NOVEL METHODS FOR DETECTING FRACTURES IN PROSTHETIC HEART VALVES

S.C. Chan, R. Clifford, S. Majumdar, N. Nair, S. Ramakrishnan, Y. Li, P. Ramuhalli, L. Udpa and S. S. Udpa
Michigan State University, East Lansing, MI, USA

Abstract: This paper describes the use of two simple electromagnetic methods for detecting strut fractures in prosthetic heart valves. The first method involves immersing the heart valve in a uniform time varying electromagnetic field and measuring the perturbation of the field in regions proximate to the strut. *In vitro* tests done to date indicate that the method is capable of discriminating between intact and fractured struts. The second method that is currently being investigated involves the use of electromagnetic-acoustic transduction methods for exciting the resonant modes of the outlet strut. Differences between the frequencies associated with the resonant modes of intact and fractured struts are exploited to diagnose the state of the valve.

Introduction: Heart valves play a critical role in regulating blood flow through the cardiovascular system. Diseases of the heart valve can either be congenital or caused by infections such as rheumatic fever or endocarditis. Problems could also arise simply as a consequence of aging. The disease can lead to either stenosis, where the valve fails to open completely, or regurgitation, where the valve fails to close completely. In instances where the damage cannot be repaired through surgery, replacement with a prosthetic device is often indicated. One of the more common popular mechanical devices that was implanted extensively between 1979 and 1986 is the Bjork-Shiley Convexo-Concave (BSCC) valve. The BSCC valve consists of a pyrolytic carbon disc that serves as an occluder to block the flow of blood in one direction but allows flow in the other direction. The valve employs two struts as shown in Figure 1 to hold the disc in place. The outlet strut is TIG welded to the suture ring while the inlet strut is integral to the ring. Although the exact reason has not been determined, a combination of circumstances including fatigue and perhaps stress corrosion, causes one of the welds, anchoring the outlet strut, to fracture [1-2]. The failure of the other weld can cause the strut to separate from the suture ring, thereby allowing the disc to detach from the valve. This is usually fatal and consequently there is considerable interest in methods that can detect separation of one of the legs of the strut from the suture ring [3-7]. This paper describes a simple electromagnetic method that allows the detection of single leg separation (SLS) failures in BSCC valves.

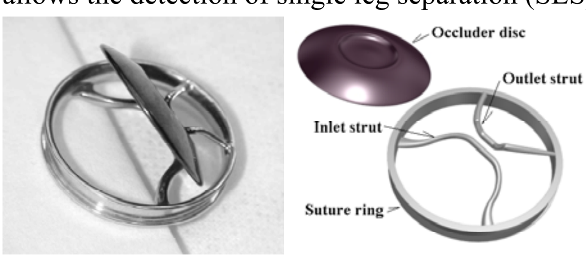

Figure 1 Björk-Shiley Convexo-Concave (BSCC) Heart Valve.

Gradiometer Based Method: The method involves immersion of the heart valve in a spatially uniform time varying field as shown in Figure 2. The field, which is established by exciting a pair of large Helmholtz coils, is oriented in a direction that is parallel to the plane of the suture ring. Consequently the current induced in the ring is minimal. Since the plane of the outlet strut is not parallel to the plane of the suture ring, eddy currents are induced in the ring. These eddy currents perturb the field in the vicinity of the strut. If the strut weld is fractured, the eddy current path is interrupted and consequently the perturbation of the field, if any, is minimal. Thus the presence of a perturbation in the field is an indication of an intact outlet strut (IOS) while the absence of a perturbation indicates an SLS condition. The perturbation is detected by measuring the gradient of the field using a gradiometer. The gradiometer is mounted in a catheter which is inserted into the femoral artery and threaded through the arterial system to position it close to the outlet strut. Figure 3 shows the catheter assembly containing the gradiometer at the tip while Figure 4 shows a prototype of the Helmholtz coil assembly together with a surgery table with a metal-free bed that was specially built. The coil pair is oriented at an angle to ensure that the field produced by the pair is parallel to the suture ring in sheep. These animals are currently being used to test the viability of the approach.

Figure 5 shows the block diagram of the associated instrumentation. The signal generator produces the excitation waveform that is amplified to drive the excitation coils. An impedance matching circuit, shown in Figure 6 ensures that the total load impedance of the circuit and the excitation coils is matched to that of the amplifier output stage at the excitation frequency. The pair of excitation coils generates a uniform magnetic field around the heart valve during the test.

