Published in final edited form as:

Ann Thorac Surg. 2009 October ; 88(4): 1312–1316. doi:10.1016/j.athoracsur.2009.04.133.

Evaluation of a Shape Memory Alloy Reinforced Annuloplasty Band for Minimally Invasive Mitral Valve Repair

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Abstract

Purpose—An in vitro study using explanted porcine hearts was conducted to evaluate a novel annuloplasty band, reinforced with a two-phase, shape memory alloy, designed specifically for minimally invasive mitral valve repair.

Description—In its rigid (austenitic) phase, this band provides the same mechanical properties as the commercial semi-rigid bands. In its compliant (martensitic) phase, this band is flexible enough to be introduced through an 8-mm trocar and is easily manipulated within the heart.

Evaluation—In its rigid phase, the prototype band displayed similar mechanical properties to commercially available semi-rigid rings. Dynamic flow testing demonstrated no statistical differences in the reduction of mitral valve regurgitation. In its flexible phase, the band was easily deployed through an 8-mm trocar, robotically manipulated and sutured into place.

Conclusions—Experimental results suggest that the shape memory alloy reinforced band could be a viable alternative to flexible and semi-rigid bands in minimally invasive mitral valve repair.

Mitral valve reconstruction has become a well-established, surgical procedure for the treatment of regurgitation, and a critical component of successful valve reconstruction is the annuloplasty band [1]. These bands can be broadly categorized as flexible, semi-rigid, and rigid. The rigid bands have a solid metal core (frequently titanium) enabling aggressive remodeling of the annulus; however, their rigidity has been shown to decrease natural annular motion during the cardiac cycle [2]. Flexible bands accommodate the dynamic nature of the mitral annulus, but have been criticized for lack of remodeling capability [3]. Semi-rigid bands combine rigidity at the anterior region with flexibility along the posterior region; several centers have reported excellent outcomes with semi-rigid bands [1, 3].

In November 2002, the Food and Drug Administration approved the use of the da Vinci Surgical System (Intuitive Surgical Inc, Sunnyvale, CA) for mitral valve repair, providing patients with the many benefits of robot-assisted surgery [4]. Due to physical limitations,

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Disclosures and Freedom of Investigation The authors have no commercial associations or sources of support that may pose a conflict of interest. The authors had full control over the design of the experiments, methods used, outcome measurements, analysis of data, and production of written report.

Disclaimer The Society of Thoracic Surgeons, the Southern Thoracic Surgical Association, and *The Annals of Thoracic Surgery* neither endorse nor discourage use of the new technology described in this article.

however, neither rigid nor semi-rigid bands can be robotically deployed through 8-mm trocars and manipulated within the confined spaces of the heart; flexible bands are currently the only option for robot-assisted mitral valve replacement.

In this article, an alternative annuloplasty band is presented that addresses specific needs of minimally invasive mitral valve repair. In its low-temperature martensitic phase, this band is flexible enough to be inserted through an 8-mm trocar and manipulated within the heart using laparoscopic and robotic instruments. In its high-temperature austenitic phase, this band recovers sufficient rigidity to provide remodeling forces similar to other semi-rigid bands. To determine the efficacy of this novel annuloplasty band, an ex vivo study was performed, which included mechanical testing, dynamic pressurization, and robotic evaluation.

Technology

Device Design

The shape memory, alloy-reinforced band features a core of 0.50-mm diameter, nickel-titanium (NiTi) wire (Fort Wayne Metals, Fort Wayne, IN), encased in a 2.38-mm diameter silicone sheathing and enclosed by a polyester knit sewing cuff. As with other semi-rigid bands, which feature ultra-high, molecular weight polyethylene or cobalt alloy cores, the prototype band exhibits excellent corrosive properties, low cytotoxicity response, and magnetic resonance imaging compatibility. Nickel-titanium has been used extensively in other medical devices, including stents, vena cava filters, and angioplasty guide wires [5]. However, these applications utilize only the super-elastic properties of NiTi; the prototype band utilizes the temperature-induced shape memory effect. Below its martensitic finish temperature (M_f), NiTi exists in its compliant martensitic phase and is easily deformed and manipulated. When heated above its austenitic finish temperature (A_f), NiTi undergoes an internal phase transformation in which the material changes from its compliant martensitic phase to its stiffer austenitic phase [5]. Both phase transition temperatures can be specified by varying the material composition and annealing of the alloy.

