

An Intra-Annular 'Hemispherical' Annuloplasty Frame for Aortic Valve Repair

J. Scott Rankin

Centennial Medical Center, Vanderbilt University, Nashville, TN, USA

Background and aim of the study: A 'Hemispherical' model of aortic valve geometry was developed in which normal human cadaveric aortic valve leaflets could be represented as three hemispheres nested within a cylindrical aorta. By mathematically describing the junction between the leaflets and aorta, the normal three-dimensional annular geometry of the aortic valve could be defined. In this study, a prototype annuloplasty frame based on this model was tested as a repair device in isolated porcine aortic root preparations.

Methods: Eight isolated porcine aortic roots were perfused with water at a constant pressure of 75 mmHg, and valve leakage was measured before and after the vertical incision of one to three sub-commissural areas to create valve incompetence. Annuloplasty frames then were sutured directly to the valve annuli, and the degree of leakage re-determined. The model predicted that the leaflet free-edge length could be used to define the valve diameter necessary to create competence, and this interaction was tested by varying frame size within the protocol. Post-

repair leaflet function also was evaluated using high-speed video. Differences were assessed using a two-tailed paired *t*-test.

Results: All eight normal porcine aortic valves had negligible baseline leak. With sub-commissural incision, the mean (\pm SD) regurgitant volume was increased to 522 ± 378 ml/min. After annuloplasty frame insertion, the measured leak decreased to 52 ± 40 ml/min ($p = 0.004$). The best results were obtained with a frame diameter 5-6 mm smaller than the leaflet free-edge length. Data recorded using high-speed video suggested a normal dynamic valve function after frame insertion.

Conclusion: A three-dimensional 'Hemispherical' intra-annular annuloplasty frame was developed for aortic valve repair. Insertion of the frame into the disrupted porcine valve annuli routinely and effectively restored valve competence. These positive initial results support the continued testing and application of this aortic annuloplasty device.

The Journal of Heart Valve Disease 2010;19:

A need exists for a stable annuloplasty technique during aortic valve repair. Most current approaches utilize the 'sub-commissural annuloplasty', which closes the top 1 cm of all three aortic commissures (1,2). This technique reduces annular circumference and favorably alters valve geometry by raising the leaflets to a more vertical orientation with a greater coaptation area. Coupled with leaflet 'plication' techniques to correct prolapse (3-7), this method currently allows the repair of most tricuspid and bicuspid aortic valve pathologies associated with pure aortic insufficiency.

Yet, concern persists regarding the long-term performance of commissural annuloplasty, since suture annuloplasty of the commissures does not control the entire annulus and leaves a potential for late dilatation and recurrent valve dysfunction. This principle certainly has been confirmed for mitral and tricuspid repair (8-10), and likely also pertains to the aortic valve (11-13). Thus, the study aim was to develop and test a three-dimensional (3-D) annuloplasty frame for restoring and maintaining the normal geometry of the entire aortic valve annulus.

Materials and methods

Geometric model

The design of this device was based on a 'Hemispherical' model of aortic valve geometry (14),

Address for correspondence:
J. Scott Rankin MD, 320 Lynnwood Blvd., Nashville, TN 37205, USA
e-mail: jsrankinmd@cs.com

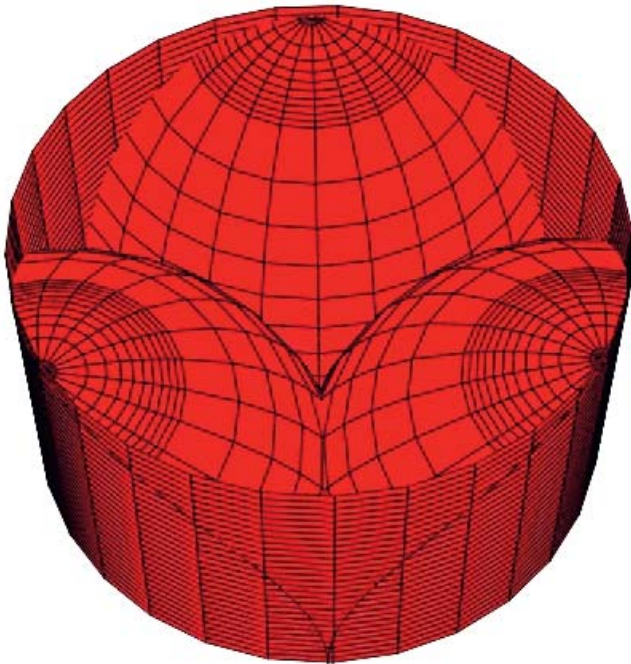


Figure 1: Model of aortic valve geometry in which the three leaflets are represented as segments of hemispheres nested within a cylindrical aorta. The dark line of leaflet-aortic intersection defines the geometry of the aortic 'annulus fibrosus'. With the model, the heights of the commissural posts are equal to one radius of annular diameter.

