The Heart Surgery Forum #2003-49374
6 (4), 2003

Online address: www.hsforum.com/vol6/issue4/2003-49374.html

Sutureless Robot-Assisted Mitral Valve Repair: An Animal Model

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(#2003-49374 . . . April 29, 2003)

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ABSTRACT

Background: Robotic mitral valve repair with the da Vinci robotic surgical system has been performed in more than 70 patients at our institution. This procedure reduces the need for blood transfusions, shortens hospital stay, and hastens return to normal activities. However, the robot-assisted repair also requires longer cardiopulmonary bypass and arrested-heart times than conventional open repairs. Because of increased risk of myocardial damage, arrhythmia, and other significant morbidities associated with longer arrested-heart time, a more efficient tissue approximation and adherence technique was evaluated to reduce operating time.

Methods: Twelve Dorset sheep were divided equally into 2 groups. In the control group Cosgrove-Edwards annuloplasty bands were secured to the posterior annulus with conventional 2-0 Ticron mattress sutures placed with robotic assistance. In the experimental group, the band was secured with double-armed nitinol U-clips placed with robotic assistance. Postoperative echocardiography was used to assess mitral valve function, and the animals were sacrificed at 3 or 6 months for histological evaluation.

Results: Total U-clip placement time was significantly decreased at 2.6 ± 0.2 (mean ± SEM) minutes versus total suture placement time at 4.9 ± 0.4 minutes (P = .001). The main difference in time occurred between clip deployment at 0.75 ± 0.1 minutes and suture tying at 2.78 ± 0.2 minutes (P = .000003). Pathologic review showed excellent band incorporation at 3 and 6 months. Echocardiographic imaging showed no discernible mitral valve stenosis or regurgitation.

Conclusions: With more cardiac procedures progressing toward minimally invasive approaches, novel technology to improve existing techniques must be evaluated. Nitinol U-clips help to reduce arrested-heart time and may improve outcome by decreasing morbidity. U-clip placement is intuitive, easily learned, and effective in securing the annuloplasty band to the mitral annulus.

INTRODUCTION

More than 70 robotic mitral valve repairs with the da Vinci robotic surgical system (Intuitive Surgical, Sunnyvale, CA, USA) have been performed at our institution with good outcome. Our experience has shown that minimally invasive mitral valve repair reduces the need for blood transfusions, decreases length of stay, and improves recovery time [Felger 2001]. Robotic mitral valve repair with the da Vinci system yields comparable results but with smaller incisions and a more precise working environment [Nifong 2003]. However, with current technology, cardiopulmonary bypass and arrested-heart times are increased compared with the times for both videoscopic and conventional open techniques [Nifong 2003].

Extended arrested-heart time contributes to depressed myocardial function postbypass. Previous work showed that even with hypothermic protection, ischemic arrest causes depressed postoperative myocardial performance [Buckberg 1975, Nelson 1975]. Some of the factors contributing to extended arrested-heart time in robotic surgery are robotic arm insertion, robotic setup time, and patient-side surgeon expertise. However, we have observed that all of these times decrease continuously as more procedures are performed. In contrast, we also have observed that suture tying is quickly learned and that the learning curve for suture tying plateaus early in the surgeon's robotic operative experience with no statistical improvement after 20 cases.

Knot tying takes an exorbitant amount of time during annuloplasty band placement. With an average of 10 sutures per annuloplasty band, a significant amount of time is dedicated to the repetitive motions of instrument tying [Nifong 2003]. Therefore we investigated use of a novel self-closing clip for speed, adherence properties, strength, fatigability, ease in use, and reliability.

Selected as Best Surgical Video, Sixth Annual NewEra Cardiac Care: Innovation & Technology Conference, Dana Point, California, USA, January 3-5, 2003.

Received April 23, 2003; accepted April 29, 2003.

