Final Report:
Assessment of Outlet Strut Status on Bjork-Shiley Prosthetic Valves Using X-Ray Computed Tomography

Principal Investigator: James D. Thomas, MD, FACC, FASE
Collaborating Investigators: Sandra Halliburton, PhD, FSCCT
Paul Schoenhagen, MD, FACC, FACR

Introduction and Background

In the 1980's, it became apparent that certain patients implanted with the Bjork-Shiley Convexo-Concave valve were at risk for a rare but catastrophic structural failure of the outlet strut apparatus,[1] leading to disk embolization and a risk of death approaching 65%, even with emergency surgery. Risk factors have been identified (such as young age, mitral position of valve, larger valves, and 70° opening angle) for determining patients at highest risk,[2,3] which form the basis for the current guidelines for elective valve explanation. Unfortunately, most of the valves explanted under these guidelines have been completely normal (92% in one study[4]) while patients who were considered to be at low risk have suffered fatal strut fracture. Thus, there remains a need for assessment tools to assist physicians in identifying individuals at particular risk for complications. Prior imaging[5-7] and acoustic[8] methods have focused on identifying valves with fracture of a single leg of the outlet strut (single leg separation, SLS), but none have proven reliable in patient selection, with sensitivities in an animal study ranging from 24-31%[9]. A study using micro-computed tomography (CT) scanning on explanted valves was highly predictive,[10] suggesting that with further advances in clinical CT imaging, that identification of SLS may be possible in patients. The aim of this work was to determine the feasibility of state-of-the-art clinical CT scanners to identify valves with SLS under ideal conditions in-vitro.

Methods

Experimental Setup

Pfizer Corporation provided 20 explanted valves, 10 with and 10 without proven SLS. The valves were mounted in a plexiglass aorta model in the open position (Figure 1) to reduce any potential artifact that might arise from the central disc.

Figure 1: Aorta model viewed from side (left) and top (right) with valve suspended in the open position.

Preliminary Imaging

Two valves with the most obvious strut fractures were imaged on state-of-the-art Siemens and Philips CT scanners using multiple data acquisition and image reconstruction techniques. The optimal CT protocols for maximizing the likelihood that SLS could be visualized were identified based on review of the data by two independent reviewers (Dr. Sandra Halliburton and Dr. Paul Schoenhagen) (Tables 1 and 2).

Table 1. Optimized protocol for Philips Brilliance iCT 256-slice scanner.

Acquisition Mode	Retrospective ECG-gated Helical
Tube Potential	140 kVp
Tube Current-Time Product	Max value
Pitch	0.16
Rotation Time	0.27 sec
Collimated Detector Row Width	128 x 0.6 mm
Reconstructed Slice Thickness	0.6 mm
Reconstruction Algorithm	Iterative Model Reconstruction (IMR)

Table 2. Optimized protocols for Siemens FLASH 64-slice dual source scanner with Stellar detectors.

Acquisition Mode	Retrospective ECG-gated Helical	Retrospective ECG-gated Helical
Tube Potential	140 kVp	100/140 kVp
Tube Current-Time Product	Max value	Max value @ 100 kVp
		Max value @ 140 kVp
Pitch	0.23	0.21
Rotation Time	0.28 sec	0.28 sec
Collimated Detector Row Width	64 x 0.6 mm	64 x 0.6 mm
Reconstructed Energy Level	Monochromatic 105 keV	Monochromatic 105 keV
Reconstructed Slice Thickness	0.5 mm	0.5 mm
Reconstruction Algorithm	SAFIRE, Strength 3; I36f	SAFIRE, Strength 3; I36f

Data Acquisition and Reconstruction

All valves were placed in the custom holder and imaged on the Philips and Siemens scanners using the optimized protocols. Single energy data from both scanners was reconstructed at the scanners' console. Dual energy data from the Siemens scanner was transferred to a workstation for reconstruction of monochromatic images. Three image sets (Philips single energy, Siemens single energy, Siemens dual energy) were generated for each of the 20 valves for a total of 60 image sets. Each image set had approximately 150 images.

Data Analysis

Image sets were examined independently by certified CT readers (Dr. Paul Schoenhagen, Dr. Michael Bolen, Dr. Leonardo Rodriguez, Dr. Richard Grimm) using dedicated advanced workstations and software. Image sets were presented in random order and blinded to the SLS status. Readers assigned an image quality rating to each data set (1 = good; 2 = sufficient; 3 = insufficient) and indicated the level of evidence for SLS (0 = no SLS; 1 = possible SLS; 2 = definite SLS). Sensitivity for correctly classifying valves as fractured was calculated from the reader data.

