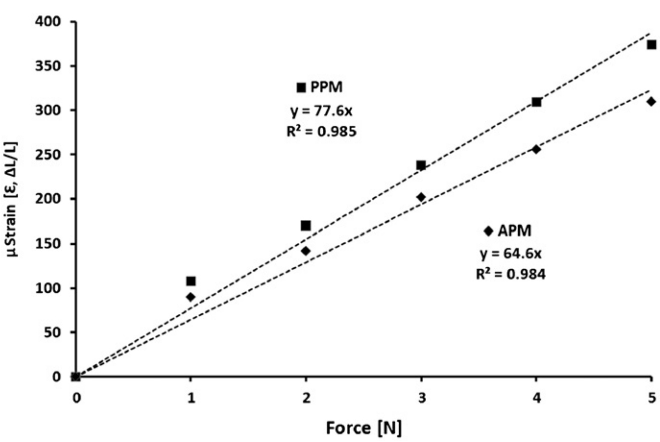

Fig. 4. Example of calibration of the traction suture force measurement system. PPM: Posterior Papillary Muscle, APM: Anterior Papillary Muscle.

relocated 5 mm. Force measurements were recorded synchronously with the ECG and hemodynamic data. Stabilization of the animals and MV functionality was monitored with left ventricular and left atrial pressure measurements, pulmonary flow, and epicardial echocardiography.

2.4. Data acquisition

Wheatstone bridge completion, supply current, and strain measurements were acquired with dedicated data acquisition hardware (compact DAQ model 9172 and NI-9237, National Instruments, Austin, TX, USA) and recorded with virtual instrumentation software custom built by utilizing graphical programming LabVIEW version 8.2 (National Instruments).

3. Results

The force measuring system was designed for calibration and zeroing immediately prior to experiments. In the unlikely situation that the bracket of the force transducer needed replacement, re-calibration was necessary, since the fixation of the bracket to the modified caliper was dependent on screw tightness, applied washers, etc. Fig. 4 shows an example of a calibration of the posterior PM (PPM) and anterior PM (APM) strain gauges. Fig. 5 shows the system in use. Fig. 6 shows an example of the force

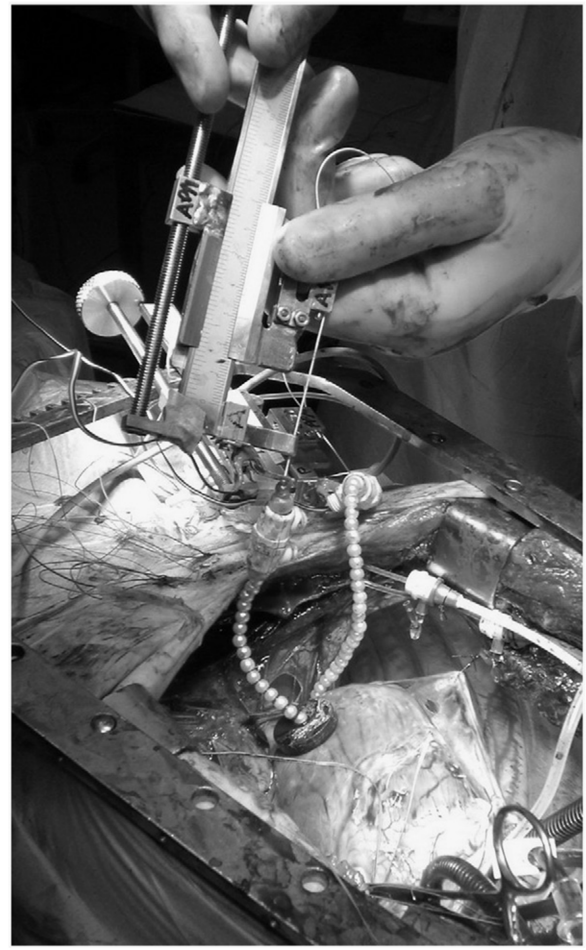

Fig. 5. External traction suture tightening and force measurement device in use. The anterior papillary muscle is being relocated, and the posterior papillary muscle relocation system is seen in the background.