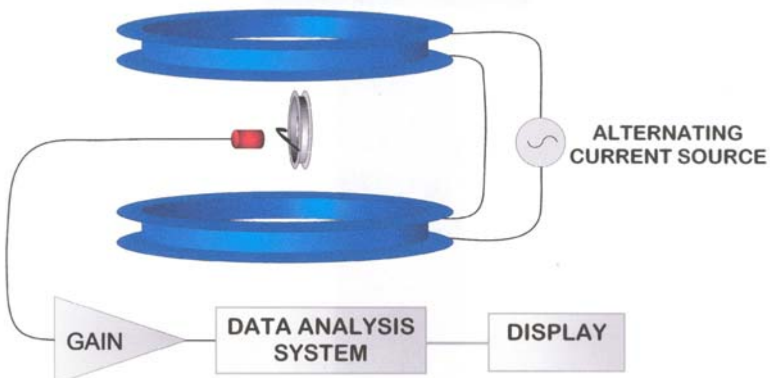

Figure 2: Gradiometer Based Method for Detecting SLS Failures in BSCC Valves

The gradiometer consists of two coaxial pancake coils mounted on a nonmagnetic and electrically non-conducting spindle. The signal from the gradiometer is applied to a lock-in amplifier (LIA) that uses the excitation signal as the reference signal to improve the signal-to-noise ratio. The LIA provides the amplitude (V) and phase (θ) (relative to the reference signal) as well as the inphase (X) and quadrature components (Y) of the difference in the voltage induced in the two coils comprising the gradiometer.

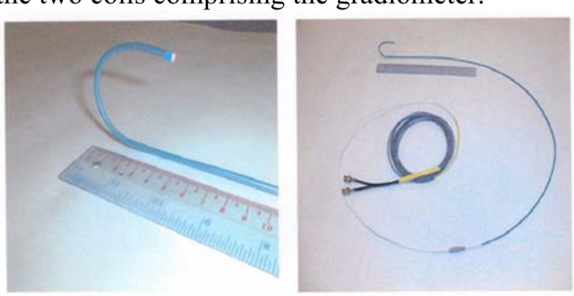

Figure 3: Catheter tip containing the gradiometer (left) and the complete catheter assembly (right)

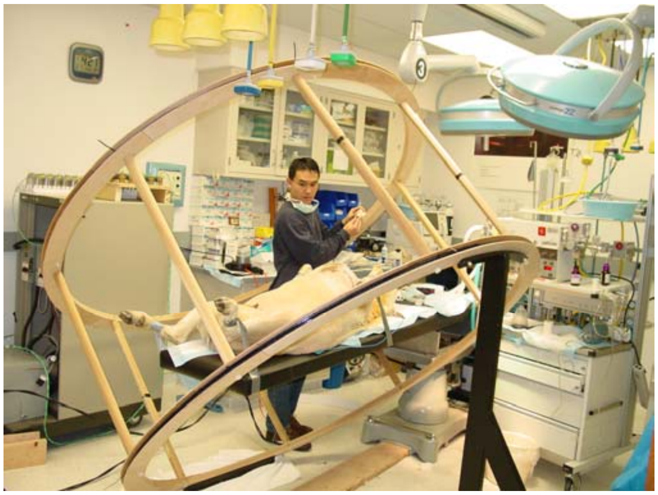

Figure 4: Excitation Coil Assembly and the Surgery Table

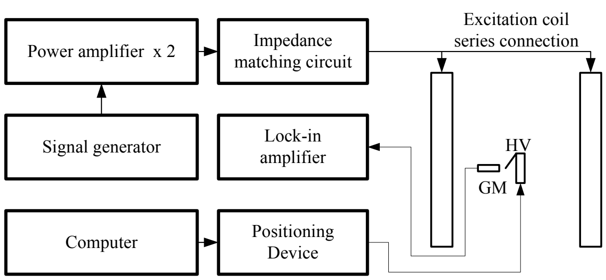

Figure 5: System Block Diagram

A finite element model was employed to simulate and optimize the design of the Helmholtz coil. Figure 7 shows the cross-sectional plane of the excitation coils modeled by the model. The symmetry of the geometry was exploited by simulating only one half of the axisymmetric geometry. The final design of the Helmholtz coil is as follows. Each excitation coil consists of several turns of wire and has a mean radius of 1 m. The coils are electrically connected in series and are spaced 1m apart. The excitation frequency and current is set at 45.4 kHz and 14.6 Amperes (peak-to-peak) respectively, the magnetic flux density at the center of the coil arrangement is 0.06 mT (0.6 gauss). The simulation results indicate, and the experimental results confirm, that the variation in the magnetic flux density is less than 0.5% within a cylindrical volume of radius 0.25m and 0.5 m high.

