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Methods. A bicuspid pulmonary valve is created with polytetrafluoroethylene and sutured into the right ventricular outflow tract. PTFE Bicuspid Pulmonary Valves were placed in 126 patients (age: range = 3.1 to 64.7 years, mean = 17.9 years; weight: range = 14.2 to 113.6 kilograms, mean= 55.4 kg). All patients had pulmonary insufficiency, pulmonary stenosis, or both, most commonly after previous repair of tetralogy of Fallot (71 patients). Follow-up was up to 8.3 years (range = 0 - 8.3 years, mean = 3.34 years).

Results. Operative mortality was 1 patient (0.8%). Late mortality was non-valve related in three patients (2.4%). Six patients out of 126 (4.8%) have required replacement of the PTFE Bicuspid Pulmonary Valve due to immobile and calcified leaflets. All six who required replacement of the PTFE Bicuspid Pulmonary Valve initially received a valve constructed from porous 0.6 mm PTFE material. We currently use nonporous 0.1 mm PTFE, which does not allow cellular in-growth and thickening. Early echocardiographic follow-up of these valve leaflets made with 0.1 mm PTFE has demonstrated improved leaflet mobility and pliability, and lower transvalvar gradients.

Conclusions. PTFE Bicuspid Pulmonary Valve implantation is a safe, effective, and demonstrates acceptable performance for the intermediate –term. It is anticipated that utilizing thinner 0.1 mm PTFE will result in improved valve function and durability. Long-term follow-up is necessary to determine the true value of this technique.

Polytetrafluoroethylene Bicuspid Pulmonary Valve Implantation – Experience with 126 Patients

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Keywords: tetralogy of Fallot, pulmonary stenosis, pulmonary insufficiency, database, congenital heart disease; outcomes; cardiac surgery; results of treatment

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Results. Operative mortality was 1 patient (0.8%). Late mortality was non-valve related in three patients (2.4%). Six patients out of 126 (4.8%) have required replacement of the PTFE Bicuspid Pulmonary Valve due to immobile and calcified leaflets. All six who required replacement of the PTFE Bicuspid Pulmonary Valve initially received a valve constructed from porous 0.6 mm PTFE material. We currently use nonporous 0.1 mm PTFE, which does not allow cellular in-growth and thickening. Early echocardiographic follow-up of these valve leaflets made with 0.1 mm PTFE has demonstrated improved leaflet mobility and pliability, and lower transvalvar gradients.

Conclusions. PTFE Bicuspid Pulmonary Valve implantation is a safe, effective, and demonstrates acceptable performance for the intermediate –term. It is anticipated that utilizing thinner 0.1 mm PTFE will result in improved valve function and durability. Long-term follow-up is necessary to determine the true value of this technique.

Background

As the population of children with repaired congenital heart disease ages, an increasing number of patients will benefit from pulmonary valve insertion [1]. We have previously described pulmonary valve implantation with a Polytetrafluoroethylene (PTFE) Bicuspid Pulmonary Valve [1, 2, 3]. In 2005, we reported our initial experience with a PTFE Bicuspid Pulmonary Valve in 41 children and adults [1, 2]. We have since modified this technique somewhat by changing from PTFE with 0.6 millimeter thickness to PTFE with 0.1 mm thickness [3]. We have now placed PTFE Bicuspid Pulmonary Valves in 126 patients. The purpose of this manuscript is to update our series of patients undergoing placement of PTFE Bicuspid Pulmonary Valves at The Congenital Heart Institute of Florida (CHIF).

Material and Methods

Patients

At The Congenital Heart Institute of Florida (CHIF), 126 consecutive patients underwent placement of the PTFE Bicuspid Pulmonary Valve from December 1, 2000 through September 25, 2009. These 126 patients are all of the patients at CHIF who received a PTFE Bicuspid Pulmonary Valve as of September 25, 2009. Patient demographics are presented below:

- Weight: Mean = 55.4 kg (range = 14.2 - 113.6)
- Age: Mean = 17.9 (range = 3.1 – 64.7 years)
- Follow-up up to 8.3 years
- Follow-up: Mean = 3.34 years (range = 0 - 8.3 years)

The diagnoses of these 126 patients are presented in Table 1. In general, our indications for pulmonary valve replacement are evolving [2, 3] but currently include patients with moderate to severe pulmonary insufficiency and/or stenosis and any of the following problems:

(1) exertional symptoms of NYHA Class II or greater,
(2) decreased performance capacity on exercise testing,
(3) significant right ventricular dilation (greater than 150 milliliter per meter^2 by magnetic resonance imaging),
(4) significant right ventricular dysfunction,
(5) significant ventricular arrhythmias, and/or
(6) QRS duration greater than 180 milliseconds.