Results

Typical images from a valve with SLS are presented in Figure 2.

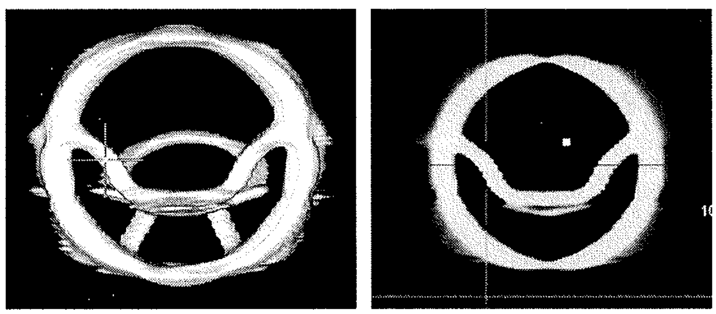

Figure 2: Typical volume rendered image (left) and multiplanar reformat (right) from valve with left outlet offset. The offset is not visible on either image.

None of the four readers were able to accurately detect either cracks or offsets in any of the valves from either Siemens or Philips CT images. Based on analysis of the 60 image sets, Readers 1 and 2 indicated there was no evidence of SLS in any of the valves. Reader 3 indicated a possible strut offset on one image set from valve 10018; this reading was a false positive because the valve was intact. Reader 4 indicated a possible strut offset on two image sets from valve 10421 and one image set from valve 10018; these three readings were all false positives. The sensitivity for all readers for detection of SLS was 0%. All data are available in the accompanying spreadsheet (Bjork-Shiley Final Results).

Discussion and Conclusions

The experimental setup for in-vitro imaging of valves in the absence of cardiac motion provided ideal conditions for imaging of the Bjork-Shiley valves and visualization of SLS. The three image sets for each valve provided to the readers were of the highest quality available from commercially available diagnostic CT scanners. The Philips data set was reconstructed using model based iterative reconstruction algorithms newly developed to provide decreased noise and increased spatial resolution in CT images compared to standard reconstruction algorithms. One of the Siemens data sets was acquired using dual energy capabilities proven to improve material differentiation and reduce artifacts from high attenuating materials like those used to construct the Bjork-Shiley valves. Still, the spatial resolution of the images was not sufficient to visualize the submillimeter cracks in the stationary valves. The inability of a single reader (all highly trained in CT) to accurately detect a single SLS in high quality images obtained under ideal conditions establishes without question that clinical diagnostic CT scanning is not an appropriate method for assessing valve status in patients.

References

1. Brubakk O, Simonsen S, Kallman L, Fredriksen A. Strut fracture in the new bjork-shiley mitral valve prosthesis. *The Thoracic and cardiovascular surgeon*. 1981;29:108-109
2. van der Graaf Y, de Waard F, van Herwerden LA, Defauw J. Risk of strut fracture of bjork-shiley valves. *Lancet*. 1992;339:257-261
3. Walker AM, Funch DP, Sulsky SI, Dreyer NA. Patient factors associated with strut fracture in bjork-shiley 60 degrees convexo-concave heart valves. *Circulation*. 1995;92:3235-3239
4. Blot WJ, Signorello LB, Cohen SS, Ibrahim MA. Single leg separation prevalence among explanted bjork-shiley prosthetic heart valves. *The Journal of heart valve disease*. 2007;16:657-661
5. Vrooman HA, Maliepaard C, van der Linden LP, Jessurun ER, Ludwig JW, Plokker HW, Schalij MJ, Weeda HW, Laufer JL, Huysmans HA, Reiber JH. Quantitative assessment of the presence of a single leg separation in bjork-shiley convexoconcave prosthetic heart valves. *Investigative radiology*. 1997;32:540-549
6. Chandler JG, Hirsch JL, O'Neill WW, Oesterle SN, Miller DC, Kennedy JA, Faichney A. Radiographic detection of single strut leg separations as a putative basis for prophylactic explantation of bjork-shiley convexo-concave heart valves. *World journal of surgery*. 1996;20:953-959; discussion 959-960
7. O'Neill WW, Chandler JG, Gordon RE, Bakalyar DM, Abolfathi AH, Castellani MD, Hirsch JL, Wieting DW, Bassett JS, Beatty KC, et al. Radiographic detection of strut separations in bjork-shiley convexo-concave mitral valves. *The New England journal of medicine*. 1995;333:414-419
8. Dow JJ, Plemons TD, Scarbrough K, Reeder H, Hovenga M, Wieting DW, Chandler JG. Acoustic assessment of the physical integrity of bjork-shiley convexo-concave heart valves. *Circulation*. 1997;95:905-909
9. Hopper KD, Gilchrist IC, Landis JR, Abolfathi AH, Localio AR, Wilson RP, Pae WE, Jr., Kunselman AR, Wieting DW, Griffith JW, Pierce WS, Potok PS, TenHave TR, Chandler JG. In vivo accuracy of two radiographic systems in the detection of bjork-shiley convexo-concave heart valve outlet strut single leg separations. *The Journal of thoracic and cardiovascular surgery*. 1998;115:582-590
10. Brendzel AM, Rambod E, Jorgensen SM, Reyes DA, Chmelik MS, Ritman EL. Three-dimensional imaging of fractures in outlet struts of bjork-shiley convexo-concave

