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A Novel Shape Memory Alloy Annuloplasty Ring for Minimally Invasive Surgery: Design, Fabrication, and Evaluation

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Abstract

A novel annuloplasty ring with a shape memory alloy core has been developed to facilitate minimally invasive mitral valve repair. In its activated (austenitic) phase, this prototype ring has comparable mechanical properties to commercial semi-rigid rings. In its pre-activated (martensitic) phase, this ring is flexible enough to be introduced through an 8-mm trocar and easily manipulated with robotic instruments within the confines of a left atrial model. The core is constructed of 0.50 mm diameter NiTi, which is maintained below its martensitic transition temperature (24 °C) during deployment and suturing. After suturing, the ring is heated above its austenitic transition temperature (37 °C, normal human body temperature) enabling the NiTi core to attain its optimal geometry and stiffness characteristics indefinitely. This article summarizes the design, fabrication, and evaluation of this prototype ring. Experimental results suggest that the NiTi core ring could be a viable alternative to flexible bands in robot-assisted minimally invasive mitral valve repair.

Keywords

Mitral valve repair; Robotic surgery; Annuloplasty ring; Nitinol

INTRODUCTION

Mitral valve regurgitation occurs when the mitral valve, which is located between the left atrium and left ventricle, does not close properly during systole, thereby allowing a residual amount of oxygenated blood to leak back into the left atrium. Mitral valve regurgitation is often due to a structural abnormality of the valve, and is amenable to surgical intervention.¹² When possible, mitral valve repair is preferable to mitral valve replacement because of its efficacy, durability, and freedom from long-term anticoagulant drug therapy.²¹ A critical

component of most mitral valve repair techniques is reduction and stabilization of the mitral annulus by placement of an annuloplasty device. This is achieved by securing a full ring or partial band around the mitral annulus.

Commercial annuloplasty rings span a wide range of shape and stiffness characteristics; they can be broadly categorized as being rigid, flexible, or semi-rigid. Rigid rings have a solid core, usually titanium or a similar metal, enabling aggressive remodeling and support of the mitral annulus. They immobilize the posterior portion in a horizontal plane, thereby maintaining a theoretically optimal orifice area¹⁶; however, the rigidity of these rings has been shown to decrease natural annular motion during the cardiac cycle.²⁰ Flexible rings feature a polyester sewing cuff surrounding a compliant core, usually silicone. Researchers have shown that flexible rings allow for more natural motion of the mitral annulus, improved end-diastolic diameter, and increased left ventricle volume output.^{2,4,11} However, reported disadvantages of flexible rings include reduced annular remodeling and annular stability as compared to rigid rings.⁶

Semi-rigid rings were developed to provide flexibility along the mitral valve's anteroposterior axis and rigidity along its transverse axis, thus allowing natural movement while maintaining annular support.^{6,20} Semi-rigid rings are typically saddle shaped to better conform to the annular geometry of the mitral valve. Researchers have reported excellent outcomes associated with semi-rigid rings.^{14,18,20}

The conventional "open chest" approach to mitral valve repair is through median sternotomy, which involves a 25–30-cm skin incision and splitting of the sternum, allowing complete exposure and surgical access to the heart.⁸ Due to the surgical trauma of the sternotomy, patients in general require 9 weeks of recovery before resuming normal activities.⁸ Recent advances in closed-chest cardiopulmonary bypass, myocardial protection, three dimensional visualization, and robotic instrumentation have led to effective minimally invasive procedures for mitral valve repair.¹⁰ Patients experience less scarring, decreased pain levels, fewer complications, decreased hospital stays, and faster return to normal activity levels.⁸