Operative Technique

The surgical technique for creation and placement of the PTFE Bicuspid Pulmonary Valve has been previously described in detail [1, 2, 3]. The initial 84 patents in this series received valves constructed from PTFE with 0.6 mm thickness. The next 42 patients received valves constructed from PTFE with 0.1 mm thickness. PTFE with 0.1 mm thickness has been used since May 12, 2006. In this series, the majority of PTFE Bicuspid Pulmonary Valves were inserted in a reoperative setting, after previous cardiac surgery, most

commonly after previous repair f tetralogy of Fallot. A small number of these valves were inserted at the time of primary cardiac operation, usually as treatment for pulmonary insufficiency. Postoperatively, Daily low dose aspirin is used to minimize neointimal hyperplasia. No other form of anticoagulation is used unless the patient has other indications for anticoagulation.

Database and Statistics

Informed consent for pulmonary valve insertion was obtained in all cases and included a detailed explanation of the novel nature of the bicuspid pulmonary valve and a detailed explanation of alternative valves available for right ventricular outflow tract reconstruction. This research is under Institutional Review Board protocol numbers 03-0513 and 03-0801 through the University of South Florida College of Medicine.

A registry and database (a component of the CardioAccess International Clinical Outcomes Database: Comprehensive Cardiovascular and Thoracic Module, CardioAccess Inc, Saint Petersburg, FL and Fort Lauderdale, FL: http://www.cardioaccess.com) has been prospectively maintained on all patients and has been utilized for data collection and analysis. Follow-up was performed utilizing the CardioAccess Database, office charts, and phone interviews. Follow-up variables analyzed included annual and latest follow-up echocardiographic quantification of pulmonary stenosis and pulmonary insufficiency.

Data are presented as percentages, mean values, median values, and ranges where appropriate. The Kaplan-Meier method was used to create survival curves for both the patients and the valves.

Results

Four patients out of 126 (3.2%) died during the follow-up. Operative mortality [4] was 1 patient (0.8%) who died from a cerebrovascular accident. Late mortality was non-valve related in three patients (2.4%) who died from suicide, motor vehicle accident, and our oldest patient (64.7 year old) who died late from a myocardial infarction. Six patients out of 126 (4.8%) have required replacement of the PTFE Bicuspid Pulmonary Valve due to immobile and calcified leaflets. Figure 1 shows freedom from death and freedom from replacement of the PTFE Bicuspid Pulmonary Valve after 8.3 years follow up, in the total study population of 126 patients, as documented by Kaplan-Meier curve.

All deaths and all replacements of the PTFE Bicuspid Pulmonary Valve were in patients who received the valve constructed with 0.6 mm PTFE. Figure 2 shows freedom from death after 8.3 years follow up, stratified by valves constructed with 0.6 mm PTFE and valves constructed with 0.1 mm PTFE, as documented by Kaplan-Meier curve. Figure 3 shows freedom from replacement of the PTFE Bicuspid Pulmonary Valve after 8.3 years follow up, stratified by valves constructed with 0.6 mm PTFE and valves constructed with 0.1 mm PTFE, as documented by Kaplan-Meier curve.

Tables 2 and 3 show the annual progression of the development of pulmonary insufficiency and pulmonary stenosis, respectively, in the PTFE Bicuspid Pulmonary Valve, in the total study population of 126 patients.

Tables 4 and 5 show the annual progression of the development of pulmonary insufficiency and pulmonary stenosis, respectively, in the PTFE Bicuspid Pulmonary Valve, stratified by valves constructed with 0.6 mm PTFE and valves constructed with 0.1 mm PTFE.

Comment

Outcomes of surgery for congenitally malformed hearts continue to improve, and more patients survive after surgery for congenital heart disease each year [5, 6, 7]. As of 2000, more adults than children are alive with congenital heart disease [8]. Pulmonary valve implantation is one of the more common operations performed in adults with congenital heart disease [8, 9]. Our rationale for the development of the PTFE Bicuspid Pulmonary Valve was based on the following facts:

(1) A suboptimal clinical experience exists with the current choices for pulmonary valve implantation in older patients, and indeed the ideal pulmonary valve does not exist.
(2) Favorable experimental and clinical results had been previously reported with PTFE monocusp pulmonary valves, especially in smaller patients [10].

