Leaflet arrest in St Jude Medical and CarboMedics valves: an experimental study

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Abstract

Objective: Two patients who suffered acute failure of their St Jude Medical Masters aortic valve prostheses due to leaflet arrest that were unrelated to suture material are presented. It was hypothesized that the valves failed because force applied to bear upon the valve annulus caused the hinge mechanism to become restricted or to arrest. Methods: A study was designed to measure the force that would cause leaflet arrest in three sizes of St Jude Medical Masters valves and CarboMedics mechanical valves. A specially manufactured pushrod device was used to apply a variable force to the sewing cuff, low annulus level, or to the pivot guards of all the valves. Results: For every valve size tested, the St Jude Medical Masters valves required significantly less force applied than did the CarboMedics valves to cause one or both leaflets to arrest (P < 0.0004). Conclusions: A force applied on the valve ring of mechanical valves can cause leaflet arrest. The force required to arrest the leaflets is within an order of magnitude of that measured in other in vivo animal studies. We conclude that force on the valve rings in patients after aortic valve surgery could cause leaflet malfunction and even arrest in some patients.

Keywords: Mechanical valve; Valve replacement; Valve malfunction

1. Introduction

Bileaflet mechanical heart valves are currently the most commonly implanted design of valve prosthesis. The St Jude Medical Masters (SJM) valve and the CarboMedics (CM) valve are the most popular models of bileaflet valves available to surgeons today. Most reports of patient outcomes have focused on the valves’ hemodynamic performance, thromboembolism rates, and structural integrity [1–4].

We report two patients whose aortic valve replacements with bileaflet mechanical valves were complicated by acute arrest of both valve leaflets in the closed position. Both patients required re-replacement in the same operation and both survived. A previous report [5] described a similar SJM aortic valve malfunction discovered on a pre-discharge echocardiogram. This patient was found to have both leaflets’ motion severely restricted, causing a resting gradient of 60 mmHg. These surgeons used an elementary C-clamp device to note the force on the sewing cuff required to arrest the leaflets of the valve. However, the device was not specifically designed to measure valves.

A specially designed device was used to measure the force required to arrest mechanical valve leaflets. The hypothesis tested was that mechanical valve leaflet arrest can be caused by physiologically produced forces on the valve ring annulus.

2. Case histories

2.1. Patient 1

A 56-year-old man presented with aortic stenosis. In the operating room, after sizing the annulus with the appropriate valve sizers from the manufacturer, he underwent uneventful implantation of a 25-mm SJM valve using interrupted 2-0 Ethibond mattress sutures with pledgets on the ventricular side. The valve was seated. It was rotated slightly to obtain more favorable clearance from the septum.
However, it was noted that it was very difficult to rotate the valve, and when the leaflets were tested, neither moved at all. To make certain that no pledget, suture, or annular tissue was impeding the valve from opening, the left atrium was opened and the aortic outflow tract inspected using a dental mirror placed through the mitral valve. The aortic valve prosthesis could be plainly seen from the left ventricular cavity, and it was clear that no obstructing tissue, pledget, or suture was the cause for the double leaflet arrest. The valve was explanted and the annulus re-sized. Once again, a 25-mm SJM sizer was accommodated by the patient’s annulus. In light of the problems, however, a 23-mm SJM Masters series valve was inserted in the same manner. Free leaflet mobility was assured. Inspection of the explanted SJM Masters series valve revealed an apparently normal valve prosthesis, with free leaflet mobility.

2.2. Patient 2

A patient with a history of aortic stenosis and coronary artery disease underwent combined aortic valve replacement and coronary artery bypass grafting. There was an abundance of calcium extending into the annulus and the posterior mitral area. Rather extensive resection was performed after which measurements were made and a 23-mm SJM Masters series valve inserted with Teflon felt buttressed mattress sutures. After seating the valve, it was noted that both leaflets opened with difficulty. Nothing was seen inside the left ventricular cavity to account for the impeded leaflet mobility. After most of the valve sutures had been tied, the prosthesis was rotated approximately 90° to see if the valve leaflets would open properly. They did not. The valve was explanted, and a 23-mm CM valve prosthesis implanted. Following explant of the valve, the surgeon noted that only slight pressure applied to the hinge mechanism resulted in arrest of the leaflets. The valve was returned to St Jude Medical for analysis.

