MODIFIED CONDUIT PREPARATION CREATES A PSEUDOSINUS IN AN AORTIC VALVE-SPARING PROCEDURE FOR ANEURYSM OF THE ASCENDING AORTA

Mechanical valved conduit replacement of the aortic root is a durable and appropriate procedure for many diseases of the ascending aorta, but may sacrifice an anatomically salvageable aortic valve. For young active patients and for patients with "systemic" arterial disease (atherosclerosis, Marfan's syndrome) who may require future operations, life-long anticoagulation with its attendant thromboembolic versus hemorrhagic risks is not ideal. Several techniques have been suggested as aortic valve-sparing options. Recently, a procedure was described that combines the freehand homograft techniques with the standard Bentall techniques (David procedure). This innovative technique replaces the ascending aorta with a Dacron cylinder, spares the aortic valve, and restores competence and thus offers an excellent alternative. The durability of this procedure that places the aortic valve inside a cylindrical conduit without sinuses of Valsalva is unknown. In selected patients, we have used this technique to spare the aortic valve. On the basis of experimental data and preliminary computer modeling, with the hope of improving the durability, we have modified the conduit to create a "pseudosinus" in our most recent nine patients. We have done the David procedure in 10 patients. The pseudosinus modification was done in the most recent nine patients. Patients' ages ranged from 37 to 71 years (mean 49.9 years). There were five female and five male patients. Five patients had Marfan's syndrome and five patients had annuloaortic ectasia. There has been no mortality and all patients have had both early and late follow-up echocardiography. Five patients have zero to trace aortic insufficiency, four patients have trace to mild aortic insufficiency, and one patient has mild or "1+" aortic insufficiency. Aortic insufficiency has not progressed in any patient during the 18 months of follow-up. The patient with 1+ aortic insufficiency has no activity limits, good ventricular function, and no evidence of congestive symptoms. One patient who had extensive thoracoabdominal aneurysmal disease has undergone subsequent replacement of the descending aorta to the level of the renal arteries and has done well. Aortic valve-sparing replacement of the aortic root is an excellent procedure for any patient with an ascending aortic aneurysm and an anatomically salvageable valve. We believe that by modifying the proximal conduit and creating a "pseudosinus" into which the leaflets can retract without contact of the cylindrical conduit we may increase the longevity of the native aortic valve in this procedure. (*J THORAC CARDIOVASC SURG* 1995;109:1049-58)

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Aortic valve insufficiency is increasing as a reason for aortic valve surgery.^{1,2} Until recently, the procedure of choice was replacement of the aortic

root with a composite valved conduit and reimplantation of the native coronary arteries. In 1992 Dr. Tirone David described a reconstructive procedure in which the native aortic valve is spared and resuspended within a tubular conduit during aortic root replacement.³ However, by resuspending the aortic valve within a tubular conduit the David procedure creates an abnormal environment for the valve. How this abnormal reconstruction affects long-term valve durability remains a question. To improve durability in this reconstructive technique, we have modified the David procedure. To provide

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Fig. 1. Measurements used for mathematical derivation of increased length from C_1 (original circumference of conduit) to C_2 (modified circumference of conduit). See text for explanation of variables.

a more natural environment for the aortic valve, we created three "pseudosinuses" in the supra-ventricular region by scalloping the base of the conduit around each commissural position. In our initial 10 patients, the nine most recent underwent this modified reconstruction. This report explains the theoretic basis for this modification, presents the cases of our patients and their early follow-up, and demonstrates echocardiographic results in the two techniques.

Methods

Theory. The sinuses of Valsalva are crucial for normal function of the aortic valve and root, and any aortic reconstruction must be done with this fact kept in mind. The sinuses, in concert with the sinotubular junction, create eddy currents within the supra-ventricular region that initiate valve closure and promote coronary artery blood flow. This eddy formation assists in leaflet coaptation and ensures early and coordinated closure of all three aortic leaflets. The curvilinear configuration created by the unique attachment of the aortic leaflets to the sinuses of Valsalva allows for load or stress sharing between the valve leaflets and aortic wall. Any aortic reconstruction that disrupts this load-sharing configuration will result in increased stress, increased fatigue, and decreased durability of the valve.