At The Congenital Heart Institute of Florida (CHIF), we previously published our experience with our initial 41 patients undergoing PTFE Bicuspid Pulmonary Valve implantation from December 1, 2000 through October 31, 2003 [2]. In this initial series, PTFE Bicuspid Pulmonary Valves were placed in 41 patients (age: range = 5.0 to 64.7 years, median = 15.7 years; weight: range = 14.2 to 99.0 kilograms, median= 52.0 kg). All patients had pulmonary insufficiency, pulmonary stenosis, or both, after previous intervention for tetralogy of Fallot (27), pulmonary stenosis (11), pulmonary atresia with intact ventricular septum (2), or double outlet right ventricle (1). In this initial series, all patients left the operating theater with transesophageal echocardiography documenting no pulmonic stenosis and zero to trace pulmonic insufficiency. Median hospital length of stay was 5 days (range, 3 to 15days; mean, 5.8 days). Follow-up including echocardiography ranged from 0.2 to 3.1 year (median follow-up = 1.5 years) and revealed significant improvement in New York Heart Association Classification, pulmonary insufficiency, and right ventricular end diastolic dimension. In this initial report, we concluded that: "Polytetrafluoroethylene bicuspid pulmonary valve reconstruction of the right ventricular outflow tract is a safe, effective, and durable technique for the short term. Appropriate oversizing minimizes outflow tract obstruction while maximizing competence. Long-term follow-up is necessary to determine the true value of this technique."

Our updated experience of 126 patients treated with PTFE Bicuspid Pulmonary Valve implantation has revealed that six of our early implants using the porous 0.6 mm PTFE material have been explanted due to immobile and calcified leaflets. We currently use nonporous 0.1 mm PTFE, which does not allow cellular in-growth and thickening, as reported by others in monocusp applications [10]. Early echocardiographic follow-up

of these valve leaflets made with 0.1 mm PTFE has demonstrated improved leaflet mobility and pliability, and lower transvalvar gradients [3]. It is anticipated that utilizing this thinner PTFE will result in improved valve function and durability.

We hypothesize that the valves constructed with 0.1 mm PTFE will be less likely to develop stenosis over time, in comparison to the valves constructed with 0.6 mm PTFE, secondary to the fact that the nonporous 0.1 mm PTFE does not allow cellular in-growth and thickening. Our early data support this hypothesis and show that not only are the valves constructed with 0.1 mm PTFE less prone to develop stenosis over time, in comparison to the valves constructed with 0.6 mm PTFE, but the valves constructed with 0.1 mm PTFE retain their competence just as good as the valves constructed with 0.6 mm PTFE. Of course, it is possible that the failure of the six 0.6 mm thick PTFE valves may not be related to the thickness of the PTFE and the potential cellular in-growth and thickening of the PTFE, but may rather be related to the fact that these valves were inserted early in the experience. This result may simply reflect the true durability of the valve, which may very well be seen at an equivalent interval in the patients whose valves were constructed out of 0.1mm PTFE. Further follow-up is necessary to determine if this possibility is true.

From this experience of 126 patients treated with PTFE Bicuspid Pulmonary Valve implantation, we believe that PTFE Bicuspid Pulmonary Valve implantation meets the following criteria:

(1) Safe, effective, and demonstrates acceptable performance for the intermediate-term
(2) Non-immunogenic
(3) Easily constructed and inexpensive

We also postulate that the nonporous 0.1 mm PTFE may last longer than porous 0.6 mm PTFE because the 0.6 mm PTFE can develop immobile and calcified leaflets secondary to cellular in-growth and thickening.

Clearly, the surgeon must be prepared for a wide variety of clinical circumstances and the appropriate surgical techniques must be selected for the given situation. The “ideal” valve for right ventricular outflow tract reconstruction is not available. A variety of valve options are currently available, all with significant shortcomings, especially with regard to durability and long term function. In the future, advances in technique and technology for right ventricular outflow tract reconstruction will include better materials for valve construction, potentially including bioengineered valves [11], and novel methods of implantation, including percutaneous transcatheter valve insertion and perventricular transcatheter valve insertion.

Tables

Table 1: Table 1 documents the diagnoses of the initial 126 consecutive patients who underwent placement of the PTFE Bicuspid Pulmonary Valve from December 1, 2000 through September 25, 2009 at The Congenital Heart Institute of Florida (CHIF).

Diagnosis	**Number**
TOF	71
Pulmonary Insufficiency	20
Pulmonary stenosis	12
Pulmonary atresia-IVS	6
Pulmonary atresia-VSD	4
TOF, Absent pulmonary valve	4
Truncus arteriosus	2
Other	7
TOTAL	**126**

Table 2. Table 2 documents the annual progression of the development of pulmonary insufficiency (Grade 0-4) in the PTFE Bicuspid Pulmonary Valve, in the total study population of 126 patients.