3. Material and methods

A push-rod device (Fig. 1) manufactured by the CM valve engineering department (Austin, TX) was used to apply a variable force to the sewing cuff, low annulus level, or to the pivot guards of all the valves (Fig. 2). The design of the device allowed us to add (and remove) weights sequentially. The valves were inserted into the device in an inverted position to allow us to determine free leaflet mobility. The standard soft implement supplied with each CM valve was used to move the leaflets while gradually adding weights to the pushrod device. Measurements included the applied force (in Newtons) required to cause (1) one leaflet to arrest, (2) both leaflets to arrest, and subsequently, (3) the valve to reopen as the weights were removed. The pushrod could be applied to the annulus at the sewing cuff, the low annulus level, or at the level of the pivot guard in the axis of the line of leaflet closure. Because only the SJM Masters valves have an exposed pivot guard, we could not compare differences between valve types at this lowest level. The force required to cause leaflet arrest when the force was applied perpendicularly (90°) to the line of leaflet closure at the sewing cuff level was also measured.

Three valve sizes were tested from each manufacturer: 21, 23, and 25 mm. Three valves in each of these sizes from each manufacturer were tested. Each measurement was repeated thrice on every valve. The measurements are reported as mean ± standard deviation (SD). Differences between measurements of valves from SJM and CM of the same size were tested using an unpaired Student’s t-test. Differences between measurements of SJM Masters valves at each of three different sites of applied force (sewing cuff, low annulus level, low pivot) were examined using analysis of variance for each valve size. Differences between measurements of CM valves at both sewing cuff and low annulus level levels were examined using paired Student’s t-tests. Analysis of the data was performed using the spreadsheet Microsoft Excel, and the statistical software package StatView 5.0 (Abacus, Inc.). Graphical presentation...
of data was executed using CricketGraph III (Computer Associates). A \( P \)-value less than 0.05 was considered sufficient to distinguish significant differences between groups.

4. Results

4.1. Axial applied force—differences between manufacturers

The results are presented in tabular form in Table 1 and in Figs. 3 and 4. For every valve size tested, the SJM Masters valves required significantly less force applied than did the CM valves to cause one or both leaflets to arrest (\( P < 0.0004 \)). The mean force required to cause one leaflet to malfunction (arrest) was 60–69% less than that required to cause one leaflet to arrest in CM valves. Once arrested, the SJM valves would not open until significantly less force was applied (\( P < 0.0001 \)). The differences were significant between SJM valves and CM valves both at the sewing cuff level and the low annulus level.

4.2. Axial applied force—differences within manufacturers—SJM valves

An analysis of variance demonstrated that the pivot guard required the least force applied to cause one leaflet to arrest in SJM valves (\( P < 0.0001 \)). The low annulus level required less force applied to cause leaflet arrest than did the sewing cuff level (\( P < 0.0001 \)). (Table 1 and Figs. 5 and 6).

4.3. Axial applied force—differences within manufacturers—CM valves

The force applied to cause one leaflet arrest at the sewing cuff level was not significantly different from the force required at the low annulus level for the 21 mm CM valve (\( P = 0.82 \)), but it was significantly different for 23 (\( P = 0.002 \)), and 25 mm valves (\( P = 0.008 \)). (Table 1).

4.4. Perpendicularly applied force—differences between manufacturers

The perpendicularly applied force at the sewing cuff level required to cause leaflet arrest was greater than
the device could apply (98 N) for both CM and SJM Masters valves in all three sizes tested.

5. Discussion

This report details the clinical circumstances of two patients who experienced intraoperative arrest of both leaflets of their aortic valve prostheses in the static state, i.e. the arrested heart. An experimental design was constructed to test the hypothesis that common prosthetic aortic valve designs can experience leaflet arrest from axially applied forces. All tested prostheses’ leaflets could be arrested in this manner. The experiment demonstrates that the SJM Masters aortic prostheses leaflets are arrested by only 60–69% of the force that is required to cause leaflet arrest in the CM prostheses.

One of the valves that malfunctioned in a patient was sent back to SJM for analysis. This analysis determined the valve rotation system and ring mounts to be within specification. Hydrodynamic testing was within guidelines for normal operation for an SJM valve. No leaflet hesitation or dysfunction was seen at the time of testing at the SJM laboratory. In their report to the surgeon, SJM laboratory concluded that “the minimum compressive pressure required to impede leaflet motion while applying pressure to the orifice ring is greater than the pressures expected in clinical use.” They further suggested that “pressures at the prosthesis–tissue interface must be less than capillary venous pressure; that is, less than 10–20 mmHg. This conclusion is based upon the fact that capillary rupture in the tissue annulus has not been observed for SJM implants.”

They surmised that the leaflet arrest or restriction must have been caused by extrinsic calcium or tissue.