The creation of pseudosinuses by conduit modification is simple. In the originally described procedure, a Dacron cylinder (conduit) of "fixed" diameter and circumference is matched to a "fixed" anatomic diameter and circumference, that is, the anulus. In our technique, scalloping the base of the conduit increased the circumference of the cylinder. When this new increased circumference is sewn to the "fixed" anatomic anulus, the cylindrical shape of the conduit is modified. The goal was to guide this reshaping so that the conduit would bulge outward at three locations and create pseudosinuses. These pseudosinuses would allow the aortic valve leaflets to open without abutting the conduit wall and theoretically would recreate the configuration necessary for the load sharing between leaflets and conduit similar to that of the native aortic root configuration.

Before clinical application of this technique, mathematical support for this concept was derived. Fig. 1 illustrates the appearance of the modified free edge of conduit as if

the conduit had been cut along its long axis and laid out flat. C_1 indicates the circumference of the unmodified conduit, and C_2 is the new free edge length of the modified conduit. If the valve is considered to be symmetric, the relationship between C_1 and C_2 can be based on the height of the scallops that are cut into the graft. For the purpose of mathematical analysis, it is assumed that both the upper and lower curvatures of the scallop are arcs of a circle. The length of each of these arcs (3 upper and 3 lower arcs) can be determined simply on the basis of the known diameter of the graft and the chosen scallop height.

For each upper and lower scallop, the arc length, s , is defined by the formula

$$s = R\theta \quad (1)$$

where R is the radius of circular arc (in millimeters) and θ is the angle (radians). R and θ are not directly known; however, they can be calculated from the chord length c_1 and arc height h_1 . The trigonometric formula⁴ that defines the relationship is

$$c_1 = \sqrt{4h_1(2R - h_1)} \quad (2)$$

Solving for R gives

$$R = \frac{c_1^2 + 4h_1^2}{8h_1} \quad (3)$$

Next, the trigonometric formula defining the angle θ is

$$\theta = 2\sin^{-1} \frac{c_1}{2R} \quad (4)$$

Substituting equation 3 into equation 4 gives

$$\theta = 2\sin^{-1} \frac{4h_1c_1}{c_1^2 + 4h_1^2} \quad (5)$$

Substituting equations 3 and 5 into equation 1 gives the arc length based only on chord length and height:

$$s = \frac{c_1^2 + 4h_1^2}{4h_1} \sin^{-1} \frac{4h_1c_1}{c_1^2 + 4h_1^2} \quad (6)$$

Finally, knowing that c_1 is equivalent to $\frac{1}{6}$ of the original circumference (C_1 , which can be calculated from the diameter $[D]$), and knowing that h_1 is $\frac{1}{2}$ of the scallop

Fig. 2. Graphic representation of increase in free edge length (modified circumference) for various scallop heights for several conduit sizes.

height (H), the final equation for the new free edge length (C_2) of the modified conduit is 6 times the arc length s , or

$$C_2 = 6s = \frac{(\pi D)^2 + 36H^2}{12H} \sin^{-1} \frac{12\pi DH}{(\pi D)^2 + 36H^2} \quad (7)$$

The relationship between scallop height and resultant modified free edge length is shown for varying graft diameters in Fig. 2. It can be seen that a significant increase in free edge length can be achieved by scalloping the graft.

Fig. 3 shows the idealized geometric result if this new free edge length (C_2) is attached to the original annular circumference (C_1) in the same horizontal plane and with symmetric fixation of the three commissural posts. The physical result is that the extra material in the scallops will be forced to bulge upward and outward creating pseudosinuses.

In addition to creating pseudosinuses, we wanted to know the amount of bulging that could be created, so the maximum degree of bulging or "additional sinus depth" was also calculated by trigonometric relationships. In Fig. 3, the numeric value of the additional sinus depth is $h_3 - h_2$. Once again assuming circular arcs, the relationship between chord length (c), chord height (h), and arc length (s) defined in equation 6 holds true. In this case the chord length c_2 is constant (and can be calculated from diameter). The two arc lengths of interest are equivalent to $1/3$ of C_1 and C_2 , respectively. The values for h_2 and h_3 can then be solved implicitly from equation 6.

The relationship between scallop height and resultant additional sinus depth is shown for varying graft diameters in Fig. 4. It can be seen that a definable increase in sinus depth can be gained by scalloping the graft.