Table 2. Pulmonary Insufficiency - All Patients

Year of Follow-Up	*1*	*2*	*3*	*4*	*5*	*6*	*7*
Mean	1.5	1.9	2.0	2.0	2.1	2.2	2.0
Standard Error	0.1	0.1	0.1	0.1	0.1	0.2	0.2
Median	1	2	2	2	2	2	2
Mode	1	2	2	2	2	2	2
Standard Deviation	0.8	0.8	0.8	0.8	0.8	0.9	0.8
Range	3	3.5	4	3.5	3.5	3.0	2.5
Minimum	0	0	0	0	0	1	1
Maximum	3	3.5	4	3.5	3.5	4.0	3.5
Count	79	68	55	48	36	19	12

Table 3. Table 3 documents the annual progression of the development of pulmonary stenosis in the PTFE Bicuspid Pulmonary Valve, in the total study population of 126 patients. Values from individual patients are echocardiographic estimates of mean gradients (in mm Hg), and not peak instantaneous gradients. N/A = not applicable.

Table 3. Pulmonary Stenosis – All Patients

Year of Follow-Up	*1*	*2*	*3*	*4*	*5*	*6*	*7*
Mean	14.5	16.3	17.4	18.7	18.6	20.6	14.7
Standard Error	1.1	1.2	1.2	1.6	1.4	2.3	4.8
Median	13	15	16	18	18	21	10.5
Mode	8	15	21	18	25	32	N/A
Standard Deviation	9.4	9.3	8.8	10.2	8.2	9.6	9.6
Range	49	52.8	51	50.7	40	36.5	20.2
Minimum	0	2.2	0	0	0	0	8.76
Maximum	49	55	51	50.7	40	36.5	29.0
Count	73	57	52	40	33	17	4

Table 4. Table 4 documents the annual progression of the development of pulmonary insufficiency (Grade 0-4) in the PTFE Bicuspid Pulmonary Valve, stratified by valves constructed with 0.6 mm PTFE and valves constructed with 0.1 mm PTFE.

Table 4. Pulmonary Insufficiency – Stratified by Valve Thickness

Year of Follow-Up	*1*	*2*	*3*	*4*	*5*	*6*	*7*
0.6 mm PTFE							
Mean	1.6	1.9	2.0	2.0	2.1	2.2	2.0
Standard Error	0.1	0.1	0.1	0.1	0.1	0.2	0.2
Median	2	2	2	2	2	2	2
Mode	1	2	2	2	2	2	2
Standard Deviation	0.9	0.8	0.8	0.8	0.8	0.9	0.8
Range	3	3.5	4	3.5	3.5	3.0	2.5
Minimum	0	0	0	0	0	1	1
Maximum	3	3.5	4	3.5	3.5	4.0	3.5
Count	51	57	54	48	36	19	12
0.1 mm PTFE							
Mean	1.3	1.7	2.0				
Standard Error	0.1	0.2	0.0				
Median	1	2	2				
Mode	1	2	2				
Standard Deviation	0.6	0.6	0.0				
Range	3	2	0				
Minimum	0	1	2				
Maximum	3	3	2				
Count	28	11	2				

Table 5. Table 5 documents the annual progression of the development of pulmonary stenosis in the PTFE Bicuspid Pulmonary Valve, stratified by valves constructed with 0.6 mm PTFE and valves constructed with 0.1 mm PTFE. Values from individual patients are echocardiographic estimates of mean gradients (in mm Hg), and not peak instantaneous gradients. N/A = not applicable.

Table 5. Pulmonary Stenosis – Stratified by Valve Thickness

Year of Follow-Up	*1*	*2*	*3*	*4*	*5*	*6*	*7*
0.6 mm PTFE							
Mean	17.4	16.4	17.4	18.7	18.6	20.6	14.7
Standard Error	1.4	1.4	1.2	1.6	1.4	2.3	4.8
Median	15	15	16	18	18	21	10.5
Mode	15	15	21	18	25	32	N/A
Standard Deviation	9.3	9.8	8.8	10.2	8.2	9.6	9.6
Range	49	52.8	51	50.7	40	36.5	20.2
Minimum	0	2.2	0	0	0	0	8.76
Maximum	49	55	51	50.7	40	36.5	29.0
Count	46	47	52	40	33	17	4
0.1 mm PTFE							
Mean	9.6	15.5	11.5				
Standard Error	1.4	2.0	3.5				
Median	9	16.5	11				
Mode	0	N/A	N/A				
Standard Deviation	7.4	6.4	4.9				
Range	26	20	6.9				
Minimum	0	6	8				
Maximum	26	26	15				
Count	27	10	2				

LEGENDS TO FIGURES

Figure 1. Figure 1 shows freedom from death and freedom from replacement of the PTFE Bicuspid Pulmonary Valve after 8.3 years follow up, in the total study population of 126 patients, as documented by Kaplan-Meier curve. The curve shows all 126 patients. The upper red line is patient survival. The lower blue line is valve survival.