The ultimate goal of robot-assisted mitral valve repair is to perform the surgery through an endoscopic approach, using only five small ports on the right chest wall: three for the robot arms, one for the binocular telescope, and an 8-mm "access port" through which sutures and other materials can be introduced or removed from the right pleural space. This approach would minimize pain experienced by the patient, as it would require little or no spreading of the ribs, and would hopefully allow for even better outcomes. One impediment to this goal is the need for a mini-thoracotomy incision if a semi-rigid annuloplasty ring is being used, since such a ring cannot be introduced into the pleural space or heart through an 8-mm trocar. Furthermore, rigid and semi-rigid rings are difficult to manipulate robotically within the confines of the left atrium; thus flexible rings are generally used.^{7,10,22} In order to provide an annuloplasty ring that is flexible enough to be deployed through a trocar, yet stiff enough to provide the benefits of a semi-rigid ring, a prototype ring with a NiTi shape memory alloy core (SMAC) ring has been developed.¹³ The NiTi core remains flexible in its low-temperature martensitic state for deployment, placement, and suturing. A transformation to its austenitic phase occurs at normal human body temperature, thus providing the final desired mechanical properties. This article summarizes the design, fabrication, and experimental evaluations of this prototype SMAC ring.

METHODS AND MATERIALS

NiTi Core

The prototype ring has three main components: a NiTi wire core, a silicone sheath, and a polyester sewing cuff. Unlike other semi-rigid rings, with cores made from cobalt alloys or ultra high-molecular-weight polyethylene, the SMAC prototype takes advantage of NiTi's unique shape memory characteristics. When heated above a critical temperature (the austenitic start temperature, A_s), NiTi undergoes an internal phase transformation in which the material changes from a compliant martensitic phase to a rigid austenitic phase.⁵ For the application described here, the austenite finish temperature (A_f) must be below normal human body temperature (37 °C) in order for the ring to retain the desired mechanical properties and optimal shape *in vivo*. Patient body temperature can be lowered to 26 °C or below during cardiac procedures,^{8,22} thus the martensite transition temperature must be above this temperature to ensure ring flexibility during insertion through the 8 mm trocar and manipulation within the heart.

The mechanical properties of the activated prototype (the NiTi core in its austenitic phase) were designed to match those of commercially available semi-rigid rings. A popular commercial ring was targeted for comparison: the Carpentier Edwards Physio (Edwards Lifesciences LLC, Irvine, CA, USA). The success of this semi-rigid ring in mitral valve repair has been well documented.^{6,14,20} In order to establish the requisite mechanical properties of the prototype's NiTi core, physical testing was performed on a Physio ring using an EnduraTec material testing machine (Bose Corporation, Eden Prairie, MN, USA). Experimental data from these tests were used in conjunction with finite-element analysis (FEA) to facilitate the design process. An FEA model was developed using ANSYSTM Release 9 software (Canonsburg, PA, USA) with 5994 solid92 elements. By simulating compression of the FEA model for a range of elastic moduli (80–120 GPa), it was determined that a Young's modulus of 94.8 GPa best matched the Physio's mechanical characteristics.

Based on the aforementioned design requirements, 0.50 mm diameter NiTi wire in a cold-worked state (55.6 wt.% Ni, $A_f = 39$ °C) was obtained for prototyping (NiTi #8, Fort Wayne Metals, Fort Wayne, IN, USA). Brass mandrels were designed and fabricated for shape setting the NiTi so that the prototype could conform to the non-planar shape of the mitral annulus. Each mandrel featured a three-dimensional saddle-shaped groove (26, 28, 30, or 32 mm inner-trigone dimensions) with stainless steel screws and pins to secure the NiTi wire during heat treatment. Annealing at 600 °C in air for 30 min followed by furnace cooling was found to produce the desired saddle shape and an A_f of 37 °C. Confirmation of A_f temperature was done by compressing the ring in the anterior–posterior direction using a universal testing machine (Applied Test Systems, Inc., Butler, PA, USA) in a temperature-controlled water bath.

Silicone Sheathing and Sewing Cuff

A custom silicone sheath, 2.54 mm OD, was fabricated from MoldMax 30TM (Smooth On, Easton, PA, USA). Although this saddle-shaped sheath conformed perfectly to the NiTi core in its austenite phase, experimental testing revealed that the molded sheath significantly increased the overall stiffness of the ring, especially in its martensitic phase. Silicone surgical tubing (2.38 mm OD, 0.80 mm ID) was determined to have less effect on the ring's stiffness, and met FDA and ISO 10993 biocompatibility standards. For this reason it was chosen for prototype fabrication.