During the fabrication process, the austenitic shape of the NiTi core is set to conform to the shape of the mitral annulus. In its activated (austenitic) phase, this prototype band provides the same mechanical properties as commercial semi-rigid bands. In its pre-activated (martensitic) phase, this band is flexible enough to be introduced through an 8-mm trocar and is easily manipulated within the heart. Figure 1 illustrates both configurations of the band as it undergoes a heat-induced phase transformation from martensite at 24°C to austenite at 37°C, a process that completes in approximately 5.0 seconds using a warm saline bath.

Technique

Mechanical Testing

The mechanical properties of the activated NiTi core prototype were selected to match commercially available semi-rigid bands. Two semi-rigid bands were targeted: the Carpentier Edwards Physio bands (Edwards Lifesciences, Irvine CA) and the SJM Séguin bands (St. Jude Medical, St. Paul MN). Full rings were selected (rather than partial bands), because they provide additional support to the anterior portion of the mitral valve. The success of these semi-rigid rings in mitral valve repair has been well documented [2, 3, 6].

Compression tests were conducted using a universal testing machine (Applied Test Systems Inc, Butler, PA). Mechanical testing of the prototype was done with the NiTi in its austenite state (37°C), because this represents the final state for implanted bands. Additional tests

were conducted in its martensitic state (24°C) to illustrate the compliance of the prototype during deployment. All bands were compressed 4 mm in the anterior–posterior orientation at 2.5 mm/min loading rate.

Dynamic Flow Testing

The second phase of the evaluation consisted of dynamic flow testing, which was completed on a left ventricular pulse duplication system [7]. This computer-controlled system dynamically pressurizes explanted porcine hearts, accurately replicating the pressure waveforms and flow rates of in vivo mitral valves. The system allows for control of numerous measurements, including heart rate, systolic fraction and stroke volume. By measuring changes in cardiac output and left heart pressures, mitral regurgitation in this system can be quantified.

A randomized study using the Physio (five) and prototype bands (five) was conducted using a heart rate of 60 strokes per minute and a systolic fraction of 35%. Each band was tested in a separate freshly explanted heart using heated (40°C) 0.9% saline solution. The stroke volume was adjusted for each heart depending on size and tissue compliance, which ranged from 35 mL/stroke to 40 mL/stroke. The stroke volume was kept constant throughout each experiment to ensure constant fluid input. Because of the unique anatomy and tissue compliance of each heart, a baseline aortic output measurement was initially taken. For each baseline measurement, aortic outflow resistance was increased until peak ventricular pressure reached 120 mm Hg; the heart was then dynamically pressurized for 1 minute while the aortic output was collected and measured. The left ventricle pressure was then increased to 150 mm Hg (simulating a stressed heart), and the output was measured again. An atriotomy was performed to expose the mitral valve. Valve failure was induced by stretching the mitral annulus in the anterior–posterior and transverse directions until a significant increase in the anterior–posterior distance occurred without decreasing the transverse length to simulate annular dilation. In addition, chordae tendineae connecting the P2 leaflet to the papillary muscles were severed to simulate chordal rupture. The valve was subjected to 35 mm Hg static back pressure to ensure adequate mitral valve failure. The incision from the atriotomy was closed with cyanoacrylate adhesive and suture. Output measurements were repeated at both 120 and 150 mm Hg peak left ventricular pressure for 1 minute. The mitral valve failed regurgitant fraction (FRF) was calculated as the percent difference between the failed valve output and baseline output measurements.

To perform the repair, the atriotomy was reopened to expose the mitral valve. The valve was repaired with a triangular resection and leaflet reapproximation using a running monofilament suture (4-0 Prolene [Ethicon, Sommerville, NJ]). All bands were sutured to the annulus using the parachute technique. The band size was determined by the physical anatomy of the annulus, which ranged from 26 mm to 31 mm. The bands were secured to the annulus with an average of 12.6 (range, 12 to 14) 2-0 TI CRON braided polyester sutures (USS, Norwalk, CT). Static pressure was used to ensure there was no leakage through the valve before closing the atriotomy. The output measurements were again taken at 120 mm Hg and 150 mm Hg peak left ventricular pressure for 1 minute. The repaired regurgitant fraction (RRF) was calculated as the percent difference between repaired output and the baseline output. Measured data is presented in Table 1. Endoscopic images of implanted Physio and prototype bands are shown in Figure 2.