Figure 2. Figure 2 shows freedom from death after 8.3 years follow up, stratified by valves constructed with 0.6 mm PTFE and valves constructed with 0.1 mm PTFE, as documented by Kaplan-Meier curve. The upper curve shows patients who received valves constructed with 0.6 mm PTFE. The lower curve shows patients who received valves constructed with 0.1 mm PTFE.

Figure 3. Figure 3 shows freedom from replacement of the PTFE Bicuspid Pulmonary Valve after 8.3 years follow up, stratified by valves constructed with 0.6 mm PTFE and valves constructed with 0.1 mm PTFE, as documented by Kaplan-Meier curve. The upper curve shows patients who received valves constructed with 0.6 mm PTFE. The lower curve shows patients who received valves constructed with 0.1 mm PTFE.

FIGURE 1

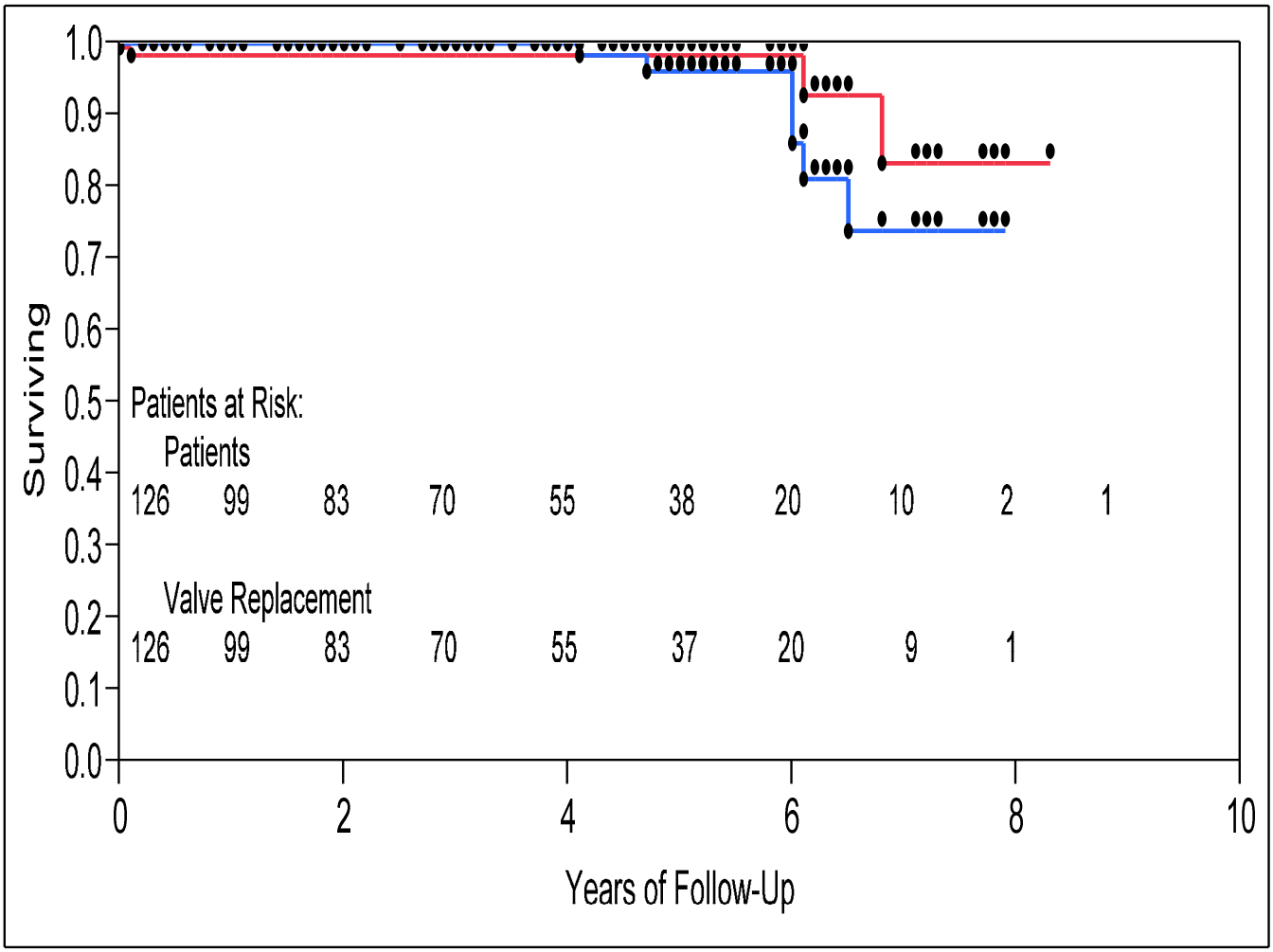
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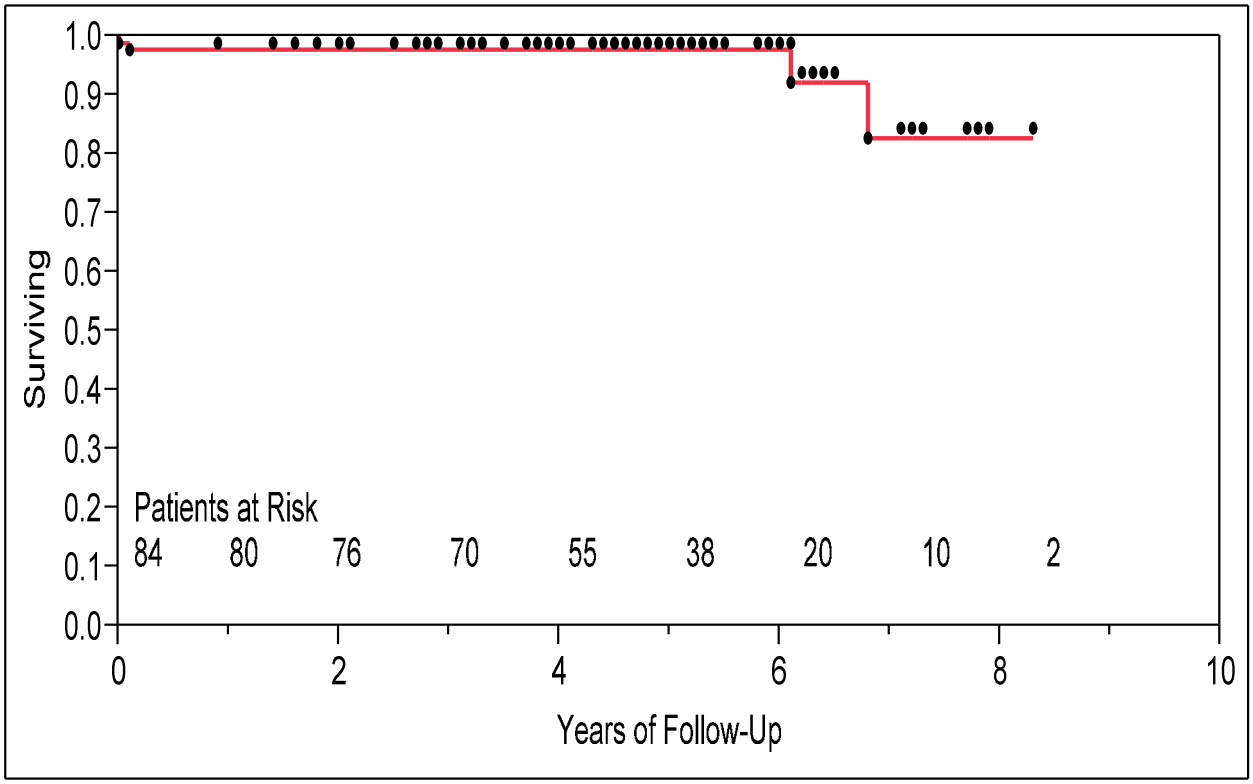
Figure 2.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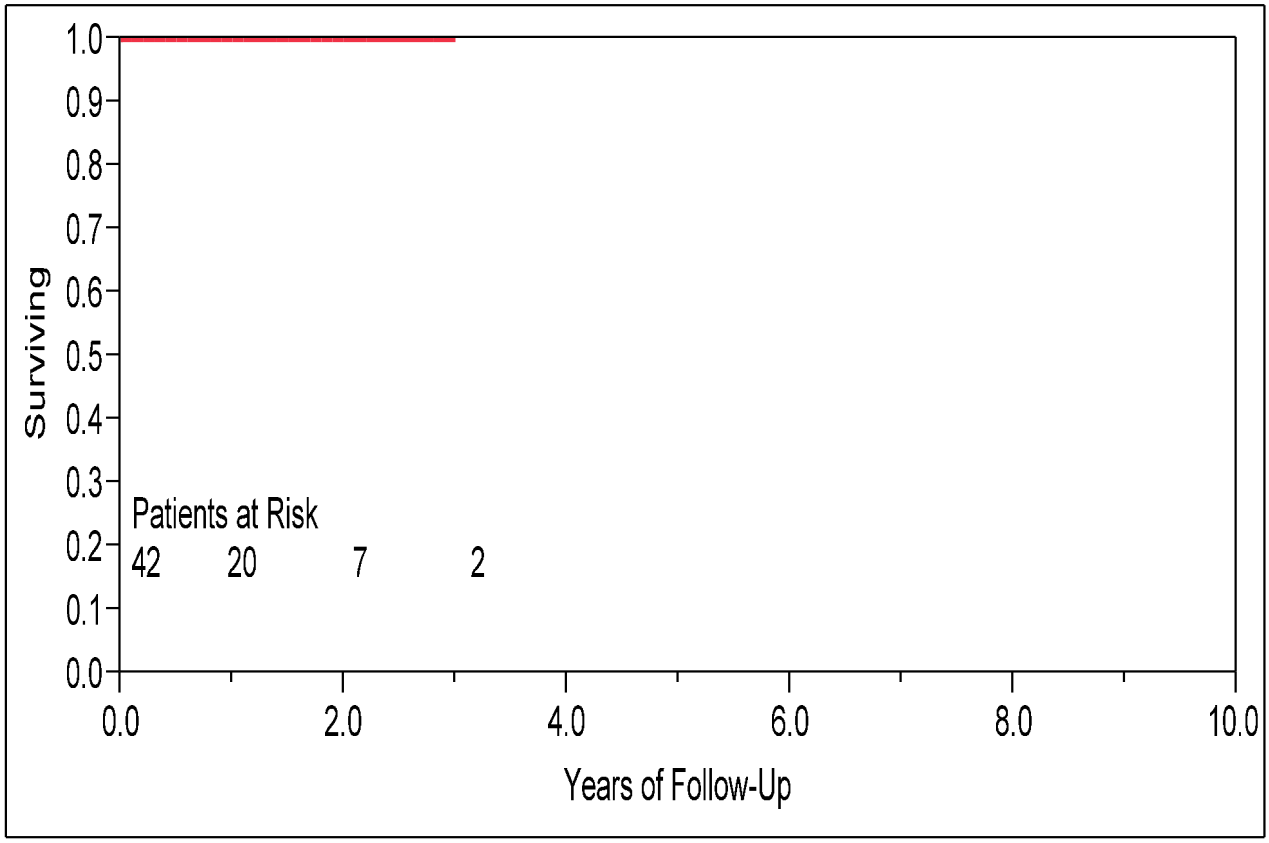