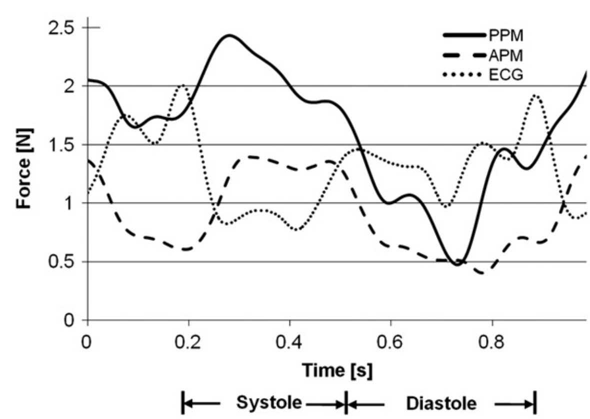

Fig. 6. Example of simultaneous porcine ECG and traction suture forces recorded. Force trace curves is displayed for the posterior papillary muscle (PPM) and anterior papillary muscle (APM) respectively. PPM force was measured at 15 mm displacement and the APM force was measured at 0 mm displacement. This results in a higher baseline and peak force measured by the displaced PM. Systole is defined from the porcine ECG as the duration from the QRS complex (rapid depolarization of the right and left ventricles) to the T-wave, (repolarization / recovery of the ventricles).

curves generated. This data is recorded during an experiment in which the posterior PM has already been relocated with the traction suture system, and hence the force on the suture (APM and PPM) does not reach zero. During these experiments, peak force was seen following the ECG R-wave, at the onset of the systolic isovolumic contraction ($p < 0.001$).

4. Discussion

A dedicated traction suture PM relocation and force measurement system was developed with a methodical approach. The system enables force transfer for external assessment of the tension in the traction suture as well as the possibility of obtaining very precise relocation of the myocardium overlying the papillary muscles by moving and locking the sliding caliper. Originally the design was optimized to detect the point where the traction suture was no longer slack. Hence, in summary, the transducers served three purposes: (1) eliminate slack in traction suture (define 0 mm PM repositioning), (2) PM relocation quantification in a chronic setup where the amount of repositioning from onset of traction suture force (as the suture is tightened from slack to taut) was recorded and maintained in surviving animals, and (3) traction suture force measurements. As seen in Fig. 4, the strain values recorded during calibration are in the same order of magnitude as those simulated in the design phase of the bracket (Fig. 2b) onto which the strain gauge was attached. It is important to notice that the FEM simulations were solely performed to guarantee that a minimum amount of strain would be transferred to the gauge and hence create a signal in the data acquisition system.

The first indications of the traction suture force obtained with this system are similar to measurements obtained in the second order MV strut chordae tendineae (Lomholt et al., 2002), but an order of magnitude smaller than the measured total force on the PMs (Jensen et al., 2001b). This preliminary observation may be explained by the fact that the traction suture is not bearing the load entirely alone, as it is assisted with the rest of the subvalvular apparatus, which is kept intact. Detailed reports on these and future measurements in acute and chronic settings are future perspectives from our group.

The force might be expected to be highest when the ventricle is most dilated in the peak diastolic phase (during atrial contraction at the P-wave, see Fig. 6). However, in diastole, the ventricular muscle is relaxed. Hence, the highest force is experienced during isovolumic contraction, when the ventricular myocardium is initially activated at the highest systolic left ventricular volume. Therefore, when the muscle activates, the force peaks, and then decreases as the ventricle empties and eventually recovers with repolarization. The force increases again at the P-wave (during atrial contraction and depolarization when the ventricles fills), although it does not reach the same value as during isovolumic contraction.

The new device can help in investigating better annuloplasty techniques accompanied by adjunct PM repositioning towards the annulus through traction suture (also known as the "ring plus string" procedure). This, in turn, will facilitate more competent valves following repair and should be considered a beneficial effect by relieving potential excessive leaflet tethering and stress development associated with many of the existing repair techniques in use today. Adding our knowledge about annuloplasty devices, the new information about forces required to relocate the PMs should be combined with saddle shaped annuloplasty to avoid adverse lack of leaflet curvature and overall valvular force balance as much as possible.

The relocation force required is not depending on the direction in which it is applied: the traction suture pulls the PMs closer to the anterior annulus in a hoisting fashion. Other suggested devices designed to relieve the chronic ischemic incompetent situation with indirect relocation methods generate a push on the PMs from the epicardium (Levine and Schwammenthal, 2005). This new system described may be utilized as a general standard PM relocation force measurement device, which can be used as a reference guide for all PM relocation techniques. It may also be hypothesized that the forces generated on traction sutures are directed by the LV force balance. Hence, a future perspective could be to utilize this system to determine the exact forces generated on traction sutures throughout the cardiac cycle.

Conflict of interest statement

Sten L. Nielsen and J. Michael Hasenkam are co-owners of ENOVACOR ApS

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