Patients and technique. Between June 1992 and August 1993, we performed 10 aortic valve-sparing operations for primary aortic root pathologic conditions, using the modified technique in the most recent nine patients. For the modified technique, the conduit was trimmed to create three symmetric scallops in the "annular" end of

Fig. 3. Idealized geometric configuration attained with new free edge length (C_2) attached to annular circumference (C_1) and commissural posts and additional sinus depth that results ($h_3 - h_2$). See text for explanation of variables.

the Dacron conduit, with each scallop having a maximal height of 5 to 7 mm depending on conduit size (Fig. 5). Other than the difference in trimming of the base of the conduit, the technique of insertion is similar to the technique described by David with symmetric, subvalvular stitches along the proximal conduit, resuspension of the valve within the conduit, and reimplantation of the coronary arteries (Fig. 6).

In our series, there were five female and five male patients. The underlying pathologic conditions were equally divided between documented Marfan's disease (5 patients) and annuloaortic ectasia (5 patients). The patients' ages ranged from 37 to 71 years with an average age

Fig. 4. Graphic representation of relationship between scallop height and resultant additional sinus depth shown for several conduit sizes.

Fig. 5. Creation of three symmetric scallops in proximal conduit and circumferential subvalvular stitch placement.

Fig. 6. Completed conduit placement and valve resuspension with creation of pseudosinuses.

of 49.9 years. Two patients had bicuspid aortic valves. Both had distinct commissural posts and relatively normal alignment in relation to the coronary ostia. In each circumstance, the patient's strong desire to avoid anticoagulation therapy was an additional motivating consideration.

The decision as to which patients are appropriate candidates for this operation is multifactorial. The patients selected tended to be younger, but any patient with aneurysmal disease of the ascending aorta and an anatomically functional and salvageable valve was considered a

Table I. Patient data summary

Patient	Age (yr)	Marfan's syndrome	Additional procedures	Crossclamp time (min)	CPB time (min)	Complications	AI
1	55	+	CABG × 2	168	226	None	TR-M
2	37	+	CABG × 1, IABP, RVAD	113	329	RVAD	0-TR
3	47	—	None	148	183	None	0-TR
4	56	+	None	165	216	Amaurosis fugax, paroxysmal atrial fibrillation	0-TR
5	55	—	CABG × 2	148	183	Bilateral pleural effusion	TR-M
6	42	—	None	139	174	None	TR-M
7	43	—	None	170	196	None	0-TR
8	46	+	None	140	158	Pacemaker and atrial fibrillation	TR-M
9	71	—	TAA replacement	171, DHCA = 15	249	None	0-TR
10	47	+	None	127	161	None	Mild (1+)

CPB, Cardiopulmonary bypass; AI, aortic insufficiency; CABG, coronary artery bypass grafting; TR, trace; M, mild; IABP, intraaortic balloon pump; RVAD, right ventricular assist device; TAA, transverse arch aneurysm; DHCA, deep hypothermic circulatory arrest.

candidate for this procedure. The only outlier in our group was the 71-year-old man. His case was unique in that he had a combined ascending aortic aneurysm with aortic insufficiency and a transverse arch aneurysm and, in addition, he had a large thoracoabdominal aneurysm that would necessitate later surgical intervention. This complex anatomy that dictated multiple surgical procedures was a clear indication for valve sparing for the benefit of avoiding anticoagulation in this patient.

It was difficult to determine before operation whether the patients' anatomy made them good candidates for this procedure. Despite having preoperative echocardiographic data, the valvular anatomy could not always be defined. In one patient early in the series, bicuspid anatomy was first identified intraoperatively. This patient was reluctant to consider anticoagulation because of life-style choice. Intraoperative assessment showed that the valve was pliable, only one commissure was fused, and commissural post alignment was nearly normal. As a result of these findings, even though the valve was bicuspid, we spared the valve. The resuspension of this valve and its postoperative function were quite acceptable. After that experience, we have continued to spare selected bicuspid valves. If the bicuspid valve is pliable, noncalcified, and has near normal commissural post alignment so that resuspension can be accomplished, we will consider a valve-sparing procedure.

Results

Our results with this valve-sparing procedure for aortic aneurysmal disease have been excellent, with no mortality and minimal morbidity (Table I). One patient required right ventricular assistance because of inadequate retrograde myocardial protection but did well. The operation is technically challenging with an average aortic crossclamp time of 145.9 minutes and an average cardiopulmonary bypass

time of 209.6 minutes. Additional procedures were done in four patients, with three having concomitant coronary artery bypass grafting and one having repair of transverse arch aneurysm with the use of deep hypothermic circulatory arrest.

