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doi:10.1016/j.jtcvs.2005.08.004

Reply to the Editor:

We appreciate the remarks forwarded by Dr Gerosa. However, we believe that their comments strengthened the concerns we pointed out in our brief communication.¹ For implantation of the St Jude Medical (SJM) Regent aortic valve (St Jude Medical, Inc, St Paul, Minn), they describe a modified technique, using tourniquets to pull down the valve before tiding. This kind of maneuver is normally not necessary when inserting supra-annular prostheses provided by other manufactures.

The main message of our report was that, being presented with a new modification of the SJM valve, we encountered technical problems in routine valve replacement operations, using standard, widely recognized suture techniques. In the cases presented, the leaflets were unmovable and rotation was impossible due to entrapment of the subvalvular tissue into the hinge. Whether or not the

term “acute leaflet arrest” is correct remains a minor issue; the situation was unexpected and very unpleasant. The operations were performed by senior cardiac surgeons who had implanted a large number of several types of aortic valve prostheses during more than 25 years. Further, since publishing our negative results, other colleagues have confidentially reported anecdotal cases similar to ours.

In contrast to other prostheses that can be implanted entirely above the ring, the hinges of the SJM Regent valve are still placed below the annulus. Consequently, this valve cannot be regarded as a true supra-annular valve. Therefore, we find the statement in the first line of Gerosa’s letter, claiming that the SJM Regent valve “represents the ultimate step in bileaflet valve engineering,” difficult to accept.

Eivind Øvrum, MD, PhD
Geir Tangen, MD
Oslo Heart Center
National Hospital
Oslo, Norway

Reference

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doi:10.1016/j.jtcvs.2005.08.026

St Jude Medical Regent valve To the Editor:

The recent publication by Øvrum and Tangen¹ describes acute leaflet arrest with implantation of the St Jude Medical Regent valve (St Jude Medical, Inc, St Paul, Minn), specifically accumulation of subvalvular tissue into the leaflet and hinge mechanism. Several issues need to be raised with this brief report.

The St Jude Medical Regent valve, as noted, is implanted in the supra-annular position; only the pivot guards are intra-annular (Figure 1). My colleagues and I have described our technique for implanting all St Jude Medical valves utilizing everting mattress sutures and have used this technique in more than 5000 patients monitored for up to 25 years.^{2,3} We have not had issues of annular tissue impingement preventing the opening of the valve with any of the St Jude Medical models. Although leaflet opening has been impeded rarely by hypertrophic septa, turning the valve has provided relief. Utilizing ventricular-to-aortic suture (noneverting), particularly if the depth of the bite into aortic annulus is too great or the valve is not seated properly, can force annular tissue into the lumen of the prosthetic valve.

Figure 1. The St. Jude Medical HP valve (left) is seated intra-annular, while the Regent sewing ring supra-annular. **Note:** The sewing ring of the HP model diameter is equal to the pivot diameter, while the sewing ring of the Regent model is off-set 0.5 mm. The pivot guard on the Regent must be positioned properly intra-annularly.

The initial Regent valve implanted in these 3 cases was likely oversized and the pivot guard not seated properly. In each case, the Regent valve was replaced with a valve of a smaller effective tissue annulus diameter (ETAD) compared with the St Jude Medical standard model and a smaller effective orifice area (EOA) determined from industry-provided data.^{4,5} In case 1, a 25-mm tissue annulus diameter (TAD) St Jude Medical Regent valve (TAD 25 mm, ETAD 28 mm, EOA 2.6 cm²) was replaced with a 23 mm Regent valve (TAD 23 mm, ETAD 26 mm, EOA 2.5 cm²). In case 2, a 27-mm Regent valve (TAD 27 mm, ETAD 30 mm, EOA 3.5 cm²) was replaced with a 27-mm CarboMedics standard valve (Sulzer Carbomedics, Inc, Austin, Tex) (TAD 27 mm, ETAD 27 mm, EOA 2.2 cm²). In the third case, a 25-mm Regent valve was replaced with a 25-mm CarboMedics standard valve (TAD 25 mm, ETAD 25 mm, EOA 1.5 cm²); again a smaller valve by ETAD with a markedly smaller EOA. Suture technique may have compounded the oversizing. The high EOA in all Regent valves makes oversizing unnecessary.⁶ The calculations of Pibarot and associates⁷ for patient-prosthesis mismatch indicate only 1 patient (case 3), after a 25-mm CarboMedics valve implant was at risk for mismatch (EOA 1.5 cm², EOAI 0.6 cm²/mm²).