We do not find this argument from SJM compelling. Most importantly, it fails to explain adequately why both leaflets of the valves in both patients were so rigidly restricted. For this reason, and because visual inspection of both valves demonstrated no impinging tissue, we believe that another mechanism must account for the leaflet arrest in our patients. It may also explain the bileaflet restriction previously reported by Mashiko et al. [5].

Our study demonstrated that an average of only 13.7 N of force applied to the pivot guard is required to arrest leaflets in the 21 mm SJM Masters valve. (This was achieved with just 1.4 kg of applied mass.) Valve prostheses are implanted by securely tying sutures from the annular tissue of the patient to the sewing cuff of the prostheses. We note that our patients both experienced bileaflet arrest in the static heart. Additionally, the left ventricle generates pressures occasionally exceeding 200 mmHg during systole. This magnitude of pressure is translated into considerable, additional force applied on the prosthetic annulus with each systole, which could give rise to a dynamic leaflet arrest during part of the cardiac cycle. The additional myocardial forces on a mechanical valve annulus generated by the beating heart in systole have been measured in vivo in pigs after mitral valve replacement [6]. There was a maximum force developed by the normal porcine myocardium of 6–8 N on the prosthetic mitral valve rings at 140 mmHg aortic pressure. This correlated with a maximum deformation of 40 µm with mitral prostheses mounted in the anatomic position. One might reasonably expect even greater forces in hypertrophied human patient hearts after mechanical aortic valve replacement. Furthermore, because the valve testing device can only apply force in a single direction, this study cannot determine whether there are additional, unmeasured forces that might be applied as the three dimensions of the native aortic valve annulus in vivo are converted to a single plane by being sutured to the prosthetic valve annulus. The use of everting, pledgetted sutures might also lead to additional forces on the prosthetic annulus, particularly if they result in narrowing of the left ventricular outflow tract after the valve sizing has been performed.

The fact that the beating normal, porcine heart generates forces of the same order of magnitude as those we determined to cause leaflet arrest in some mechanical valves is significant. One must question whether a safety margin of maximum force tolerance less than 2.5 (equivalent to 20 N, or 8 × 2.5 N) is acceptable in such a critical design. All three sizes of SJM valves’ leaflets were arrested by forces of 20–35 N when applied at the pivot guard level.
Our data demonstrate that the SJM Masters prosthesis is significantly more susceptible to leaflet arrest than is the corresponding size of CM prosthesis. Furthermore, the pivot guards are the most vulnerable part of the SJM Masters valves for deformation: this study showed that the pivot guard requires the least amount of force applied to cause leaflet arrest. It is noteworthy that the valves from both companies were able to withstand substantially greater force (>100 N) when it was applied perpendicularly to the line of closure of the leaflets. We believe that this is further evidence that the pivot guards are the sites most sensitive to external applied force.

The reason that the SJM valves are less robust than the CM valves probably relates to a fundamental design difference. SJM modified their standard valves in order to make the SJM Masters valves rotatable. Unlike the ATS, CM, or Medtronic-Hall valves, SJM valves do not have a rigid titanium ring within their valve housing. Thus, the only structural support is offered by the pyrolytic carbon, which has been reduced in the prosthetic annulus to accommodate the rotating mechanism that SJM uses in their valves. The sewing ring of the SJM valve is held inside a rectangular groove in the valve housing by a triple-wrap Elgiloy spring coil wrapped in cloth (Fig. 2). A suture could conceivably snag this spring coil and could prevent rotation of the leaflets and possibly lead to additional forces on the prosthetic valve annulus.

The possibility that this same problem with SJM valves also exists in the mitral prostheses is suggested by the report from Jaggers which described an SJM Standard series mitral prosthesis that had one leaflet arrest for no apparent anatomic reason. Unfortunately, the SJM Standard series valves were not available for our study in sufficient numbers for a statistically significant comparison.

The small amount of force required to arrest the prostheses is clinically relevant. The position of the SJM valve in the aortic outflow tract places the hinge mechanism within the pivot guard directly against the subannular tissues of the left ventricular outflow tract. In this position the hinge mechanisms will be subjected to the static compression of the outflow tract tissues, as well as to systolic compressive forces. We believe that this structural feature of the SJM Masters valves makes them more vulnerable to leaflet arrest from axially applied forces. The study of pig hearts by Hasenkam et al. [6] suggests that this mechanism could operate to cause leaflet mobility restriction without complete leaflet arrest. It is possible that compression by the subannular tissues may cause this leaflet restriction or arrest only when the heart is hyperdynamic, such as during heavy exercise or emotional stress. This suggests that the diagnosis of this condition may be difficult under the resting conditions in the echocardiography or cardiac catheter laboratories.

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References