The sewing cuff is intended to be in direct contact with the mitral valve annulus; therefore, it must be biocompatible and capable of retaining sutures. Polyester materials are biocompatible, durable, and have been used for heart valve sewing rings, vascular grafts, and endovascular stent grafts.²³ Therefore, a polyester knit fabric was selected as the sewing cuff material and was securely sewn around the SMAC ring.

Prototype Activation

Several preliminary tests were conducted to evaluate the characteristics of the SMAC prototype ring. Figure 1 illustrates the prototype's heat-induced phase transformation from martensite at 24 °C to austenite at 37 °C, a process that completes in approximately 5.0 s using a warm saline bath. In its low-temperature martensitic phase, the SMAC prototype was easily straightened and successfully deployed through an 8-mm trocar in preliminary testing (Fig. 2). The semirigid Physio could not be deformed, and therefore could not be deployed through the trocar, as shown in Fig. 3.

Evaluation Methods

In order to determine the efficacy of this novel annuloplasty design, five *ex vivo* evaluation stages were performed. Mechanical testing compared the compressive force vs. displacement of the SMAC ring to a Physio ring and another commercial semi-rigid ring, the SJM® Séguin Annuloplasty ring (St. Jude Medical Inc., St. Paul, MN, USA). In order to evaluate the effectiveness of each ring in correcting mitral valve regurgitation, static pressure tests were conducted by a cardiothoracic surgeon using explanted porcine hearts. Dynamic flow comparisons to the Physio ring were performed on a left heart pulse duplication system.¹⁵ Cyclic fatigue tests were performed to ensure that the SMAC ring's NiTi core would resist cyclic softening and cracking. Finally, qualitative robotic manipulation comparisons between a SMAC ring and a semi-rigid Physio ring were completed.

Mechanical Compression Tests

Compression tests were conducted using an ATS universal testing machine (Applied Test Systems, Inc., Butler, PA, USA) on the SMAC, Physio, and SJM® Séguin rings. Mechanical testing of the SMAC ring was conducted with the NiTi in its austenite state (37 °C), which represents the final state for the implanted ring as well as the martensite state (24 °C) to illustrate the SMAC ring's compliance during deployment. Rings were compressed 4 mm in the anterior–posterior orientation at a 2.5 mm/min loading rate using a 6.4-mm square mandrel. Rings were secured in a customized fixture on the anterior side in a water bath in the same manner as A_f temperature testing described previously.

Static Pressure Tests

Static pressure tests were performed by a cardiothoracic surgeon with training and clinical experience in robot-assisted mitral valve repair. An explanted porcine heart from a 70–100 kg swine was mounted in a fixture, and the left atrium was removed to access the mitral valve (Fig. 4). Mitral valve regurgitation was induced by cutting several of the chordae tendineae along the middle scallop of the posterior leaflet, thereby creating severe mitral regurgitation with a flail “P2” segment¹ of the posterior leaflet. Back-pressurizing the valve to 108 mmHg was accomplished using a static column of saline solution. Mitral regurgitation was assessed by collecting and measuring the saline solution that flowed back through the valve. The SMAC ring was sutured into place and then activated by resistive heating where a small electrical current (1.5 A) produced adequate heat for phase transformation. Mitral regurgitation was again quantified.

Dynamic Flow Tests

In order to evaluate the SMAC ring in a more physiologically realistic environment, dynamic flow testing was completed using a left ventricular pulse duplication system.¹⁵ This system dynamically pressurizes explanted porcine hearts, repeatedly subjecting the mitral valve to pressure waveforms and flow rates similar to those found *in vivo* (Fig. 5). By measuring changes in cardiac output and left heart pressures, mitral regurgitation in this system can be quantified.