In summary, the problems Øvrurum and Tangen encountered can be explained by implantation techniques, depth of sutures, and oversizing of the Regent valve rather than by the valve itself.

Robert W. Emery, MD
Cardiac Surgical Associates, PA
Minneapolis, MN 55407

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doi:10.1016/j.jtcvs.2005.08.067

Reply to the Editor:

We appreciate the interest in our brief report¹ regarding acute leaflet arrest in the St Jude Medical (SJM) Regent aortic valve (St Jude Medical, Inc, St Paul, Minn). The remarks forwarded by Dr Emery clearly indicate that specific precautions must be taken regarding the technique of implantation. His figure 1 demonstrates the shorter distance from the subvalvular tissue to the hinges. He proposes everting mattress sutures for inserting all the types of SJM valves, and this is certainly a safe technique. However, we are not convinced that this is the most common procedure for implantation of supra-annular prostheses. To our knowledge, the most preferred technique is ventricular-to-aortic sutures for supra-annular valves, to optimize the orifice area.

These circumstances were the main reason for our publication. We used standard and widely recognized suture techniques for aortic valve replacement, and severe technical problems occurred with the SJM Regent valve. The reported cases were routine operations without any particular difficulties from the patient's side. After the valve was tied down, the leaflets were unmovable and rotation was impossible, due to entrapment of the subvalvular tissue into the hinges. The operations were performed by senior cardiac surgeons, having implanted a large number of several types of aortic valve prostheses during more than 25 years. The situation was most unpleasant, particularly considering the potential risk of pledget escape when cutting the sutures for removal of the valve. All patients had an uneventful recovery after a prolonged operation for rereplacement. However, similar negative experience has not been published with other valves, and therefore we wanted to share our experience with other surgeon colleagues.

We do not believe that oversizing was the case in any of the patients. They were

all adult male patients with normal size of the aortic ostia and candidates for 25-mm to 27-mm valves. If the SJM Regent valve has to be downsized on routine basis, the hemodynamic advantages must, at least partly, be abolished.¹

Eivind Øvrurum, MD, PhD
Geir Tangen, MD
Oslo Heart Center
National Hospital
Oslo, Norway

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doi:10.1016/j.jtcvs.2005.08.064

Mechanical aortic valve malfunction: An intraoperative BioGlue complication

To the Editor:

I read "Mechanical Aortic Valve Malfunction: An Intraoperative BioGlue Complication" by Karimi and associates. The communication reports that BioGlue (Cryolife Inc, Kennesaw, Ga) can migrate through the aortotomy suture line. It was interesting that there was an interval after the glue was applied to the suture line but before it migrated through to cause the mechanical valve incompetence (demonstrated by the altered function of the prosthetic valve on transesophageal echocardiography). Also of concern was the fact that the BioGlue migrated through 4-0 suture holes rather than a defect in the aortotomy closure.

I recently performed repair of a type I aortic dissection with ascending aorta and hemic-arch replacement and with resuspension of the aortic valve. The patient had been treated with heparin, clopidogrel, and aspirin after admission because of an assumed diagnosis of myocardial infarction. After the patient was separated from cardiopulmonary bypass, with protamine, fresh-frozen plasma, and platelets having been administered, there was still oozing from the suture line. A thin layer of BioGlue was applied, with cessation of the bleeding. The patient had a cardiac output of 7 L and excellent intraoperative myocardial function.

Forty-five minutes after return to the intensive care unit, the patient became hypotensive, with a 1-mm increase of the