Patient follow-up ranged from 4 to 20 months, with a mean follow-up of 13.3 months. New York Heart Association functional class status was most recently assessed by phone contact with either the patient, the immediate family, or the physician primarily caring for the patient. All patients are active and in New York Heart Association functional class I or II, by the follow-up telephone contact. All patients have undergone follow-up echocardiograms early (within the initial hospitalization) and late (from 3 to 6 months after operation). Early and late echocardiographic findings have remained stable without progression of any residual valve insufficiency. Five patients have zero to trace aortic insufficiency, four patients have trace to mild (1+) aortic insufficiency, and one patient has mild (1+) aortic insufficiency. Both bicuspid valves showed trace to mild AI at the time of the procedure and have remained so. Six weeks after receiving the modified David procedure, the 71-year-old patient underwent an uneventful thoracoabdominal replacement of the aorta.

The creation of pseudosinuses was confirmed both intraoperatively by visual inspection and postoperatively by echocardiography. Fig. 7, A, shows the echocardiogram in short axis of the first patient in our series, who received the originally described David procedure. There is no sinus formation seen. In contrast, Fig. 7, B, is the short-axis view of the

Fig. 7. A, Short-axis echocardiogram from first patient (without modified conduit) demonstrates no sinus formation. B, Short-axis view from patient with modified conduit demonstrates three pseudosinuses depicted by three arrows. C, Long-axis view from first patient (without modified conduit) demonstrates linear attachment of conduit to anulus and no sinus formation. D, Long-axis view of patient with modified conduit demonstrates curvilinear attachment of conduit to anulus, pseudosinus formation marked by three straight arrows, and aortic leaflet retracting into "sinus" space shown by curved arrow.

echocardiogram of a patient in whom we used the modified technique. The constructed pseudosinuses are apparent. In the long-axis view, in the first patient in whom there was no modification to the conduit, there is no evidence of bulging or sinus formation (Fig. 7, C). The similar view for the patient with scalloping of the conduit in the modified technique shows not only that a pseudosinus is present, but also that the leaflets retract without contact to the conduit walls (Fig. 7, D).

Postoperative complications have been acceptable. Persistent bilateral pleural effusions that required drainage and sclerosis developed in one patient. The effusions are now well controlled. This patient has stable trace to mild aortic insufficiency on multiple echocardiographic evaluations and has

no evidence of ventricular failure as a cause of the effusions. Another patient had an episode of amaurosis fugax several months after hospital discharge. The patient underwent evaluation including negative carotid duplex and ophthalmologic examinations that did not show retinal changes. She was found by Holter monitoring to have intermittent episodes of atrial fibrillation and flutter. She was not receiving antiplatelet or anticoagulation therapy during these episodes. She has begun to receive low-dose warfarin (Coumadin) therapy for this. Refractory atrial arrhythmias developed in one other patient that necessitated a pacemaker placement 10 months after operation and this patient has also been placed on low-dose warfarin therapy.

Discussion

The increasing prevalence of aortic insufficiency is multifactorial and recently the traditional management has been being scrutinized. Aortic valve insufficiency is caused not only by abnormalities of the valve leaflets (endocarditis, rheumatic heart disease, congenital fusion) but also by abnormalities of the aortic root and anulus that support the valve. The prevalence of both annular dilation alone or aortic root aneurysm with concomitant annular dilation appears to be increasing.^{1,2} Composite valved conduit replacement of the aortic root with reimplantation of the native coronary arteries has provided an excellent solution for most patients.⁵⁻⁷ The composite valved conduit, however, does obligate the patient to the risks of thromboembolism or anticoagulation therapy, or both, if a mechanical valve is incorporated. The estimated thromboembolic rate with mechanical valves is 1% to 2% per patient-year and there is a separate but equal risk of bleeding complications.⁸⁻¹⁴ In those circumstances in which biologic valves are used in conjunction with a conduit, there is a proven limited durability. Thus with either choice, mechanical or biologic valve, the risks are not small. Because annuloaortic ectasia often presents in the younger, more active patient population, the anticoagulation risks are frequently more unacceptable and lead to potential delays in surgical intervention until ventricular performance deteriorates. In the patients with systemic aneurysmal vascular disease (for example, Marfan's syndrome, connective tissue disorders) the natural history of the disease often includes multiple surgical procedures.¹⁵ In these patients, a mechanical aortic prosthesis with obligatory anticoagulation increases the risks of perioperative complications during subsequent operative interventions.