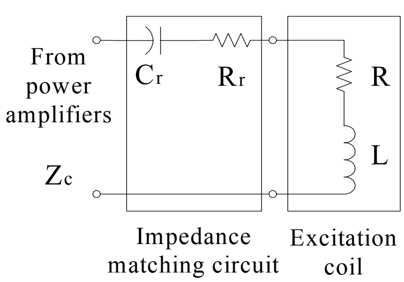

Figure 6: Impedance Matching Circuit

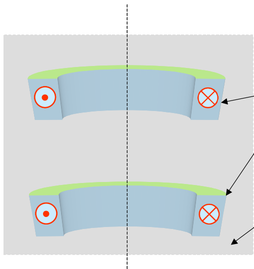

Figure 7: Cross-sectional Plane of the Excitation Coil Modeled using the Finite Element Method

EMAT Method: An alternate approach that is being investigated involves the use of electromagnetic-acoustic transduction (EMAT) techniques to generate Lorentz forces in the heart valve for exciting the resonant modes of the strut. The motivation for exciting the resonant modes lies in the fact that the dominant resonant mode frequencies associated with intact and fractured outlet struts are different, as confirmed by a number of researchers. Studies carried out by Chia [8] using finite element analysis techniques showed that the resonance frequencies associated with intact and fractured struts are measurably different. He also showed that the resonance frequency of an SLS outlet strut varied continuously depending on whether the fractured strut is in kissing contact with the suture ring or free. Experimental verification with a small sample set of valves showed that considerable variations in the resonance frequencies can occur particularly in the case of valves with kissing contacts. It is apparent that the nature of the contact has a significant influence on the frequency. Plemons et al [9] showed that the IOS resonance frequency remains fairly stable. Researchers have investigated two different types of acoustic methods as a basis for determining the condition of the valve. Active methods employ an external excitation source to excite the resonant modes of the strut. Passive methods, on the other hand, rely on the impulsive force applied to the strut by the disc during valve closure to excite the vibration modes.

The EMAT technique is an active method, which uses Lorentz forces to excite the strut. Lorentz forces [10] are generated when an electrically conducting material carrying current is placed in a magnetic field. If the frequency of the force generated in the valve matches the natural frequency of the strut, then the strut would vibrate at its resonant mode. If the frequency does not match the natural frequency, the vibration gets damped relatively quickly after the excitation is withdrawn. Consequently, if the valve is set to vibrate at frequencies that correspond to the intact and fractured outlet strut frequencies and if the strut vibration pattern is measured after the excitation is turned off, it is possible to determine the state of the strut.

The underlying scheme is illustrated in Figure 8. We use two pairs of excitation coils (which we will call A and B) each excited by an alternating current source. If the excitation frequency of the currents applied to coil pairs A and B are f_1 and f_2 respectively, then the current induced in the heart valve will have a frequency f_1 and the magnetic field generated by the second coil pair B in the vicinity of the valve will have a frequency f_2. If the current induced in the valve and the magnetic flux density in the vicinity of the valve are $I_m \text{Sin}(2\pi f_1 t)$ and $B_m \text{Sin}(2\pi f_2 t)$ respectively, the force F generated in the heart valve is given by the product:

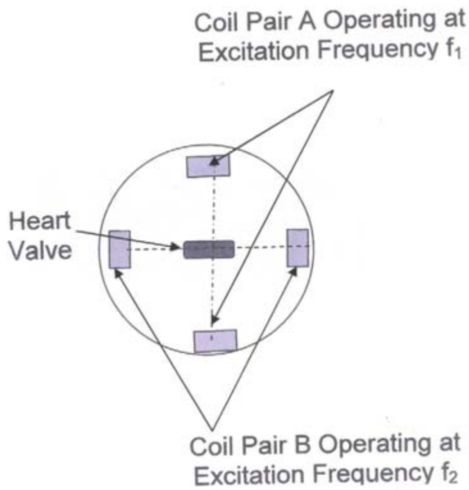

Figure 8: EMAT Method for detecting strut fractures

$$F = (B_m \mathrm{Sin}(2\pi\ f_2\ t))\mathrm{x}(I_m \mathrm{Sin}(2\pi\ f_1\ t))\mathrm{x}(\text{length of the valve ring})$$

Here, I_m and B_m are the peak values of the currents induced in the heart valve ring and the flux density in the heart valve region respectively.