in which the valve leaflets were represented as three hemispheres nested within a cylindrical aorta (Fig. 1). Assuming that the junction of the leaflets and aorta represented the 'annulus fibrosus' of the aortic valve (14), the intersection of the 3-D spherical equations for the leaflets and the cylindrical equation for the aorta produced a three-pointed, crown-shaped representation of the aortic valve annulus (Fig. 1). By programming a computerized milling machine with the 3-D coordinates of the annulus for each diameter (17 to 27 mm in 2-mm increments), one-piece frames could be machined from tubes of titanium over a variety of sizes. By using the model, the heights of the frame posts were made equal to the frame radius at each size. Subsequently, Dacron sewing rings were stitched to the frames, allowing the devices to be sutured to the aortic valve annulus. A completed prototype device is shown in Figure 2.

Experimental protocol

Eight frozen porcine hearts were thawed, and both coronary arteries ligated flush with the aorta. All extraneous heart tissue was excised, leaving only the ascending aorta, aortic root, and aortic valve. The distal aorta was attached to 1 cm (3/8th inch) polyvinyl chloride tubing connected to a water reservoir that was

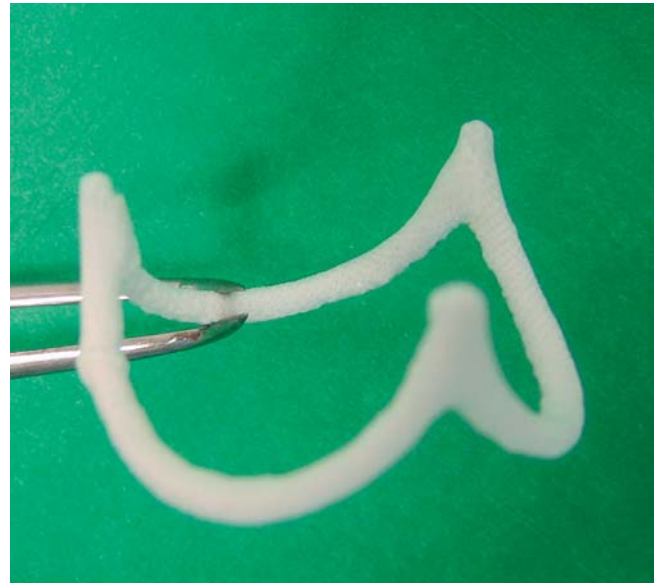


Figure 2: The prototype 'Hemispherical' annuloplasty frame (see text for details).

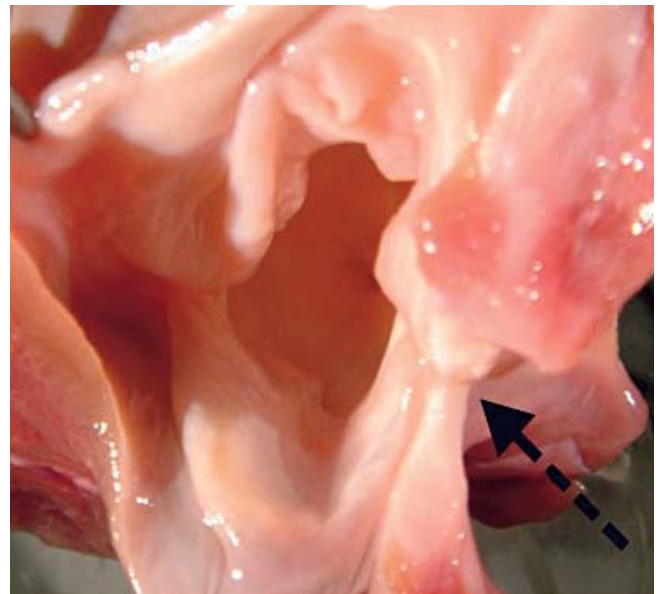


Figure 3: The vertical incision in the commissure between the right and non-coronary leaflets of the aortic valve. To create significant leak, the incision had to be carried almost to the top of the commissure. Also note the highly fibrous nature of the sub-commissural area in the porcine heart.