In 1992 Dr. Tirone David described an alternative procedure in which the native aortic valve is spared during aortic root replacement.³ The David procedure excises all aneurysmal aortic tissue from the aortic arch proximally and extends this excision to the level of the aortic anulus, sparing only a small rim of tissue adjacent to the commissural posts, thus avoiding future aneurysm formation. To facilitate positioning of the graft, that portion of the conduit adjacent to the commissural post is scalloped between the right and left coronary sinuses. Once the conduit is secured at the level of the aortic anulus, the aortic valve is resuspended inside the Dacron conduit by a technique similar to free-hand homograft implantation. Standard reimplantation of

Fig. 8. Schematic representation of aortic valve and root demonstrating role of sinus ridge in creation of eddy currents for enhanced valve closure and coronary artery perfusion.

the coronary arteries in their appropriate positions and distal reconstruction of the aortic arch with the conduit completes the procedure.^{3,16} Unfortunately, although this procedure spares the native aortic valve, the valve is resuspended in a cylinder and that is an unnatural environment for the valve.

The resuspension of the valve in a cylinder ignores the fact that the aortic valve and the aortic root are inseparable in their physiologic roles. The relationship of the aortic valve to the aortic root is one of natural synergy. Part of this synergy is the configuration of the valve, the sinuses, and the sinotubular junction. The aortic valve, the sinuses of Valsalva, the coronary ostia, and the sinotubular ridge are positioned and configured to facilitate valve closure, to encourage coronary artery blood flow, and to share stress and load bearing.¹⁷⁻¹⁹ This configuration is necessary to create eddy formation in the blood flow within the aorta. It is this eddy formation that initiates valve closure and promotes coronary artery perfusion (Fig. 8). The sharing of the stress and load bearing between the leaflets and root is an equally crucial part of the interaction of this system.²⁰ Unfortunately, as in any interdependent system, dysfunction of one component ultimately results in disruption of the other parts of the system. This interdependence of the aortic valve and root explains both aortic valvular dysfunction caused by a disease process that only involves the aortic root and the potential for early failure in any reconstructive technique that ignores it. Because all aortic valve-sparing procedures are based on the

three premises that the underlying disease arises from the aortic root or wall tissue, that the aortic valve dysfunction is all caused by the disease of the root, and that the valve should thus be saved, this same logic dictates that the aortic valve should be resuspended in as natural an environment as possible to attain normal function and durability.

The procedure as done by David suspended the aortic valve within a cylindrical conduit and thus creates an abnormal environment for the valve. Theoretically, several questions of durability arise. The most prominent question is the effect on the ability of the valve to manage stress and load bearing after resuspension in a cylindrical conduit without sinuses of Valsalva and without a sinotubular junction. How this abnormal reconstruction affects long-term valve durability remains a question for theoretic debate and laboratory investigation. However, the possible benefits of sparing a "normal" valve and avoiding anticoagulation are too compelling not to offer this type of procedure to selected patients. In initiating our experience, this question of suspending the valve in a cylindrical conduit remained. During the first procedure, after scalloping of the conduit as done by David, we observed an asymmetry to the conduit. Once the annular stitches were secured, the scalloped region of the conduit bulged outward. This bulging on either side of the commissural post appeared similar to half of a sinus of Valsalva. As a result of this observation, we discussed the theoretic possibility of creation of a pseudosinus by scalloping of the base of the conduit at all three commissural positions. The theoretic basis for creation of three pseudosinuses proved valid as outlined earlier, thus we have modified our technique to achieve this in the remaining nine patients reported on in this series.

Our initial experience with this technique has confirmed our belief that the sinuses of Valsalva are a crucial component of the aortic root. The normal aortic valve relies on their presence for initiation of valve closure and enhancement of coronary artery flow. The leaflets and the sinuses also work in concert for load sharing and thus reduce the stress of both the leaflets and the aortic wall. The creation of pseudosinuses in the conduit is an attempt to recreate this natural anatomic arrangement. This modified technique is reproducible, easily done, and potentially more durable than the procedure as it was originally described.