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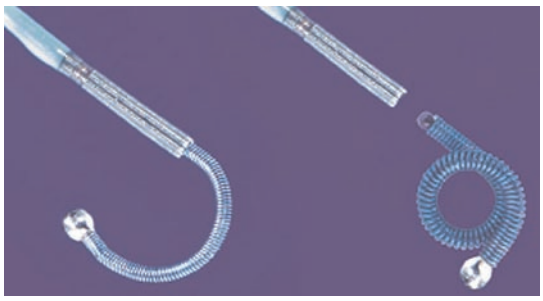

Figure 1. Single-armed clip before and after deployment.

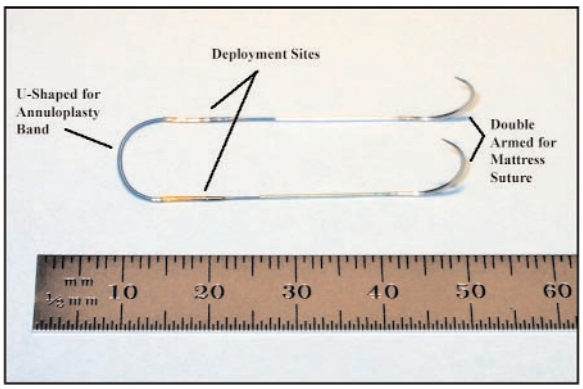

Figure 2. Double-armed nitinol U-clip.

Nitinol U-clips (Coalescent Surgical, Sunnyvale, CA, USA) have been used in cardiac surgery since 2000 and have been used in more than 35,000 coronary artery anastamoses. The clip is made of nitinol, an alloy with superelastic properties that allow the material to return to a preformed pattern. The clips are designed so that after tissue placement the element is deployed, transforming the curved nitinol to its preformed circular clip shape (Figure 1). Until recently only single-armed clips have been available for use in humans. However, double-armed clips with 3 nitinol anastomotic loops were used for testing in animal models (Figure 2).

MATERIALS AND METHODS

Twelve Dorset sheep (45-60 kg) were used after institutional approval was granted in accordance with the *Guide for the Care and Use of Laboratory Animals* [NIH 1985]. The sheep underwent general anesthesia and were placed in the right lateral decubitus position with the ventral torso elevated slightly to accommodate robotic instrumentation. Percutaneous front-limb arterial access allowed hemodynamic monitoring while the left carotid artery and jugular vein were used for cardiopulmonary bypass cannulation. A fourth–intercostal-space left minithoracotomy provided access to the heart, and a cardioplegia cannula was placed in the ascending aorta for antegrade cardioplegia. The heart was arrested with cold cardioplegia after cross-clamping of the aorta. A left atriotomy was created, and the roof of the atrium was elevated with an atrial retractor system (Cardiovations, Somerville, NJ, USA). A left atrial pump sucker assisted in maintaining a dry field while continuous carbon dioxide infusion to the thorax helped to displace air from the open heart. The da Vinci robotic surgical system was mobilized to the bedside for endoscopic repair.

Control sheep (n = 6) received either a No. 26 or a No. 28 Cosgrove-Edwards annuloplasty band (Edwards Lifesciences, Irving, CA, USA) placed by conventional suture technique. Ticron (US Surgical, Norwalk, CT, USA) 2-0 sutures were placed in an interrupted mattress fashion to secure the band to the annulus. The procedure was videotaped and times subsequently recorded for individual suture placement and knot-tying time.

Experimental sheep (n = 6) underwent similar band placement, but the nitinol U-clip double-armed anastomotic device was used. These were placed in a similar interrupted mattress fashion by the same experienced surgeon who placed the sutures in the control sheep. Again, procedures were videotaped and analyzed for individual clip placement time and clip deployment time.

After band placement the animal was weaned from cardiopulmonary bypass, all access sites were closed, and the animal was allowed to awaken from anesthesia. Transthoracic echocardiography was performed to confirm valve function. Postoperative care was provided by attending and resident staff as well as animal care technicians. Antibiotics and fluid were administered as appropriate, and feeding was reinstituted on postoperative day 1.