After multiple incisions, the leaflets were basically dangling independent of one another; however, each leaflet in this model was essentially normal and could be made to resume adequate coaptation after mounting on the annuloplasty frame.

at a height above the aorta equivalent to 75 mmHg pressure. Thus, removing a clamp on the tubing dis-

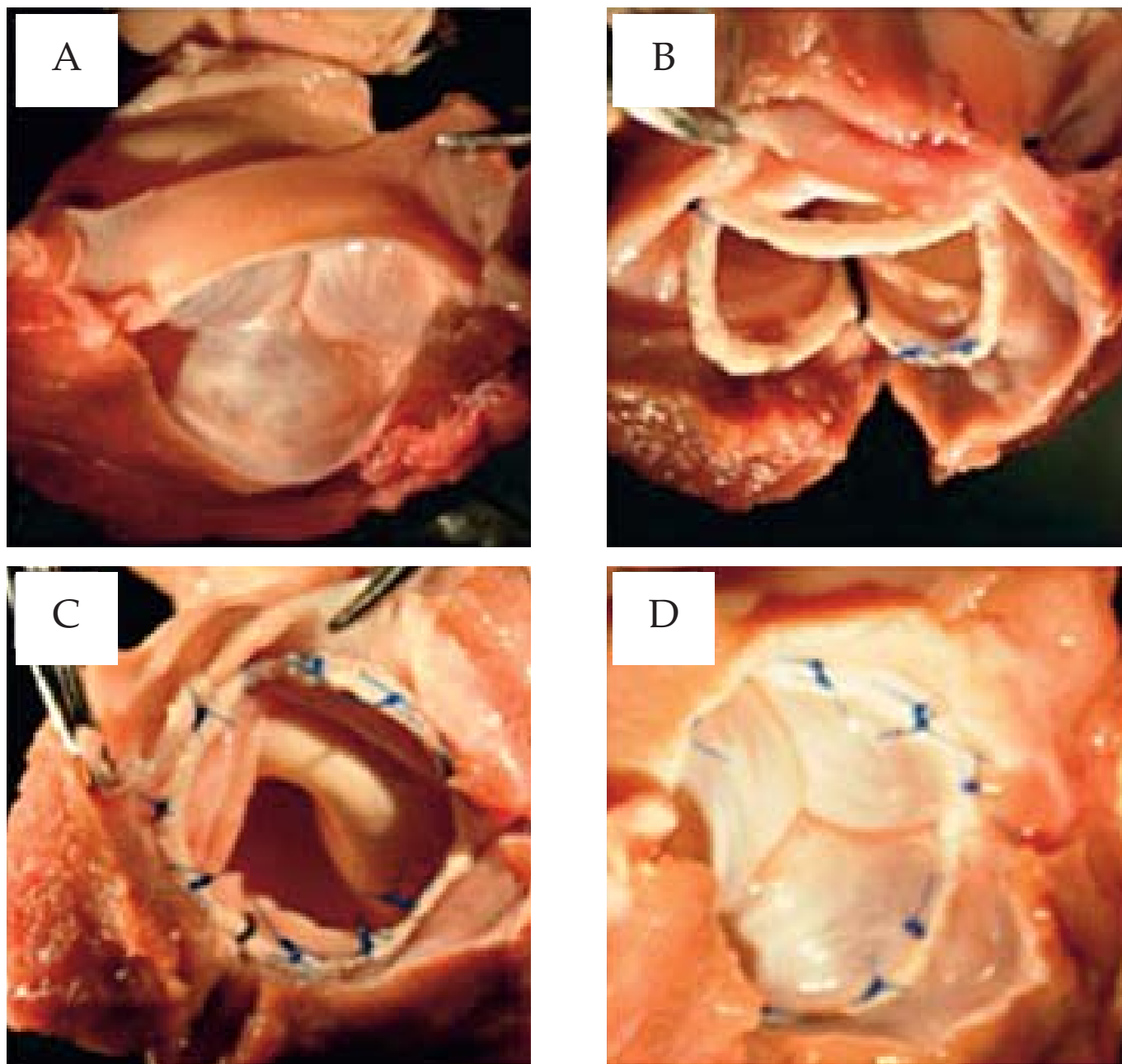


Figure 4: Sequences in the experimental protocol: A) Valve leak at baseline was minimal. B) Sub-commissural areas have been incised vertically, disrupting the annular geometry and creating aortic insufficiency; the frame is being sutured to the aortic valve annulus; posts first, and then the cusp sutures. C) The intra-annular insertion of the frame is completed. D) The aortic valve is again pressurized, and the leaflets coapt normally with minimal valve leak.

tended the aortic root with water at a pressure of 75 mmHg. Leakage of the aortic valve then was measured by 30-s collection of regurgitant water into a 500 ml beaker positioned beneath the preparation.