In conclusion, the sparing of the aortic valve in selected cases of aortic insufficiency is an excellent

alternative to procedures that require mechanical valve replacement. The long-term durability of the aortic valve in a cylindrical conduit without sinuses of Valsalva is questionable because of the alterations in stress on the valve leaflets, fluid flow dynamics, and interaction between the leaflets and the aortic wall. A simple modification of the conduit allows for creation of pseudosinuses within the conduit. We believe, for patients with aortic root aneurysms and relatively normal aortic valves, that this modified aortic valve-sparing aortic root replacement is the procedure of choice.

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Discussion

Dr. D. Craig Miller (*Stanford, Calif.*). This is a beautiful concept and wonderful theory. It builds on the solid physiologic concepts developed by Stan Nolan and his colleagues at the University of Virginia that the aortic root—the sinuses, the sinotubular ridge, and the leaflets—are one functional dynamic unit. I think all of us were impressed by the elegant mathematical modeling that was done by Karyn Kunzelman.

We also have a small number of patients in whom we have used the Yacoub, David, or Griepp procedure (these three physicians came up with similar ideas, starting with Sir Magdi Yacoub in 1975). We have always carefully excluded those patients with the Marfan syndrome, however, and I would like to go into that a bit. This operation basically is an orthotopic aortic valve autograft with Dacron cylinder replacement of the aortic root, including all of the sinuses, and coronary artery reimplantation. First, I think we have to be careful because none of us knows if this is the right way to go, and we will not know with certainty for many years. To wit, Randall Gripp and his colleagues at Mt. Sinai Hospital in New York have already abandoned this type of procedure because the durability of the aortic valve repair was not satisfactory. Tirone David himself has told me that he will not do this procedure any longer in patients with the Marfan syndrome who have a large aortic anulus because he is afraid of limited valve durability in these specific patients. Hans Borst in Hannover, Germany, however, has relied only on

this type of procedure since November 1993 and is no longer using mechanical composite valve grafts.

I am sure most of you know that the gene responsible for the Marfan syndrome has been mapped with the use of genetic linkage studies to the long arm of the fifteenth chromosome; this locus was subsequently found to be the fibrillin-1 gene. Fibrillin is a large glycoprotein structural component of the microfibrils of the connective tissue matrix and can be identified by monoclonal antibody techniques in cultured skin and aortic fibroblasts. The disease is not quite that simple, that is, just involving a mutant or abnormal fibrillin-1 gene, because there are missense mutations, nonsense mutations, frame replication errors, and premature exon termination errors. Thus the disease is pretty complex. This results in not just normal or abnormal fibrillin, but there may also be various patterns of fibrillin synthesis or deposition abnormalities.

Uta Francke and Heinz Furthmayer at Stanford are examining the aortic valve leaflets from patients with the Marfan syndrome to see whether they can identify the absence of fibrillin-1 or abnormal fibrillin synthesis or deposition. If so, do you think it is really wise to save these valves in patients with the Marfan syndrome?

Dr. Cochran. Marfan's syndrome is a concern to all of us involved in this, but we liken the situation to mitral valve repair and diseased tissue. We do not know what the long-term durability is and we are just trying to return the tissue to a normal physiologic environment and see what the long-term durability is, as we do with the mitral valve. We hope that, whatever the disease process in the tissue, the disease will not progress if the valve is in a normal physiologic state. We have to follow up these patients closely and disease progression is a concern, but we are obviously being fairly aggressive with the Marfan population.

Dr. Miller. With regard to your rationale, you state that anticoagulation therapy in young patients (if a mechanical composite valve graft is used) carries an increased risk of anticoagulation-related bleeding complications. I am not sure I agree with that. I think anticoagulation is most difficult in elderly patients and that they have the highest risk over time of bleeding.

Dr. Cochran. Right. We have only one patient who would qualify as elderly and his was a special situation: this patient needed multiple procedures and the ascending aorta replacement was the first to be done. He had a thoracoabdominal aortic replacement that was done within 6 weeks after this procedure, and he really did not want to be taking anticoagulation medications. This patient is probably in an exceptional group and he skews our age numbers. For the most part we have selected carefully a young population who are relatively adamant about not receiving anticoagulation therapy. Without our 71-year-old patient, our age mean drops to near 40 years.

Dr. Miller. It is the patient's desire to avoid anticoagulation therapy, then? You are not really saying that young patients have more bleeding complications when they are receiving warfarin?