heart valves by microcomputed tomography in vitro. *The Journal of heart valve disease.* 2002;11:114-120

A Summary of the Cleveland Clinic Final Report of the Study: Assessment of Outlet Strut Status on BSCC Heart Valves Using X-Ray Computed Tomography

The Cleveland Clinic was under contract to the Bowling Pfizer Supervisory Panel to use a new, advanced X-ray computed tomographic (CT) method to assess the outlet strut status of BSCC heart valves. Dr. James Thomas, a leading imaging specialist, was the leader of the study. Twenty BSCC heart valves explanted from patients were used for the study, 10 with proven single leg separation (SLS) and 10 without SLS. The valves for the study were obtained from the Pfizer Corporation.

The Cleveland Clinic group performed a preliminary study to optimize the systems for detection of single leg separation by carrying out a study in 2 valves utilizing two state-of-the-art scanners for X-ray CT. This was followed by the imaging of the total 20 submitted valves placed in a specialized holder under 3 different protocols. These were a Phillips single energy scan, a Siemens single energy scan, and a Siemens dual energy scan. These 3 scanning techniques produced 60 imaging sets with each set having 150 images. All images from the CT study were enhanced by a computer for analysis. These computer enhanced images were specifically utilized to help the readers focus on BSCC heart valves.

Four independent radiologists, who were certified CT readers, were presented with the images in a blinded and randomized order. The radiologists classified the quality of the images and whether they could detect the presence or absence of SLS. None of the readers were able to accurately detect either cracks or offsets for any of the BSCC heart valves. One reader indicated a possible offset in one valve, but this was proven to be false-positive. Thus, the sensitivity to detect SLS for all readers was 0%. The high specificity reported could suggest that while CT imaging might correctly detect intact valves, it is highly unlikely.

The conclusion for the study is that it is not possible to accurately detect the status of the outlet strut of BSCC heart valves, even when the highest quality CT scanners available are used to image the valves. This proved to be the case even when the heart valves were mounted in a stationary holder and not able to undergo the motion of a beating heart. Thus, the final conclusion is that radiologists highly trained to analyze CT cannot accurately detect SLS in high quality images obtained under ideal conditions, and establishes without question that CT scanning cannot be used to assess the status of BSCC heart valves in patients.

Submitted by:

Mr. David Miller
Dr. Arthur Weyman
Dr. Donald Harrison

	SE_SIEMENS				SE_PHILIPS				DE_SIEMENS			
	Sensitivity	Specificty	Positive Predictive Value	Negative Predictive Value	Sensitivity	Specificty	Positive Predictive Value	Negative Predictive Value	Sensitivity	Specificty	Positive P	Negative Predictive Value
Bolen	0	100	0	50	0	100	0	50	0	100	0	50
Grimm	0	100	0	50	0	100	0	50	0	100	0	50
Rodriguez	0	100	0	50	--	--	--	--	0	90	0	50
Schoenhagen	0	90	0	47	0	90	0	47	0	90	0	47

Low sensitivity indicates that CT is not able to correctly classify valves as fractured.

High specificity might suggest that CT is able to correctly identify a valve as intact but that is unlikely give the high negative predictive value (percentage of valves with a negative scan that do in fact have fractures).