After baseline measurements had been obtained, vertical incisions were made in one to three of the aortic valve commissures, almost to the top of the sub-commissural area (Fig. 3). Quite deep incisions (and more than one) were necessary to make the valve leak

significantly. The degree of leak was varied somewhat by increasing the depth of the incisions into the commissures and also the number of commissures incised. The clamp on the tubing again was removed, and a timed collection of increased regurgitant volume obtained.

The free-edge length of the right coronary leaflet was then measured by placing a suture next to the leaflet, and a frame diameter was selected that was 4 to 11 mm

Table I: Individual data from all eight studies.

Study no.	Leak (ml/min)			Leaflet length (mm)	Frame diameter (mm)
	Control	Incised	Repaired		
1	97	97	97	25	21
2	0	1000*	40	32	21
3	0	720	130	32	21
4	15	1000*	90	32	21
5	0	1000*	38	34	27
6	0	90	0	30	25
7	0	120	30	32	27
8	0	450	45	33	27
Mean	-	522 ⁺	52	-	-
SD	-	378	40	-	-

*p <0.005, Repaired versus Incised

*1000 denotes volumes in excess of the 500 ml/30 s capacity of the beaker.

Note: Study 1 had a small baseline leak and only one commissural incision which did not worsen the insufficiency. Extreme downsizing of the frame produced minor degrees of prolapse, and larger residual leak. A single plication stitch of a prolapsing right coronary leaflet in Study 3 eliminated regurgitation (see Fig. 5). In general, a frame diameter of approximately 5-6 mm less than leaflet free-edge length seemed to function best.

smaller than leaflet free-edge length. Based on experience with the previous model (14), a relationship should exist between the leaflet free-edge length and the valve diameter necessary to create competence; thus, by varying this relationship within the protocol,

an assessment could be obtained in the intact heart. Each frame was sutured into the aortic valve annulus just under the leaflets, using horizontal mattress sutures. The first step was to place mattress sutures of 4-0 Prolene into the top 1 cm of each commissure to

