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Aortic Homograft Root Replacement for Failed Freehand Homograft Aortic Valve: Effectiveness of a Collagen/Thrombin/ Plasma Composite Hemostat in the Setting of Technically Complicated Homograft to Root Anastomosis

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INTRODUCTION

Re-operations for complex cardiac disease, such as those involving the aortic root, present many challenges in achieving final hemostasis. Prolonged operative time and the effects of cardiopulmonary bypass can impair coagulation. Tissue-to-prosthesis and tissue-to-tissue interfaces can present mechanical issues in the dynamic setting. Finally, exposure of the suture line (i.e., proximal ventricle to root), may be obscured by the completed repair. Experience with such a case and the successful use of CoStasis, a liquid hemostatic spray by Cohesion Technologies (an investigational product provided for compassionate use in this patient under Investigational Review Board approval) is described.

CASE REPORT

A thirty-year-old male with congenital aortic stenosis and a bicuspid valve underwent freehand aortic homograft valve replacement in 1986. He developed progressive calcification of the homograft tissue over the ensuing 13 years. In March of 1998, an echocardiograph demonstrated mild to moderate left ventricular (LV) cavity enlargement with slightly reduced left ventricular systolic function, mild concentric left ventricular hypertrophy with left ventricular diastolic dysfunction, and reduced compliance. The aortic valve was abnormally thickened with Doppler evidence of stenosis and moderately severe aortic insufficiency. The pressure half time was consistent with severe aortic insufficiency. Catheterization performed September 22, 1998 demonstrated severe aortic regurgitation with mild to moderate calcification of the homograft valve; mild to moderate left ventricular enlargement with globally depressed LV function, and no significant coronary artery disease.

The nature of the problem and possible modes of therapy including the Ross procedure, aortic homograft root, and mechanical root replacements were discussed with the patient in detail. Informed of the risks and benefits of the various procedures, the patient requested an aortic root replacement using an aortic homograft.

The operative approach involved bicaval-to-ascending aortic cardiopulmonary bypass. A retrograde cardioplegic catheter was placed through the right atrium into the coronary sinus and a vent was placed through the right superior pulmonary vein into the left ventricle. A cross clamp was placed and cold blood cardioplegia was administered into the aortic root. During the remaining procedure, myocardial protection was achieved via both antegrade cardioplegia, administered to the coronaries at 20-minute intervals, and retrograde cardioplegia administered continually between antegrade doses.

The dense calcification of the original homograft involved the native aortic wall. Coronary buttons were

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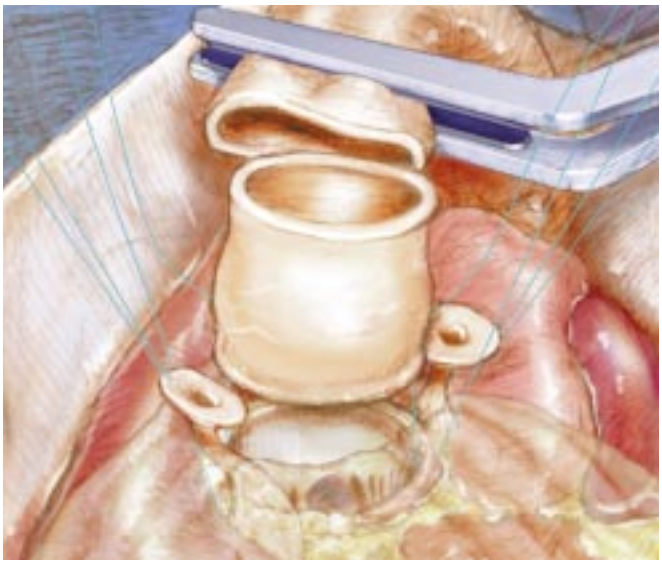

Figure 1. Prior homograft removed with coronary buttons created.

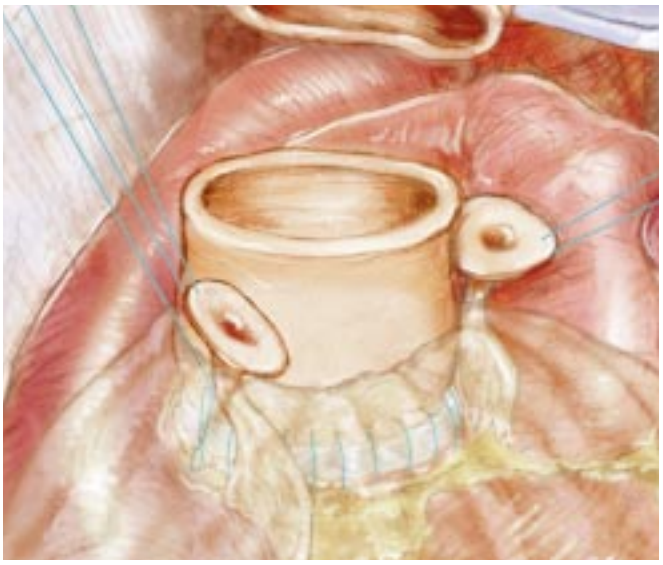

Figure 2. Proximal anastomosis to the native annular remnant performed with interrupted 2-0 sutures.