Animals were electively sacrificed 3 or 6 months after the procedure. Before sacrifice, transthoracic echocardiography was performed for assessment of valve function. The heart was sectioned for pathologic analysis.

RESULTS

Both suture placement and knot tying times in control animals were compared with both clip placement and clip deployment times in experimental animals. Definitions of data fields are presented in the Table. All data were recorded

Definition of Data Fields

Control sheep

Suture placement time: Starts when needle is grasped by da Vinci instrument, ends when needle is removed from suture after passing through tissue

Knot-tying time: Starts when needle is removed from chest, ends when suture is cut after tying

Total suture time = *Suture placement time* + *Knot-tying time*

Experimental sheep

Clip placement time: Starts when needle is grasped by da Vinci instrument, ends after both needles have completely passed through annulus and band

Clip deployment time: Starts when da Vinci instrument grasps clip deployment site, ends when needle is removed from chest

Total clip time = *Clip placement time* + *Clip deployment time*

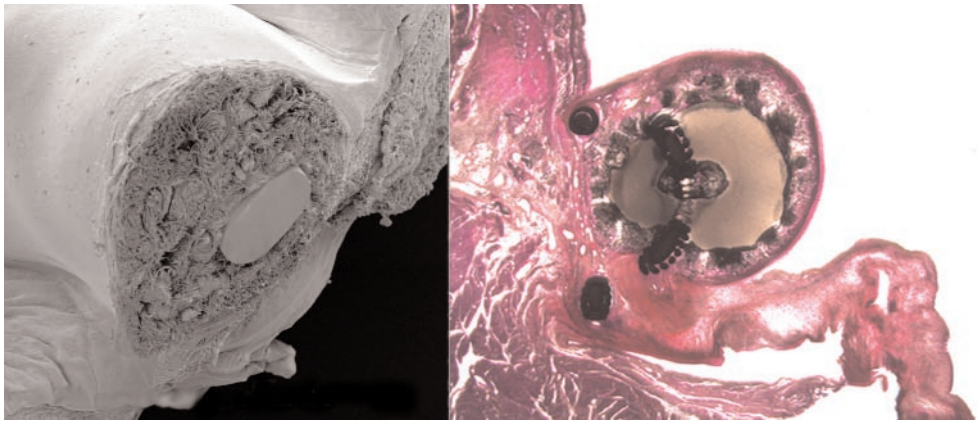

Figure 3. Left, scanning electron microscope. Right, histologic specimen (original magnification ×1.25).

to the nearest second with Microsoft Excel (Microsoft, Redmond, WA, USA). Paired *t* test was used with $P < .05$ proving statistical significance. Data are expressed as mean ± SEM. Total clip time was significantly less than total suture time (2.6 ± 0.2 minutes and 4.9 ± 0.4 minutes, respectively; $P = .001$). However, even more significant was the difference between clip deployment time and knot tying time at 0.75 ± 0.1 minutes versus 2.78 ± 0.2 minutes, respectively ($P = .000003$).

Transthoracic echocardiography before sacrifice at 3 or 6 months showed neither mitral stenosis nor regurgitation. All mitral leaflets coapted normally, and there was no evidence of other valvular dysfunction.

Histologic analysis at 3 months showed band adherence with complete endocardial envelopment (Figure 3). There were no dislodged clips, and all clips were maintained in their low-profile state. There were no broken clips. Animals sacrificed at 6 months had identical findings.

DISCUSSION

Minimally invasive and robotic cardiac surgery recently has revolutionized mitral valve surgery. With video-assisted technology and endoscopic telemanipulative techniques, valve repair can be performed with improved visualization. In addition, techniques are advancing, thus enabling less invasive mitral valve repair.