Dr. Cochran. Correct.

Dr. Miller. You also state that you would like to avoid warfarin anticoagulation in these young patients, particularly those with the Marfan syndrome, because they are

potentially going to need other operations in the future. I think all of us know these patients do unfortunately need all too many operations eventually. Therefore, I would caution use of this procedure in patients with the Marfan syndrome because I think we should do everything we can to make the initial procedure more "curative," or at least a more durable and definitive one. Could you comment?

Dr. Cochran. That is a difficult clinical question to answer, but there is not a great answer in this patient population right now. We have taken the tack that if the patient desires to avoid anticoagulation therapy, we think this is a good alternative operation. We do inform them there is the possibility in a relatively short time, because we do not have follow-up, that they may have to undergo aortic valve replacement. The patients are made aware of that and we make the decision with them in that regard.

Dr. Miller. You have already mentioned that one 71-year-old patient skewed your age numbers, which ranged from 37 to 71 years, with an average age of 50. I note that there were no children or adolescents in your series in whom this procedure might indeed have much greater theoretic appeal.

Dr. Cochran. Yes. We have been somewhat biased by Dr. David's experience. At last count, he has done his operation in more than 40 patients and he has only one patient, a 14 year old, who has progressed as far as aortic insufficiency. We have actually avoided these patients in their teenage years. We would extend the age to the younger adults, in their twenties or so, but we have avoided patients who are still growing or in whom the disease process is not defined.

Dr. Miller. The average aortic crossclamp time was just shy of 2½ hours and average pump time was 3½ hours. How do you justify these long times? I agree with you that this procedure takes a lot longer than insertion of a simple mechanical composite valve graft. In which specific patients would the long ischemic times not be acceptable?

Dr. Cochran. We have to be selective. Again, we choose patients who have good ventricular function and who can tolerate the extended procedure. There is no question it is a much bigger operation, particularly if combined with other procedures, such as coronary artery bypass grafting.

Dr. Miller. This question is theoretic also. You might want to refer it to Karyn Kunzelman. By excising these scallops in the graft, you must be distributing more stresses to other regions in the proximal suture line. Because the proximal sutures come from the left ventricular outflow tract through the myocardium to the outside, could excessive stresses there perhaps portend a higher likelihood of late disruption or recurrent aortic regurgitation in the future?

Dr. Cochran. I do not think that we have evidence that there is more stress there. There is an increased circumference but it is reduced to the original C₁ size, because we use the same annular stitches. If you are thinking that there is a radial type of expansion of the anulus, other than physiologic, I do not think that exists because we use the same numbers as if we put a conduit there. Dr. Kunzelman might address more specifics as far as the tissue stresses at that level, but we have not done that per se.

Dr. Kunzelman. I do not think we can answer that question definitively at this point. I would not predict that there are higher stresses because of the way the conduit is being reconfigured to the natural sinuses, but we are addressing this in a computer model so we will be able to answer this question in the future.

Dr. Miller. Your finite element analyses should prove to be illuminating. We look forward to an answer.

Finally, at least in theory, I think all of us find intuitively attractive this concept that the three pseudosinuses will increase the durability of the aortic valve repair, but, as you mentioned, your follow-up is short and you are being cautious. Are you going to test your hypothesis rigorously in a prospective randomized trial?

Dr. Cochran. That is the ultimate test in any procedure like this. It is difficult to randomize this patient population because we do not know what population to randomize them against. We would have a whole other group of complications in using the Bentall or valved-conduit procedure. I am not sure they would truly be the same patient population in a randomized sense, but we are discussing that. Right now we are fairly committed to this operation in this patient population and have not embarked on randomization.

Dr. Miller. I am not sure I agree with this logic for not randomizing the patients.

Dr. Cochran. In other words, one patient will face the risk of anticoagulation, and the durability of the natural valve, which is the test in the operation, would not be compared.

Dr. Miller. I am sorry, I did not state the hypothesis clearly enough. I was thinking of comparing the regular Yacoub, David, or Griepp operation (without the pseudosinuses) with your procedure incorporating the three pseudosinuses.

Dr. Cochran. Well, because David has already modified his operation to try to attain a similar bowing, although his technique is a little different from ours, I do not think anybody really wants to stay with a cylindrical conduit. For this reason, at present we are not randomizing.