developed and the aortic root was resected back to the annulus posteriorly. The annulus was densely calcified in the area of the conduction system. To avoid conduction system injury, less aggressive decalcification was employed in this area. Along the muscular septum, more aggressive decalcification exposed raw muscle for a suture base. Thus, three tissue interfaces provided the "annulus" for the proximal anastomosis: 1) relatively normal tissue posteriorly along the top of the mitral valve; 2) raw muscle along the muscular septum to the right/non-coronary commissure; and, 3) residual calcification for a distance of approximately 1/4 of the annulus including the region of the conduction system, there was calcification (see Figure 1◉). A 31-mm homograft was placed using 2-0 interrupted sutures with a pericardial gusset running the entire circumference (see Figure 2◉). Scarring of the right ventricular outflow tract placed this anastomosis deep within the cardiac structures. Homograft size was selected using preoperative annular estimations with figure eight sutures placed at each commissure. The coronary buttons were anastomosed to 5-mm punch holes using 4-0 running Prolene®, and the distal anastomosis completed with a 4-0 Prolene® suture. Following completion of the anastomosis, the cross clamp was removed. The patient was rewarmed to 37° C and weaned from cardiopulmonary support. Perfusion time for the initial procedure was 266 minutes.

During rewarming the patient spontaneously defibrillated to normal sinus rhythm and was weaned from bypass without difficulty. However, bleeding was noted along the base of the homograft annular anastomosis

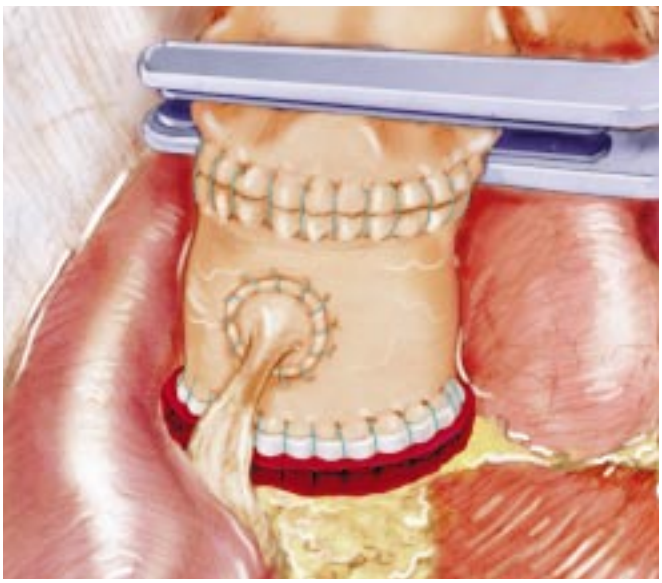

Figure 3. Reinforced proximal suture line using topical tissue adhesive.

Figure 4. Completed root replacement and coronary reimplantation.

anteriorly (see Figure 3 ◉). The right coronary anastomosis and cardiac scarring around the root structures impeded retraction for adequate visualization. Since the precise site of hemorrhage could not be ascertained, the patient was again cooled to 28° C, the cross clamp reapplied and cardioplegia was administered again both antegrade to the root and retrograde. The right coronary button was removed and repair of the anterior half of the anastomosis was performed using running 4-0 Prolene® suture. The right coronary was reimplanted again and the cross clamp released. Unfortunately, bleeding was again noted from the proximal anastomosis once active contractions had resumed. Multiple regimens including tissue glue, thrombin and Gelfoam, and Surgicel were used without resolution of the problem. CoStasis, a two-component system of bovine collagen and bovine thrombin, which is administered with autologous plasma at the time of application, was under clinical trial at our institution and, with Investigational Review Board compassionate use approval, Cohesion Technologies provided a sterile product for treatment of this patient's problem. CoStasis was administered topically to the involved area in four separate doses over 20 minutes, and was effective in stopping the proximal hemorrhage in that time (see Figure 4◉). Alternative approaches would have involved complete take-down of the coronary anastomoses and proximal suture line, and re-suture of the entire proximal anastomosis with, most likely, resection of the calcified area, producing heart block. Multiple sutures would present the potential for deterioration of the homograft proximal muscle, requiring a prosthetic root replacement. Placement of a rigid prosthetic root to the friable muscular septum would also have invited bleeding complications.

The patient was rewarmed and weaned from cardiopulmonary support without difficulty. His total cross clamp time was 259 minutes with total perfusion time of 469 minutes and a total operative time of 12 hours. Intra-operative transesophageal echocardiography confirmed closure of the bleeding site without aortic insufficiency, distortion, or external compression of the homograft aortic root. He was transferred to the intensive care unit.