A randomized study using five Physio rings and five SMAC rings was conducted using a stroke rate of 60 strokes per minute and a systolic fraction of 35%. Each ring was surgically sutured in a separate freshly explanted heart. A 0.9% saline solution heated to 40 °C was pumped through the system. The stroke volume was adjusted for each heart depending on size and tissue compliance and ranged from 35 to 40 mL/stroke. The stroke volume was kept constant throughout each experiment to ensure consistent fluid input. Because of the unique anatomy and tissue compliance of each heart, a baseline aortic output measurement was initially recorded. For each baseline measurement, aortic outflow resistance was increased until peak ventricular pressure reached 120 mmHg; the heart was then dynamically pressurized for 1 min while the aortic output was collected and measured. The left ventricle pressure was then increased to 150 mmHg, simulating a stressed heart, and output again was measured.

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. Additionally, chordae tendineae connecting the middle segment of the posterior leaflet (“P2”)¹ to the papillary muscles were severed to simulate chordal rupture. The valve was subjected to 35 mmHg static backpressure to ensure adequate mitral valve failure. The atriotomy incision was closed with cyanoacrylate adhesive and sutured. Output measurements were repeated at both 120 and 150 mmHg peak left ventricular pressure for 1 min.

In order to perform the repair, the atriotomy was reopened to expose the mitral valve. The valve was repaired with a triangular resection and leaflet re-approximation using a running monofilament suture (Fig. 6a). All rings were sutured to the annulus with interrupted sutures using the parachute technique (Fig. 6b).

The ring size was determined by the physical anatomy of the annulus, which ranged from 26 to 31 mm (trigone-to-trigone distance). The rings were secured to the annulus using interrupted horizontal mattress sutures with 12–14 sutures per ring (Fig. 7).

Static pressure (35 mmHg) was used to ensure there was no leakage through the valve before closing each atriotomy. The output measurements were again taken at 120 and 150 mmHg peak left ventricular pressure for 1 min. Endoscopic images of implanted Physio and SMAC rings are shown in Fig. 8. Mitral valve failed regurgitant fraction (FRF) was calculated as the percent difference between the failed valve output and baseline output measurements. Repaired regurgitant fraction (RRF) was calculated as the percent difference between repaired output and the baseline output.

Cyclic Fatigue Tests

Cyclical fatigue testing was conducted with the SMAC ring secured in a custom aluminum fixture (Fig. 9). The anterior portion of the ring (with open ends) was secured in the fixture, which was anchored to the base. The posterior portion of the ring was secured and the fixture was connected to a 10-g load cell (Model MLP-10, Transducer Techniques Inc.,

Temecula, CA) driven by a linear actuator (LinMot model PS01-37×120, LinMot, Inc., Elkhorn, WI, USA). In order to simulate annular movement during the cardiac cycle, the ring was subjected to a sinusoidal displacement with amplitude of 4 mm in the anterior–posterior direction. A custom LabVIEW Real-Time 8.2 application was developed to control the actuator and coordinate data acquisition (National Instruments, Austin, TX, USA). A cycle rate of 2.0 Hz was used for a total of 1.9 million cycles, which is equivalent to approximately 3.3 weeks *in vivo*. Position and force data for two sinusoidal periods were recorded every 1000 cycles. During the fatigue test, the ring was held at a constant temperature of 37 °C in a distilled water bath. A commercial temperature controller (Athena Controls Inc., Plymouth Meeting, PA, USA) with a stainless steel heating element and thermocouple positioned near the ring was used to regulate the temperature of the water bath.

Robotic Manipulation Tests

Qualitative comparisons of deployment and robotic manipulation were made between a SMAC ring in its flexible martensitic state and a Physio ring. Evaluations were conducted by a cardiothoracic surgeon trained in robotic procedures at the Intuitive Surgical Training Center in Sunnyvale, CA, USA, using the da Vinci[®] Surgical System. 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, ring manipulation and knot tying was robotically done. An explanted porcine heart was placed in a holding fixture, and a standard left atriotomy was performed to expose the mitral valve (Fig. 10).