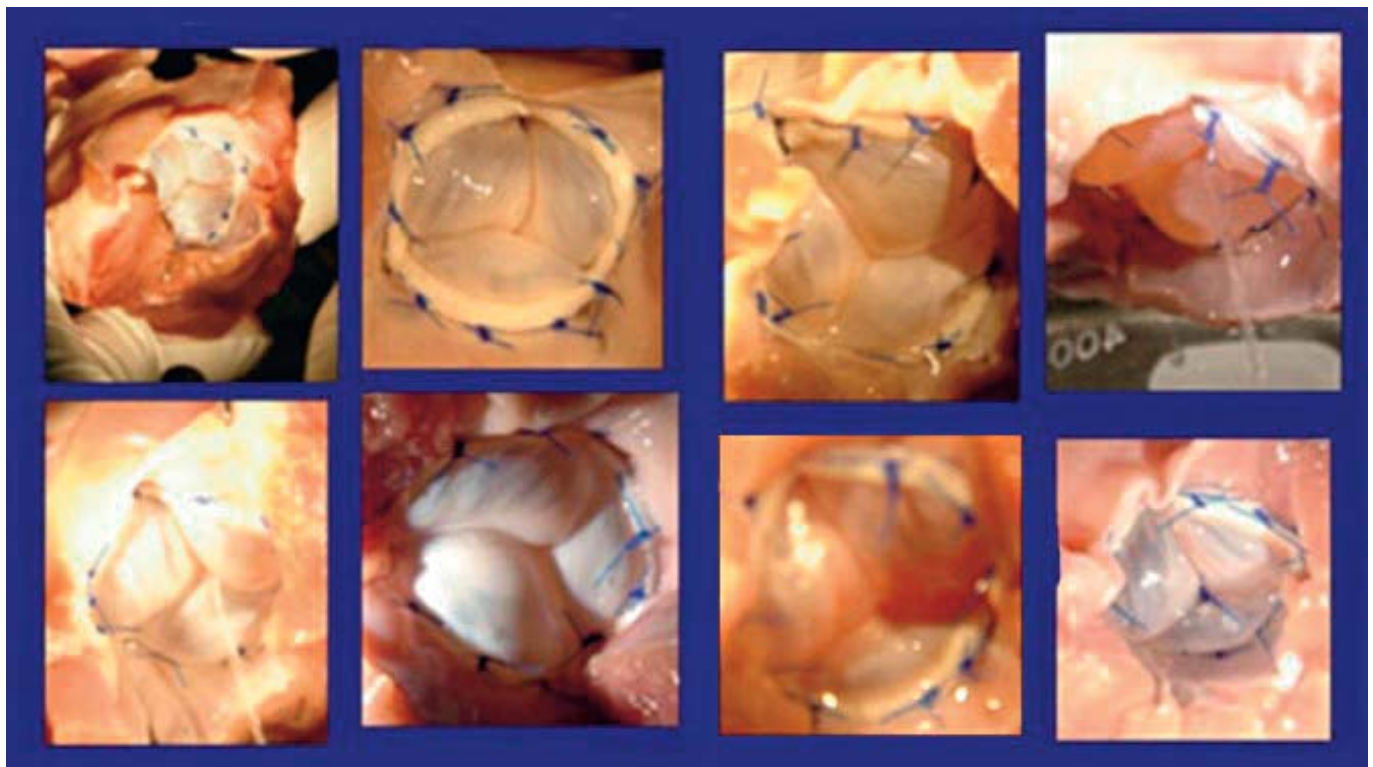


Figure 5: Photographs of pressurized valves from all eight studies after insertion of annuloplasty frames. Several of the frames had been severely downsized (see Table I), and exhibited minor degrees of 'induced' prolapse and a central valve leak. In the bottom-right valve (Study 3), a leaflet plication stitch was placed after measurements were made; this raised the leaflet, corrected the prolapse, and reduced the leak.