The patient's post-operative course was excellent with extubation the morning following surgery, removal of his chest tubes the following day with total output of 870 cc postoperatively, and subsequent transfer to the ward. Of note, close attention to myocardial preservation resulted in excellent hemodynamic outcome from prolonged cross clamp and perfusion. Careful monitoring of fluid issues on bypass resulted in minimal pulmonary morbidity with a total weight gain of only 2 kg, requiring diuresis over the ensuing several days. The patient did develop atrioventricular dissociation on the third postoperative day, which spontaneously resolved by the fifth postoperative day. He was discharged on the eighth postoperative day. Subsequently a transvenous pacemaker was placed. At the one-month follow-up, the patient exhibited excellent hemodynamic and functional outcome.

DISCUSSION

Re-operations for complex cardiac disease present many difficulties related to the tissue factor involved in both the scarring process and recurrence of the underlying pathology. In the current case, severe calcification of the previous freehand homograft involved both the homograft tissue itself and the native aortic root into which it had been inserted. Both the dense calcification and the friability of the underlying tissue are commonly encountered in such situations. Care must be taken to avoid injury to the conduction system, mitral valve, and coronary arteries. Furthermore, the potential for creation of ventricular septal defects and left ventricular-to-atrial communications is increased. Proximal anastomosis in a homograft or autograft procedure is a tissue-to-tissue anastomosis, often reinforced with autologous pericardium or synthetic material such as Teflon felt. This anastomosis is subjected to ventricular pressure as well as the dynamic process of the valve cycle. Such an anastomosis is optimized by uniform tissue-to-tissue approximation. However, this is often not possible.

In the case presented, the three different tissue interfaces: the annulus posteriorly, raw muscle along the top of the muscular septum, and calcification in the region of the non-coronary cusp and conduction system were problematic. The friability of homograft muscle could also have presented a problem, had repeat anastomoses become necessary. The availability of a fibrin sealant in situations such as the current case bridges the gap between gross surgical hemorrhage requiring further suture and suture hole hemorrhage responsive to currently available products.

In this case, a compassionate use Investigational Review Board decision allowed the use of CoStasis. This product is an investigational surgical hemostat, composed of bovine collagen and bovine thrombin. The components are mixed with the patient's own plasma at the time of application to the bleeding site, which then forms a hemostatic gel matrix. Exposure of blood to collagen promotes coagulation through both platelet activation and the activation of Factor XII. This reaction ultimately results in the formation of fibrin from fibrinogen, and the formation of a clot. The inclusion of the fibrillar collagen-bovine thrombin suspension in CoStasis provides an optimal formulation for the conversion of fibrinogen in the autologous patient plasma into a hemostatic gel.

The CoStatsis system utilizes platelet rich plasma obtained from the patient's own blood and combines it with a catalyst formed from purified bovine thrombin and collagen. To prepare CoStasis, blood is drawn from the patient into a specially designed syringe, which doubles as a centrifuge cuvette. The plasma fraction is separated within a few minutes by centrifugation. The supernatant is drawn from the cuvette into special syringes supplied with the disposable materials. The thrombin-collagen activator is drawn into a separate syringe from a sealed packet and the two syringes are connected to a junction with a spray

nozzle. An adapter plate is used to couple the two syringe barrels together allowing both components to be sprayed at the same rate onto the tissue surface.

In the current case, the material was topically applied into the area at the base of the aortic root, an enclosed space, difficult to access from above, but providing containment for the hemostat spray. Intra-operative transesophageal echocardiography confirmed closure of the bleeding site without distortion of the homograft aortic root. The development of a commercially available hemostat spray, such as CoStasis, may provide an important new weapon in our hemostatic arsenal.

Disclaimer
The author has no financial or other interest in Cohesin Technologies, supplier of the CoStasis.

REFERENCES

1. Sierra DH. Fibrin-collagen composite tissue adhesive. In: Sierra DH, Saltz R, eds. Surgical adhesives and sealants. Lancaster, PA, Technomic Publishing Co, Inc, 1996, pp 29 39.

REVIEW AND COMMENTARY

1. Editorial Board Member TL41 writes:

There are no references to the basic science or animal work on which the material is based. If "commercial in confidence" this should be stated.

Author's Response:

We did not expand the basic science or animal work in the development of this material in the interest of the case report type format.

2. Editorial Board Member LO23 writes:

This is an anecdotal case report on the use of a new adhesive — there is no substantial proof as to the effectiveness of this adhesive. Furthermore, this patient should have had a three-month follow-up angiogram to exclude the development of a possible false aneurysm at the original anastomatic site, as we do not know the long-term effect of glued high-pressure anastomoses.

Author's Response:

It is, as noted by the reviewer, an anecdotal case. However, an echocardiogram performed six weeks postoperatively shows no evidence of false aneurysm formation.

4. Editorial Board Member AR11 writes:

The usefulness of the product is well demonstrated, but since it is not available to the general public, this is a mute point. The authors failed to mention why a pacemaker was later needed. If for heart block, the entire procedure might have been made simpler by more extensive debridement in the calcified area left behind initially.

Author's Response:

Clearly the simpler procedure would be extensive debridement of the root, but to do so would be to ensure a heart block in a case such as this.

5. Editorial Board Member DK3X writes:

Are there any adverse longterm effects?

Author's' Response:

As far as adverse long term effects, we know of none but will be following the development of this product closely, as we will the other "tissue glue" materials currently being developed.