Each ring was sutured to the annulus using individually inserted and knotted sutures without the use of an annuloplasty ring holder to simulate the minimally invasive procedure. Two Physio and two SMAC rings were sutured into four separate hearts. In each trial, the placement of the first suture was varied to evaluate multiple methods of insertion.

RESULTS

Mechanical Compression

Results from the mechanical testing of the SMAC ring, Physio ring, and SJM[®] ring are shown in Fig. 11. The mechanical testing indicated that the force vs. displacement for the SMAC ring is within 5.0% of the force vs. displacement for the commercially available rings. At a displacement of 3 mm, which has been shown to be the average displacement of the mitral valve annulus,^{3,9} the SMAC ring force is within 4.3% of the Physio ring, and within 7.3% of the SJM[®] ring. In addition, the increase in stiffness from the martensitic phase at 24 °C to the austenite phase at 37 °C demonstrates the ring's unique two-phase characteristics. At an anterior–posterior displacement of 3 mm, the activated (austenitic) SMAC ring was 80.5% stiffer than the same ring in its non-activated (martensitic) state.

Static Pressure

The results from the static pressure trials are presented in Table 1. The hearts were similar in size; however, the amount of induced mitral regurgitation varied significantly between the hearts. All trials showed a decrease in mitral regurgitation after the valve was repaired and ring sutured into the place.

Dynamic Flow

Percent regurgitant fraction data for each heart at both low and high left ventricular pressure are presented in Table 2.

A statistical model was developed to compare the effectiveness of the SMAC ring to the Physio ring. Volume data were normalized by the baseline measurements to eliminate the variation in the size of the hearts. The percent regurgitant fraction is shown for both the failed valve (FRF) and the repaired valve (RRF). All hearts experienced a decrease in mitral regurgitation after repair. A mixed model using the RRF was fit to the data which allowed for the random effects of the individual hearts to be taken into consideration. The model parameters also included *ring type*, *pressure*, the crossed factors *pressure* and *ring type*, and random effects for the heart. It was found that the RRF was positively associated with the FRF; therefore, the FRF was included as a covariate. A statistical analysis was obtained using the mixed procedure of the statistical software package SAS (SAS Institute, Incorporated, Cary, NC, USA). The ANOVA table (Table 3) quantifies the degree to which different factors in the model explain variability in RRF.

Cyclic Fatigue

Test data acquired from the first and the last cycles are shown in Fig. 12. A sinusoidal model was fit to each sample. A paired *t*-test showed no statistical difference in the amplitude parameter of the first 500 samples and the last 500 samples ($p < 0.005$).

Micrographs were taken (Hirox Digital Microscope KH-7700, Hirox Co. Ltd., River Edge, NJ, USA) before and after fatigue testing to inspect for any defects or cracking. Images were taken at the maximum bend radius (the maximum strain point from ANSYS simulations) at magnifications up to 280 $\times$. The micrographs did not reveal any cracks or defects of the NiTi core.

Robotic Manipulation

Surgical assessment of the SMAC ring during robotic manipulation trials allowed for suture placement without tension on existing sutures or surrounding tissue (Fig. 13). The ductility of the unactivated SMAC ring resulted in the ring maintaining its position without the constant aid of the robotic grips which allowed the surgeon to have both robotic arms available for knot tying. Conversely, the Physio ring recoiled sharply if not held in place with robotic grips, and stress on the sutures caused significant deformation of the annular tissue as shown in Fig. 14.

DISCUSSION

Mechanical testing revealed that the SMAC prototype ring remained flexible at 24 °C. Following phase transformation to its austenitic state, the ring had comparable mechanical properties to two popular commercial semi-rigid rings.

Static pressure testing demonstrated that the SMAC ring was able to reduce mitral valve regurgitation in all trials. Minimal leakage of the valve after repair was caused by the suture holes, which, in a dead heart, do not clot and seal. The variation in the degree of failure cannot be controlled; the cutting of the chordae tendineae will result in different failure for each heart due to its unique anatomy. Static pressure testing also revealed that the SMAC ring size, which was based on average human anatomy, was larger than optimal for the porcine hearts used in the surgical evaluations. Subsequent measurements of several explanted hearts from 70 to 100 kg swine were taken to determine the optimal ring dimensions for the porcine model. The ring sizes, 26–30 mm, were determined to accommodate the variation in porcine hearts.