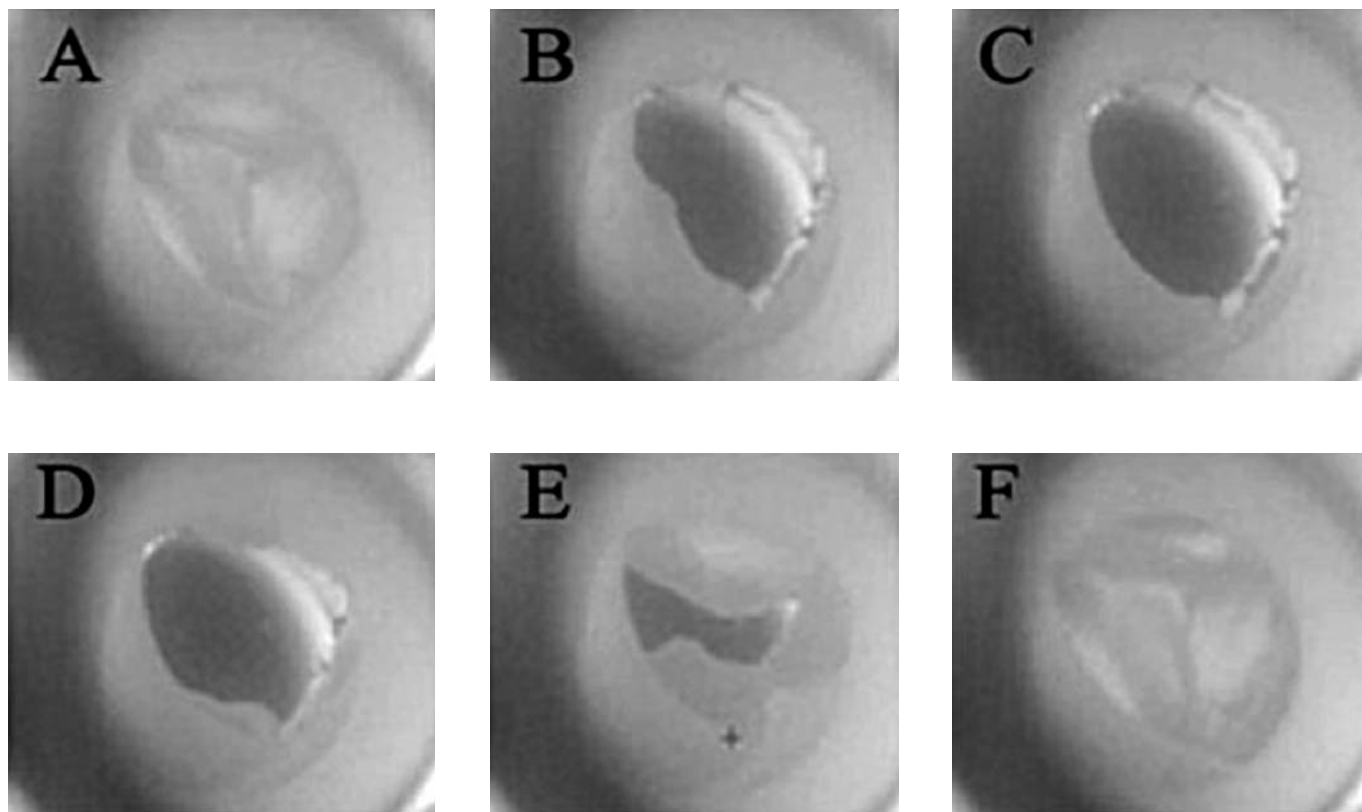


Figure 6: Sequences of valve opening and closing after annuloplasty frame insertion. High-speed video frames were acquired at 1000 fps; from frame A to B the valve leaflets open in 1 ms. Frame C shows the valve in mid-ejection, with the leaflets at maximal opening. The intra-annular annuloplasty device is visible through the valve, positioned just beneath the leaflets. In frame D, the valve begins to close, and then closes over the next two frames (E and F) in less than 2 ms. These findings suggest a relatively normal valve function after annuloplasty with the 'Hemispherical' device.

orient the frames circumferentially, incorporating the posts into each sub-commissural area with a Cabrol-like stitch (1). In this way, the frame posts were initially fixed under the commissures, and the frames were oriented to the valve. After tying all three post sutures, three additional horizontal mattress sutures were placed into the annulus of each cusp and then sutured to the Dacron sewing ring of the frame (Fig. 4). After intra-annular frame insertion, the aortic root again was pressurized and the timed regurgitant volume re-measured. Changes in valve leak from the incised regurgitant state to that obtained after frame annuloplasty were assessed using a two-tailed paired *t*-test. A *p*-value <0.05 was considered to be statistically significant.

In a ninth porcine root, another frame was sutured to the aortic valve annulus in an identical fashion, and the valve and root were mounted on a pulse duplicator which incorporated a high-speed (1000 fps) video camera to visualize valve opening and closing after frame insertion. Videos were obtained during simulated normal valve function with physiologic pressures and stroke volumes.

Results

Most valves were completely competent at control, with minor baseline leaks only in two cases (Table I). The commissural incision disrupted the leaflet geometry and produced valve regurgitation; however, the stability of the valve was impressive, and in general incisions to the top of the sub-commissural area, and of two or more commissures, were required to produce any significant leakage (Study 1 included only one incision and experienced a negligible increase in minor baseline regurgitation). Suturing the annuloplasty frames to the disrupted annuli led to reconstruction of the valve geometry in all cases (Fig. 5), but those annuli with a downsizing of the frame diameter to 10-11 mm smaller than the leaflet free-edge length tended to exhibit minor degrees of 'induced' leaflet prolapse, often involving the slightly larger right coronary cusp. Prolapse produced central jets of regurgitation (Fig. 5), but frames with diameters that were 5-6 mm smaller seemed to be associated with a more symmetrical leaflet coaptation and less residual leak. In the valve with the most prolapse and leak (Study 3; Fig. 5, bot-

tom right), a small plication stitch was taken in the leaflet free edge adjacent to the nodulus arantius, which corrected the prolapse and produced complete competence. Video frames of valve leaflets opening and closing dynamically in the pulse duplicator after frame insertion are shown in Figure 6. The dynamic function of the leaflets appeared normal, with opening and closing occurring efficiently in approximately one to two video frames, or over 1-2 ms.

Discussion

The aortic valve is contained within the aortic root and is subject to dysfunction resulting from diseases that alter the root geometry. Dilatation of the root and valve annulus is a common derangement producing aortic regurgitation, and a stable method of annuloplasty would be useful to re-establish normal valve geometry and competence. Many methods of aortic valve annuloplasty have been devised, but most have tended to distort the leaflet geometry and even increase leakage. In 1966, Cabrol and associates reported the technique of sub-commissural annuloplasty (1), in which they used horizontal mattress sutures to close the top 1 cm of each commissure. This not only reduced the annular diameter but also altered the root geometry by raising the leaflets to a more vertical coaptation plane. In cases with mild to moderate root pathology and no leaflet prolapse, the commissural annuloplasty performed well; however, with more severe root anomalies and/or leaflet prolapse, commissural annuloplasty alone was associated with a high failure rate (2). The advent of leaflet 'plication' to correct prolapse now provides an effective and reliable method of approaching a greater number of anomalies (3-7). The abandonment of ineffective methods (15), an increasing use of autologous pericardial leaflet augmentation, and the refinement of other leaflet techniques have led to an expansion of the pathologies that can be repaired (16-22). However, the achievement of a stable aortic valve annuloplasty remains a significant problem.