Use of nitinol double-armed anastomotic clips is an efficient method for adherence of annuloplasty bands to the annulus. Clip placement and deployment are easily learned. In addition, the clips have features that conventional mattress sutures do not. With conventional robotic annuloplasty suturing, one must pass the suture first through the band, then through the annulus, then through the band again. Once this process is completed, the needle is separated from the suture material and removed by the patient-side assistant. One problem with this single-armed suture method is that the band obstructs the view of the annulus while sutures are placed. With double-armed nitinol U-clips, the surgeon passes material first through the annulus and then through the band. This procedure allows easy viewing of the annulus without obstruction. In addition, one does not need to deploy the clip at this time. Unlike conventional sutures, which the surgeon needs to tie after placement for fear that the suture will be accidentally removed from the band, U-clips can be left in place without deployment. This feature allows one to retract the band and place the next clip under excellent visualization while not losing security with the previously placed clip (Figure 4). Once the subsequent clip is placed, the previously placed clip can be deployed (Figure 5). This sequence is repeated until the band is completely secured.

Nitinol U-clips have a low profile on the annuloplasty ring until tissue incorporation is complete; multiple suture knots, however, protrude into the cardiac chamber (Figure 6). This feature of U-clips results in better flow dynamics through the atrium and may decrease the stress on the ring by eliminating an obstructive component and nidus for hemolysis. Our studies showed that even after 6 months of dynamic function, the clips provided excellent adherence with no indication of strain or fatigue. All clips were

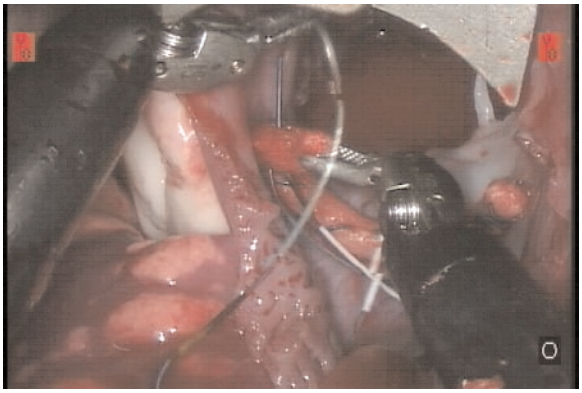

Figure 4. Placement of subsequent clip without removal of previous clip. This feature allows greater flexibility and visualization in placement of the annular stitch.

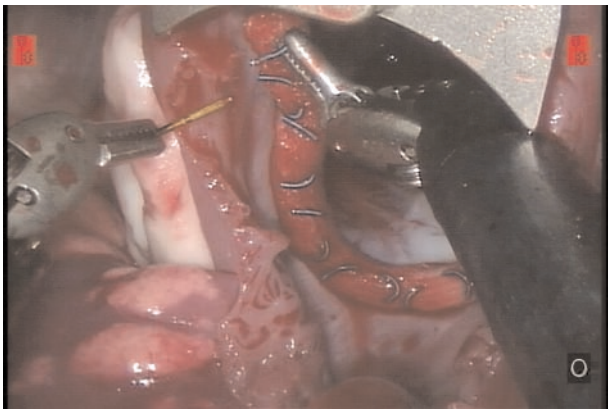

Figure 5. Deployment of nitinol clip.

accounted for in the band at necropsy. There was no indication of clip embolism or device breakage.

Nitinol double-armed U-clips are a promising technology in both efficiency and durability in mitral valve annuloplasty. As more patients undergo robotic mitral valve repair and we move toward totally endoscopic repair, tissue approximation devices will become important for an efficient procedure. U-clips have been shown to speed repair and lessen the effects of prolonged arrested-heart time, the results being comparable with or better than those with conventional suture techniques.

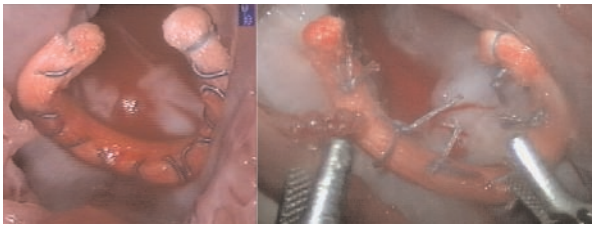

Figure 6. Comparison of completed annuloplasty with nitinol U-clips (left) and conventional suture technique (right).

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