The force F has components at frequencies ($f_1+ f_2$) and ($f_1- f_2$). If we choose f_1 and f_2 to be, say, 500 kHz and 507.5 kHz respectively, then ($f_1+ f_2$) is significantly above the resonant modes associated with any of the valve components. The beat frequency, ($f_1- f_2$), in contrast, is close to the resonant mode of an intact outlet strut. In order to detect SLS we simply set ($f_1- f_2$) to the frequency associated with a SLS strut. Any interference in the signal can be easily filtered out due to large difference in the spectral coverage i.e. ($f_1+ f_2$) is well separated from ($f_1- f_2$).

The acoustic signals can be measured using an appropriate transducer on the chest of the patient. We use a laser vibrometer to measure the acoustic signal.

Results: In vitro tests carried out to date show that the catheter based methods are very promising. The gradiometer based system was tested with 19 BSCC valves. In order to simulate the movement of the heart valve in relation to the gradiometer during the cycle, the trajectory of an aortic valve was traced from X-ray videos. The relative amplitude and direction of the heart valve movement are then programmed into a motorized X-Z positioner to create a travel path for the gradiometer (Figure 8) that simulates the relative movement between a heart valve and a catheter during the examination. Figure 9 shows some typical signals at the output of the LIA for as the distance between the outlet strut and the gradiometer is varied cyclically over a length of 5 mm for SLS and IOS valves.

Twelve of the valves which were tested were SLS and the remaining seven were IOS. The sewing ring diameter of eight of the valves was 31 mm while the rest were 29 mm valves. Five of twelve SLS valves were explanted while the other fractures were mechanically induced. Blind tests were carried out by two operators independently. In addition, a computer based algorithm was used to analyze the gradiometer signal. Table 1 summarizes the results of the *in vitro* tests.

A small prototype unit is being built to demonstrate the viability of the EMAT concept. The heart valve is held in place within elastomer sleeve inside a fluid-filled chamber. The valve is placed in the center of two field excitation systems that are orthogonal to each other. Figure 11 shows the assembly without the chamber. The frequency of one of the excitation field was set at 30 kHz while the frequency of the other excitation assembly other was set at 31.8 kHz. Figure 12 shows the spectrum of the acoustic signal as measured by a laser vibrometer with and without a valve in place. The spectrum clearly shows that the EMAT system is capable of inducing mechanical vibrations in the valve. Work is currently on going to devise means to discriminate the acoustic signal generated by an SLS and IOS valve.

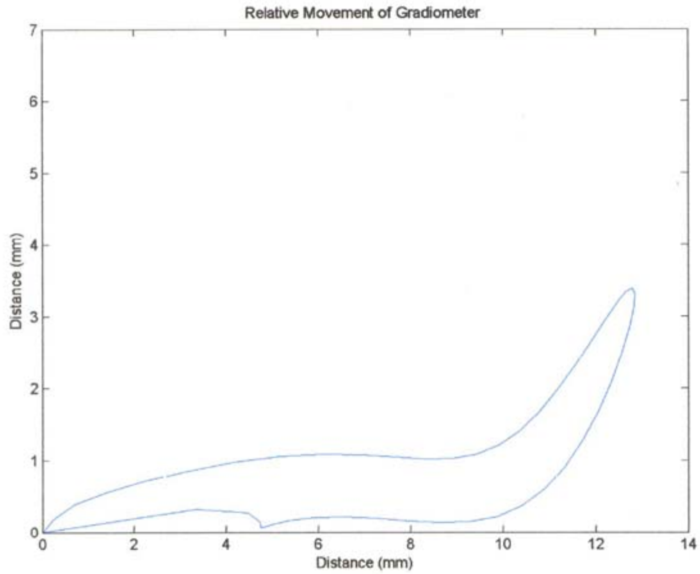

Figure 9: Trajectory of the BSCC Aortic Valve traced from an X-ray Video

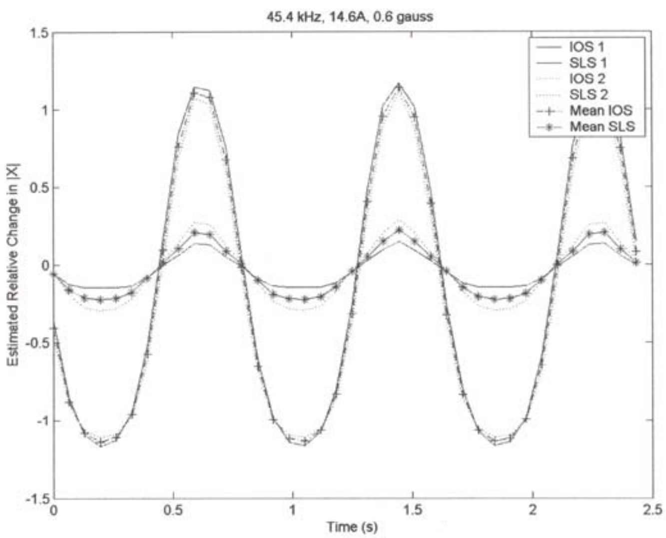

Figure10: Relative changes in |X| as the distance between the outlet strut and the gradiometer is cycled over a distance of 5 mm for IOS and SLS valves.