ANOVA analysis of dynamic testing data showed that much of the variability is explained by the degree to which the valve was damaged, FRF. Mitral valve output varies depending

on the pressure, and this difference was accounted for by taking all measurements at both pressures and using the pressure-specific outflow measurements for analysis. Results showed no evidence of any effect due to ring type or pressure. Formal tests of no effect were not rejected at levels of significance (p -value) of 0.17 or smaller. Both the Physio and the SMAC rings were able to reduce the mitral regurgitation; there was no significant difference in the RRF between the rings. Based on the dynamic flow testing, the mitral regurgitation repair is comparable between the Physio semi-rigid ring and the SMAC ring.

The explanted porcine hearts used in both the static pressure and dynamic flow test were freshly obtained; however, the tissue compliance is notably different from live hearts. A saline solution was used, which does not have the same viscosity as blood; however, the saline solution should accentuate any mitral valve regurgitation, and all testings were comparative. No sterilization of the SMAC ring was completed during these trials, both steam and water autoclaving have been shown to be effective sterilization methods that do not affect the properties or biocompatibility of NiTi.¹⁹

Fatigue testing of the SMAC did not reveal any significant changes in material properties, or result in any cracks or changes in the transformation temperature. NiTi fatigue is dependent on the material composition and processing history; therefore, these results are specific to this material. Based on these results, the SMAC ring shows promise as a safe, durable ring for annuloplasty repair.

The SMAC ring in its martensitic phase was readily manipulated using the da Vinci[®] Surgical robot. The surgical assessment of the SMAC ring demonstrated that the ring could be easily introduced through the trocar and manipulated with the robotic instruments. During robotic suturing, the flexibility of the SMAC ring allowed for clear visualization of the annulus. Overall, the subjective surgical assessment of the SMAC ring was that it was easy to manipulate, allowed for excellent visualization during suture placement, and placed minimal tension on the surrounding tissue and suture.

These *ex vivo* evaluations clearly demonstrate the feasibility and potential benefits of the SMAC ring for mitral valve repair. However, there are limitations to *ex vivo* valve models that warrant further investigation. The *in vivo* cardiac cycle subjects implanted devices to complex dynamic conditions that cannot be duplicated in bench-top tests. Cardiac muscle activation (including atrial, annular, ventricular, and papillary zones) plays a critical role in the operation of the native mitral valve, but is absent (or sometimes approximated) in *ex vivo* models. Although the individual components of the SMAC ring have been previously evaluated for biocompatibility, an *in vivo* study is required to observe any side effects, both short- and long-term, associated with device implantation. Future research will include *in vivo* animal testing to more accurately assess these issues.

CONCLUSION

Over the last decade, advances in closed-chest cardiopulmonary bypass, cardioplegic arrest methods, voice-controlled endoscopes, and three-dimensional visualization have all been enabling technologies for minimally invasive cardiac procedures.¹⁰ The SMAC ring has the potential to satisfy the need for a semi-rigid ring in robotic mitral valve repair. Current semi-rigid rings cannot fit through 8 mm trocars and are difficult to maneuver in the confined space of the left atrium with robotic instruments. The SMAC ring has similar mechanical characteristics to semi-rigid rings once deployed. The decrease in mitral regurgitation in both the static pressure and dynamic flow testing was comparable using the SMAC ring to the Physio ring. Cyclic fatigue testing has demonstrated that the ring can withstand the cyclic movement of the mitral annulus during the cardiac cycle. When sutured into place

with robotic instruments, there was reduced tension on the suture and deformation of surrounding tissue. The surgical assessment of the SMAC ring was that it provided excellent visualization of the annulus, and was easily maneuvered with the robotic instruments. These evaluations have shown that the SMAC ring has the potential to provide surgeons a viable alternative to flexible rings when performing minimally invasive robotic mitral valve repair.