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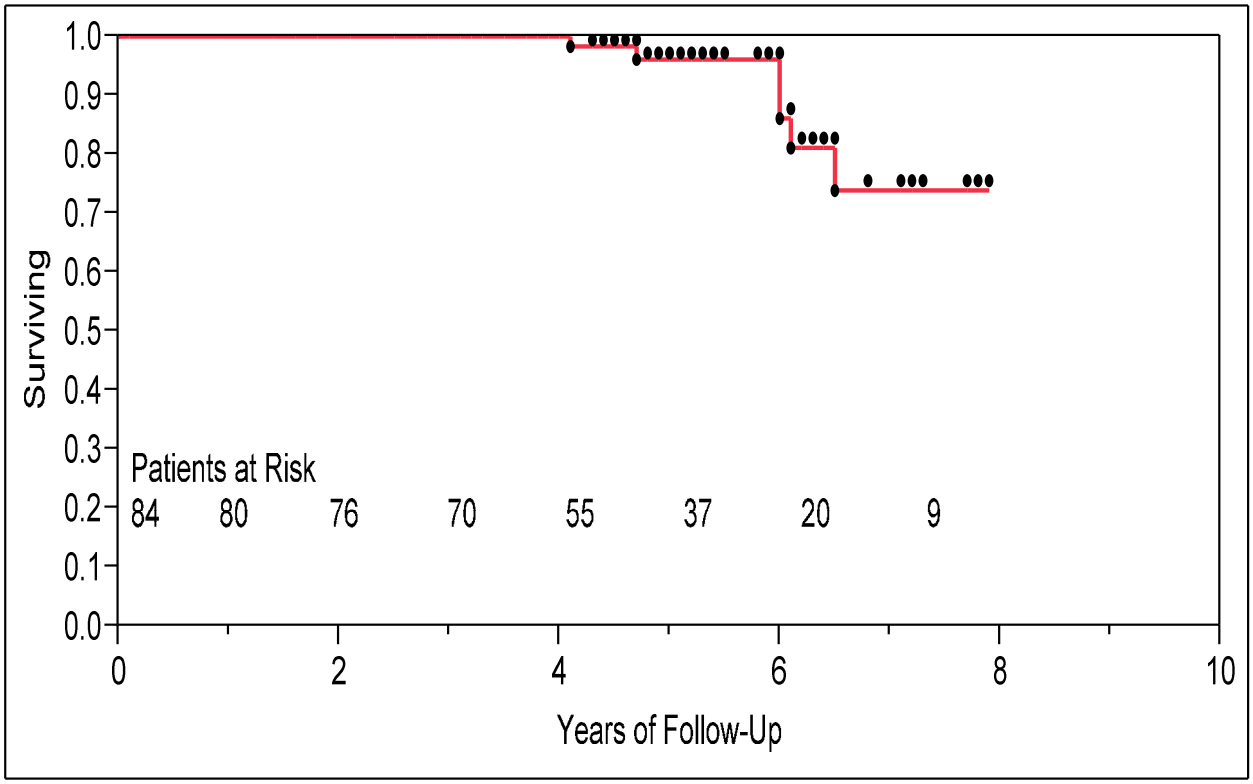
Figure 3.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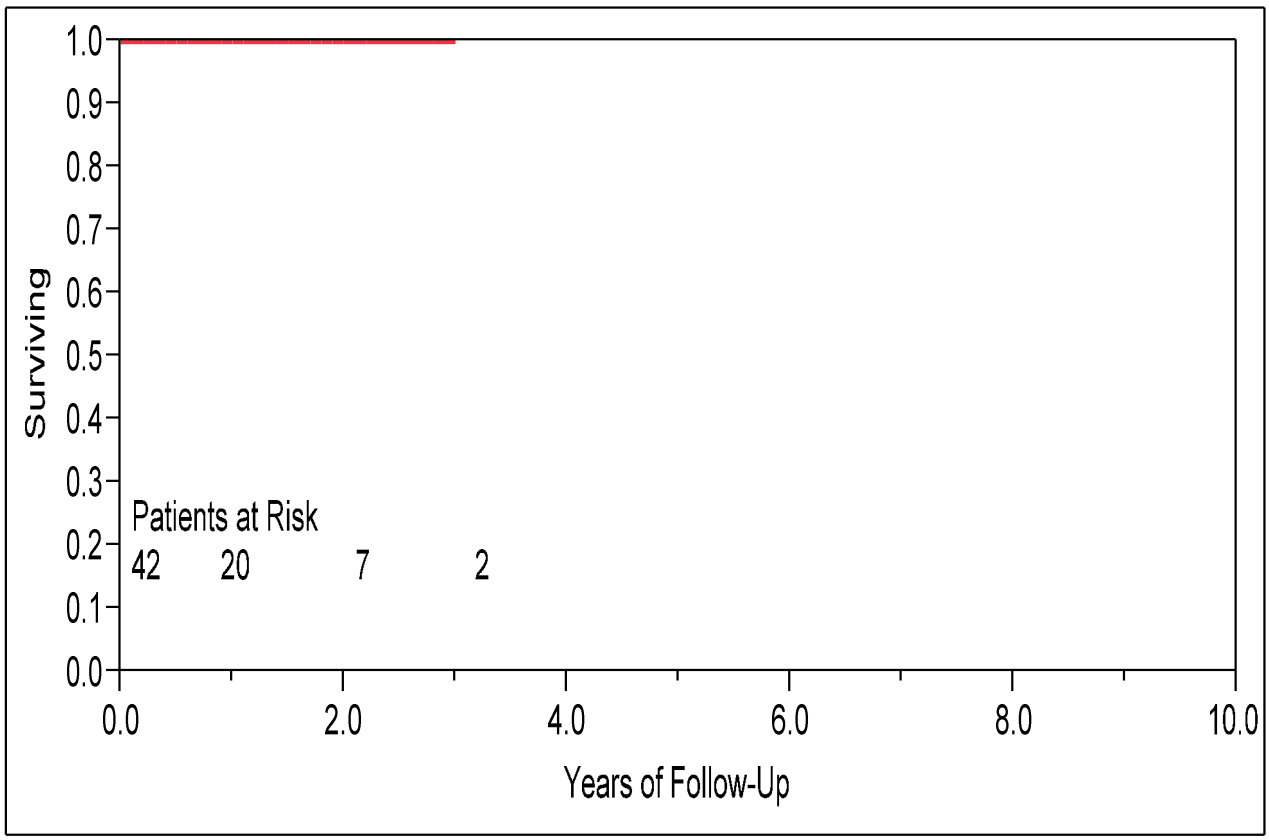
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Disclosure

Jeffrey P. Jacobs, MD is the medical director of CardioAccess, Inc.

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