Discussion: The output of the LIA was interpreted independently by two analysts and a computer. The classification results matched the condition of the valve as indicated on the exterior of the box containing the valve except in the case of samples 8 and 9. In these two cases the valves were tagged as IOS while the tests indicated that they were SLS. The valves when subsequently examined under a microscope were found to be SLS. Thus the system was able to classify all 19 BSCC valves correctly without any error.

The performance of the system will be evaluated shortly via animal tests. We plan to implant BSCC valves in several Dorsett-Suffolk crossbreed sheep and conduct tests in vivo to determine the viability of the method

Table 1: Summary of Blind In Vitro Test Results

Sample No.	Serial No.	Flange No.	Operator 1 Indication	Operator 2 Indication	Computer Indication	Known Condition
1	31MBRC12282	73225	SLS	SLS	SLS	SLS
2	31MBRC10029	85083	SLS	SLS	SLS	SLS
3	29ABC10925	73159	SLS	SLS	SLS	SLS
4	29MBC60029	A6628	IOS	IOS	IOS	IOS
5	31ABC10467	73021	SLS	SLS	SLS	SLS
6	29MBRC16797	102268	SLS	SLS	SLS	SLS
7	29ABC12556	110830	IOS	IOS	IOS	IOS
8	29ABC10937	73234	SLS	SLS	SLS	IOS*
9	29ABC11607	83740	SLS	SLS	SLS	IOS*
10	31MBRC12926	76225	SLS	SLS	SLS	SLS^{X}
11	29ABC40035	72393	IOS	IOS	IOS	IOS
12	29MBRC10776	61046	SLS	SLS	SLS	SLS^{X}
13	31MBRC60112	A2517	IOS	IOS	IOS	IOS
14	29MBRC15110	87384	IOS	IOS	IOS	IOS
15	31MBRC60939	A4567	SLS	SLS	SLS	SLS
16	31MBRC61089	A5023	SLS	SLS	SLS	SLS^{X}
17	29MBRC14924	87161	IOS	IOS	IOS	IOS
18	31MBRC10177	94382	SLS	SLS	SLS	SLS^{X}
19	29ABC11608	83986	IOS	IOS	IOS	IOS

Figure 11: EMAT system for demonstrating proof of concept

Conclusions: This paper describes two methods for detecting strut fractures in prosthetic heart valves. The first method involves the use of a pair of coils to establish a uniform time-varying field and measurement of the perturbation of the magnetic field in the vicinity of the strut using a gradiometer. In vitro tests conducted to date indicate that the method shows considerable promise. In vivo tests are planned in the near future to evaluate the performance of the system. The second method uses electromagnetic-acoustic transduction techniques to excite the resonant modes of the strut. The acoustic signal generated by the vibrating strut is measured using a laser vibrometer. Work done to date on the EMAT method shows that it is possible to induce vibrations in the heart valve.

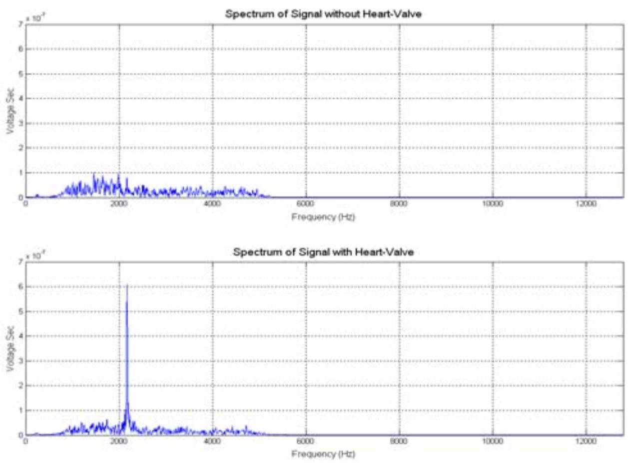

Figure 12: Spectrum of the acoustic signal measured by a laser vibrometer with and without a valve.

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