Currently, most regurgitant aortic valves (including bicuspid valves) can be successfully repaired with combinations of commissural annuloplasty and leaflet procedures, such as plication or pericardial augmentation (23). However, concern exists about the long-term fate of commissural annuloplasty, since most of the annulus is not controlled, and a potential for late annular dilatation exists. In fact, such a late postoperative problem is being encountered with increasing frequency (H.-J. Schäfers, personal communication, May 2009), suggesting the need for a more stable method of aortic valve annuloplasty. In the mitral and tricuspid valves, although suture annuloplasty of the commis-

ures was successful initially in correcting regurgitant lesions due to annular dilatation, a significant number of late recurrences occurred. The advent of mitral and tricuspid ring annuloplasty (24) improved these outcomes, and it is now clear that the geometric control of the entire annulus is advantageous during cardiac valve repair.

The development of a similar 'annuloplasty ring' for the aortic valve has been hampered by the fact that the aortic annulus is not a 'ring' (14). There also has been a lack of understanding of the complex 3-D aortic valve geometry. Therefore, an effort was made to define annular geometry in the human cadaver laboratory (14), and this led to the development of a 'Hemispherical' model of the aortic valve, in which the junction of the leaflets and aorta could be represented mathematically (see Fig. 1). From this model, a prototype annuloplasty frame was developed (Fig. 2) which, in the present study, was tested as a repair device in incompetent aortic valves.

The results of the present study were encouraging. In a simple model of isolated porcine aortic roots, severely disrupted and leaking valves could be made competent by the intra-annular insertion of the annuloplasty frame. Moreover, the restoration of leaflet geometry and coaptation seemed excellent (Fig. 5), and the residual leak was minimal (Table I). Extreme downsizing of the frame tended to produce minor degrees of leaflet prolapse, and it appeared that the best leaflet coaptation occurred at a frame diameter of 5-6 mm less than leaflet free-edge length in valves with symmetrical leaflets (Table I). This finding was of much interest, and suggested that the leaflet measurements could be used both preoperatively and intraoperatively to determine the frame diameters and geometry necessary to produce valve competence, independent of any pathologic root dilatation or other anomalies. Finally, high-speed videos of valve function were consistent with normal valve dynamics after repair (Fig. 6).

It should be stressed that this frame would comprise only one component of aortic valve repair, namely a stable, long-term method of annuloplasty. Any pre-existing leaflet prolapse or associated abnormalities would need to be addressed with leaflet plication or other procedures (3), in order to optimize the leaflet 'effective height' (25) and coaptation area. However, coupled with appropriate leaflet procedures, and including a variety of asymmetric and bicuspid frames, the clinical use of this type of annuloplasty could make aortic valve repair a routine clinical procedure with stable long-term results.

Although these results are suggestive of success in human disease states, the animal model employed in the present study may differ from the pathologic

human geometry associated with aortic insufficiency. In fact, relatively little is known about the pathologic geometry of human aortic valve disease. Therefore, further studies are currently underway to define pathologic geometry in intact humans, and to determine if the current frame designs would be appropriate for human disease states. Nevertheless, it does appear that aortic valve annuloplasty using a 3-D frame could prove effective for clinical application, and the positive outcome of the present study suggests a need for the continued development and testing of such a device.

Acknowledgements

These studies were funded in part by grants from the Sorin Group and from BioStable Science and Engineering Inc., Austin, TX, USA. Dr. Rankin is a consultant for BioStable Science and Engineering Inc. and Chief Medical Officer of HAART, Inc.