Robotic Manipulation Testing

The third phase of the evaluation consisted of robotic trials conducted on a da Vinci Surgical System by a cardiothoracic surgeon trained in robotic procedures. A qualitative comparison was performed between the prototype band in its flexible martensitic state and a Physio

band. Ease of manipulation with the robotic instruments, visualization of the mitral annulus, tension on the sutures, and deformation of the surrounding annulus tissue were evaluated. All suturing, band manipulation and knot tying was done robotically. An explanted porcine heart was placed in a holding fixture and a standard left atriotomy was performed to expose the mitral valve. Each band was sutured to the annulus using individually inserted and knotted sutures without the use of an annuloplasty band holder to simulate the minimally invasive procedure. Two Physio bands (size 30) and two prototype bands (26 mm), were sutured into four separate hearts. In each experiment, the placement of the first suture was varied to evaluate multiple methods of insertion.

Clinical Experience

Mechanical Results

The prototype band in its austenitic state (37°C) had comparable mechanical properties to the commercial semi-rigid bands (Fig 3). At an anterior–posterior displacement of 2 mm, which has been shown to be the average displacement of the mitral annulus [8], the activated (austenitic) prototype was 42.8% stiffer than the same band in its nonactivated (martensitic) state.

Dynamic Flow Testing

A mixed model using the RRF was fit to the data. The model included measurements for pressure (120 mm Hg or 150 mm Hg) and band type (Physio or prototype), and the crossed factor pressure by band type, as well as random effects for the hearts. The RRF is positively associated with the FRF; therefore the FRF was included as a covariate. A statistical analysis was performed using the MIXED procedure of the statistical software package SAS (SAS Inc, Cary, NC). The analysis of variance (ANOVA) table, shown in Table 2, quantifies the degree to which the various factors in the model explain the variability in RRF. The degree of valve failure had the most significant effect on the repaired valve, regardless of which band was used for the repair as evident by both the F-ratio and the *p*-value. Formal tests of no effect were not rejected at levels of significance of 0.17 or smaller. All bands were able to reduce the mitral regurgitation; there was no significant difference in the repaired regurgitant fraction between the band types.

Robotic Manipulation Testing

The prototype band in its martensitic phase was manipulated easily using robotic instruments. The flexibility of the band allowed for excellent visualization of the annulus for suture placement without tension on existing sutures or surrounding tissue, as shown in Figures 4C and 4D. Generally, after the fourth suture, the Physio band became more difficult to manipulate; the band recoiled sharply, and stress on the sutures caused significant deformation of the annular tissue, shown in Figures 4A and 4B. The prototype band did not exhibit these attributes and was easily straightened and deployed through an 8-mm trocar, while the Physio could not be deployed through the trocar, as shown in Figure 5.

Comment

These evaluations demonstrate that the prototype NiTi reinforced annuloplasty band has similar mechanical characteristics to semi-rigid bands once deployed, can decrease mitral regurgitation as effectively as other semi-rigid bands in a dynamically pressurized environment, and can be inserted through a trocar and easily maneuvered and sutured using robotic instruments. This novel band has the potential to provide surgeons with a viable alternative to flexible bands when performing minimally invasive mitral valve repair, with potential indications for conventional (open) procedures and other heart valves. Continued

refinement of this prototype, followed by clinical trials and United States Food and Drug Administration approval, could result in a commercially available band of similar cost to existing semi-rigid bands.

Acknowledgments

This study was funded by the National Heart, Lung and Blood Institution (NHLBI) of the National Institutes of Health (NIH), Grant No. 1 R01 HL075489-03A1. The authors thank Edwards Lifesciences for their donation of the Physio bands used in this study.