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FIGURE 1.

(a) SMAC prototype ring at 24 °C (martensitic phase) is easily straightened; (b, c) changes in shape during heating and associated phase transformations; (d) ring at 37 °C (austenitic phase) in final shape. Total time is approximately 5 s.

FIGURE 2.
SMAC prototype straightened and deployed through an 8-mm trocar using a da Vinci robotic end effector.

FIGURE 3.
Semi-rigid Physio ring cannot be inserted through an 8-mm trocar.

FIGURE 4.

(a) Explanted porcine heart with left atrium removed, secured in fixture for static pressure testing. Static column of saline provides back pressure on mitral valve. (b) Ring sutured into porcine heart and activated by Joule heating, wires connected to a power supply.

FIGURE 5.
Explanted porcine heart connected to the left heart pulse duplication system.¹⁵

FIGURE 6.

(a) Leaflet repair after triangular resection using running monofilament suture, arrow indicates repair. (b) Physio ring inserted using parachute technique.

FIGURE 7. Static pressure check after mitral valve repair: (a) SMAC ring, 26 mm. (b) Physio ring, 26 mm.

FIGURE 8.

Endoscopic pictures during dynamic flow testing. (a, d) Normal mitral valve, (b, e) valve after mitral regurgitation has been induced, arrow indicates flail leaflet. (c) Repaired valve with the SMAC ring. (f) Repaired valve with the Physio ring.

FIGURE 9. Solid model of fatigue testing set-up, anterior of ring is held fixed; posterior is displaced 4 mm per cycle at a rate of 2 Hz.

FIGURE 10. Set-up for robotic evaluation with porcine heart placed in fixture. The da Vinci® surgical robot with two robot arms and endoscope attached. Surgeon seated at console.

FIGURE 11.
Compression test results for commercial rings and SMAC ring (37 and 24 °C).

FIGURE 12.
Two periods of fatigue test data: cycle 1 vs. cycle 1.9 million.

FIGURE 13.

Robotic evaluation using SMAC ring, dashed line indicates mitral annulus. (a) Eight sutures in place, ring can be easily repositioned for visualization without stressing annular tissue. (b) One suture remaining.

FIGURE 14.

Robotic evaluation using Physio ring, dashed line indicates mitral annulus. (a) Four sutures in place, arrows indicate tissue stresses and deformation during repositioning. (b) Eight sutures in place.

TABLE 1

Static flow testing results from three individual explanted porcine hearts.

Trial	1	2	3
Inner trigone distance (cm)	3.2	3.6	3.1
Anterior-posterior distance (cm)	2.2	2.5	2.7
Maximum transverse distance (cm)	3.6	3.8	3.8
Regurgitation: failed valve (mL/min)	2275	716	533
Repair valve with activated ring (mL/min)	712	350	137
% Reduction after repair	68.7	48.9	25.7

Regurgitation is the backflow through the mitral valve.

TABLE 2

FRF and RRF for Physio rings and SMAC rings during dynamic flow testing.

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

Each ring was evaluated at low pressure, 120 mmHg and high pressure, 150 mmHg.

^a A valve that had a repaired regurgitant volume that was greater than the baseline measurement, possibly due to a natural defect.

TABLE 3

ANOVA table for mixed model for RRF, the main source of error in the model is due to FRF and the random heart effect variable.

Source	Degrees of freedom	Sum of squares (10^{-3})	Mean square (10^{-3})	F-ratio	p-value	Error degrees of freedom
Ring type	1	2.93	2.93	0.75	0.401	14.67
Pressure	1	0.53	0.53	0.24	0.641	7
Pressure $\times$ ring type	1	4.73	4.73	2.14	0.187	7
FRF	1	19.05	19.49	8.59	0.022	7
Random heart effect variable	8	61.81	7.73	3.48	0.059	7
Residual	7	15.52	2.217	—	—	—