References

1. Cabrol C, Cabrol A, Guiraudon G, et al. Le traitement de l'insuffisance aortique par l'annuloplastie aortique. *Arch Mal Coeur Vaiss* 1966;59:1305-1312
2. Rocache M, Cabrol C, Cabrol A, et al. Résultats éloignés des annuloplasties aortiques. *Arch Mal Coeur Vaiss* 1972;65:1123-1128
3. Aicher D, Langer F, Adam O, et al. Cusp repair in aortic valve reconstruction: Does the technique affect stability? *J Thorac Cardiovasc Surg* 2007;134:1533-1539
4. Schäfers H-J. Reconstruction of the bicuspid aortic valve. *Op Tech Thorac Cardiovasc Surg* 2007;12:2-13
5. Khoury G, Vanoverschelde JL, Glineur D, et al. Repair of aortic valve prolapse: Experience with 44 patients. *Eur J Cardiothorac Surg* 2004;26:628-633
6. Chiappini B, Pouleur A-C, Noirhomme P, et al. Repair of trileaflet aortic valve prolapse: Mid-term outcome in patients with normal aortic root morphology. *Interact Cardiovasc Thorac Surg* 2007;6:56-59
7. Schäfers H-J, Aicher D, Langer F. Correction of leaflet prolapse in valve preserving aortic replacement: Pushing the limits? *Ann Thorac Surg* 2002;74:1762-1774
8. Rankin JS, Alfery DD, Orozco RE, et al. Techniques of artificial chordal replacement for mitral valve repair: Use in multiple pathologies. *Op Tech Thorac Cardiovasc Surg* 2008;13:74-82
9. Rankin JS, Burrichter CA, Walton-Shirley MK, et al. Trends in mitral valve surgery: A single practice experience. *J Heart Valve Dis* 2009;18:359-366
10. Tang GH, David TE, Singh SK, et al. Tricuspid valve repair with an annuloplasty ring results in improved long-term outcomes. *Circulation* 2006;114:I577-I581
11. Carr JA, Savage EB. Aortic valve repair for aortic insufficiency in adults: A contemporary review and comparison with replacement techniques. *Eur J Cardiothorac Surg* 2004;25:6-15
12. Izumoto H, Kawazoe K, Ishibashi K, et al. Aortic valve repair in dominant aortic regurgitation. *Jpn J Thorac Cardiovasc Surg* 2001;49:355-359
13. Izumoto H, Kawazoe K, Kawase T, Kim H. Subvalvular circular annuloplasty as a component of aortic valve repair. *J Heart Valve Dis* 2002;11:383-385
14. Rankin JS, Dalley AF II, Crooke PS, et al. A 'Hemispherical' model of aortic valve geometry. *J Heart Valve Dis* 2008;17:179-186
15. Trusler GA, Moes CAF, Kidd BSL. Repair of ventricular septal defect with aortic insufficiency. *J Thorac Cardiovasc Surg* 1973;66:394-403
16. Cosgrove DM, Rosenkranz ER, Hendren WG, Bartlett JC, Stewart WJ. Valvuloplasty for aortic insufficiency. *J Thorac Cardiovasc Surg* 1991;102:571-577
17. De La Zerda DJ, Cohen O, Fishbein MC, et al. Aortic valve-sparing repair with autologous pericardial leaflet extension has a greater early re-operation rate in congenital versus acquired valve disease. *Eur J Cardiothorac Surg* 2007;31:256-260
18. Minakata K, Schaff HV, Zehr KJ, et al. Is repair of aortic valve regurgitation a safe alternative to valve replacement? *J Thorac Cardiovasc Surg* 2004;127:645-653
19. Casselman FP, Gillinov AM, Akhrass R, et al. Intermediate-term durability of bicuspid aortic valve repair for prolapsing leaflet. *Eur J Cardiothorac Surg* 1999;15:302-308
20. Schäfers H-J, Aicher D, Riodionycheva S, et al. Bicuspidization of the unicuspid aortic valve: A new reconstructive approach. *Ann Thorac Surg* 2008;85:2012-2018
21. Lausberg HF, Aicher D, Langer F, et al. Aortic valve repair with autologous pericardial patch. *Eur J Cardiothorac Surg* 2006;30:244-249
22. Schmidt KI, Jeserich M, Aicher D, et al. Tricuspidization of the quadricuspid aortic valve. *Ann Thorac Surg* 2008;85:1087-1089
23. Rankin JS. Techniques of multiple valve repair. Abstract and surgical video submitted to the Society of Thoracic Surgeons meeting, 2010
24. Carpentier A. Cardiac valve surgery - the 'French correction'. *J Thorac Cardiovasc Surg* 1983;86:323-337
25. Schäfers H-J, Bierbach B, Aicher D. A new approach to the assessment of aortic cusp geometry. *J Thorac Cardiovasc Surg* 2006;132:436-438