References

1. Carpentier AF, Lessana A, Relland JY, et al. The “physio-ring”: an advanced concept in mitral valve annuloplasty. *Ann Thorac Surg.* 1995; 60:1177–86. [PubMed: 8526596]
2. Sharony R, Saunders PC, Nayar A, et al. Semi-rigid partial annuloplasty band allows dynamic mitral annular motion and minimizes valvular gradients: An echocardiographic study. *Ann Thorac Surg.* 2004; 77:518–22. [PubMed: 14759429]
3. Raffoul R, Uva MS, Rescigno G, et al. Clinical evaluation of the Physio annuloplasty ring. *Chest.* 1998; 113:1296–301. [PubMed: 9596309]
4. Kypson AP. Recent trends in minimally invasive cardiac surgery. *Cardiology.* 2007; 107:147–58. [PubMed: 16877865]
5. Es-Souni. Assessing the biocompatibility of NiTi shape memory alloys used for medical applications. *Anal Bioanal Chem.* 2005; 381:557. [PubMed: 15660223]
6. Fasol R, Meinhart J, Deutsch M, Binder T. Mitral valve repair with the Colvin-Galloway future band. *Ann Thorac Surg.* 2004; 77:1985–8. [PubMed: 15172250]
7. Richards A, Cook R, Bolotin G, Buckner G. A dynamic heart system to facilitate the development of mitral valve repair techniques. *Ann Biomed Eng.* 2009; 37:651–60. [PubMed: 19224369]
8. Dagum P, Timek T, Green GR, et al. Three-dimensional geometric comparison of partial and complete flexible mitral annuloplasty rings. *J Thorac Cardiovasc Surg.* 2001; 122:665–73. [PubMed: 11581596]

Fig 1.

(A) Prototype band at 24°C (martensitic phase) is easily straightened; (A–D) changes in shape and stiffness during heat-induced phase transformation (elapsed time approximately 5.0 seconds); (D) band at 37°C (austenitic phase) in final shape.

Fig 2. Endoscopic images show (A) normal, (B) failed, and (C) repaired mitral valve for prototype band, and (D) normal, (E) failed, and (F) repaired mitral valve for Physio band. Arrow indicates flail leaflet.

Fig 3.

Compression test results show stiffness of prototype band at 24°C (martensitic phase) and at 37°C (austenitic phase) in comparison with commercial bands.

Fig 4. Pictures from robotic evaluation show flexibility of (A, B) Physio ring (Edwards Lifesciences, Irvine, CA) and (C, D) prototype band. Arrows indicate tissue deformation and suture tension. Dotted line highlights mitral annulus.

Fig 5.
(A–D) Prototype band deployed through an 8-mm trocar; (E, F) Physio band can not be deployed through the trocar.

Table 1

Regurgitant Fraction for Each Heart at Low and High Peak Left Ventricular Pressure

Heart	Band Type	Band Size	LV Pressure (mm Hg)	FRF (%)	RRF (%)
1	Physio	26	120	46.9	17.7
			150	71.8	40.4
2	Prototype	26	120	20.5	17.9
			150	21.9	19.5
3	Physio	30	120	53.1	8.2
			150	74.9	35.1
4	Physio	31	120	22.1	14.5
			150	21.7	19.7
5	Prototype	26	120	25.8	14.1
			150	26.9	6.7
6	Physio	28	120	40.7	13.0
			150	46.7	17.6
7	Prototype	30	120	16.9	3.1
			150	13.7	-6.9 ^a
8	Physio	26	120	35.1	13.2
			150	53.5	16.3
9	Prototype	26	120	39.0	16.9
			150	48.2	20.5
10	Prototype	26	120	51.6	22.7
			150	66.7	26.9

^aRepaired output was greater than the baseline output resulting in a negative repaired regurgitant fraction (RRF).

LV = left ventricular; FRF = failed regurgitant fraction.

Table 2

ANOVA Mixed Model Results From Dynamic Flow Testing

Source	Sum of Squares (10 ⁻³)	F-Ratio	P-Value
Band type	2.93	0.75	0.4013
Pressure	0.53	0.24	0.6406
Pressure by band type	4.73	2.14	0.1873
FRF	19.05	8.59	0.0220
Random heart variable	61.81	3.48	0.0587

ANOVA = analysis of variance; FRF = failed regurgitant fraction.