

## Systemic Pulmonary Shunt Performed with Shelhigh Internal Mammary Artery: Early Results

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### ABSTRACT

**Objective.** The purpose of this study was to evaluate early findings for aortopulmonary shunts using bovine internal mammary artery grafting.

**Methods.** Bovine internal mammary artery grafts biomodified with glutaraldehyde and the Shelhigh No-React process were used between May 2005 and April 2006 in our clinic for 20 cases of aorta-pulmonary artery shunts. We implanted 2 sizes of grafts, either a graft with 4-mm proximal and 5-mm distal diameters or a graft with 5-mm proximal and 6-mm distal diameters. Patients were between 20 days and 7 years of age, and the sex distribution was 55% female and 45% male. A Blalock-Taussig shunt with left thoracotomy was performed in patients 2 years of age and older, and a central shunt with sternotomy was performed for patients younger than 2 years. Eight patients underwent operation under emergency conditions. Nine patients had tetralogy of Fallot and/or pulmonary atresia (PA); 3 had transposition of the great arteries, ventricular septal defect, and pulmonary stenosis (PS); 3 had tricuspid atresia; 3 had PS and double-inlet left ventricle; and 2 had PA.

**Results.** After the operation, immediate recovery of oxygen saturation and partial oxygen pressure was observed in all patients. Pulse oximetry measurements showed patient oxygen saturation to be between 84% and 100%. One patient underwent reoperation at the third postoperative hour because of bleeding. Two patients died from causes unrelated to the graft. The hospitalization period was between 7 and 29 days. Echocardiography evaluations showed no shunt obstruction for the early (first postoperative week) or middle (postoperative week 24) period.

**Conclusion.** With this study, we assessed the use of the Shelhigh internal mammary artery graft instead of synthetic (polytetrafluoroethylene) tubular grafts in shunt operations for congenital heart diseases with decreased pulmonary blood

flow and no evidence of calcification. Further investigation involving a larger number of cases and longer-term results for patency are needed to confirm our findings.

### INTRODUCTION

Although congenital heart disease requires primary repair in some infants, some cases with decreased pulmonary blood flow may necessitate palliative pulmonary shunt operations [Sousa 1994]. In shunt operations, grafts made from synthetic materials, such as polytetrafluoroethylene (PTFE) and polyethylene terephthalate fiber (Dacron), or biological tubular grafts can be used [Silveira 2005]. In the present study, we performed central and modified shunt operations in individuals with a congenital heart disease with decreased pulmonary blood flow and used No-React<sup>®</sup>-modified biological tubular grafts of bovine internal mammary artery origin (Shelhigh, Union, NJ, USA). We present initial and near-term results for 20 cases. Modified or classic Blalock-Taussig shunts are still widely used. Disadvantages of these asymmetrical shunts are an inequality of flow between the right and left pulmonary arteries, kinking, stenosis, and even complete obstruction of the shunt graft at the distal end of the shunt with increasing age [Calder 1991; Godart 1998]. Furthermore, there is a relationship between the frequency of iatrogenic pulmonary damage and use of the modified Blalock-Taussig shunt operation, especially in neonates [Gladman 1997]. The injury of one pulmonary artery and increased pressure may hinder application of the Fontan procedure, which could be applied later [Sousa 1994]. The frequency of iatrogenic pulmonary artery injury following the modified Blalock-Taussig shunt operation has been reported to be between 35% and 65% [Bove 1987; Ullom 1987; Gladman 1997], due to the use of the patient's own subclavian artery and reduced circulation to the arm. In a central shunt, the graft is placed to the ascending aorta with pulmonary artery or pulmonary bifurcation [Gazzaniga 1976; Calder 1991]. The most important advantage of a central shunt is that it provides antegrade flow to both lungs, thereby promoting symmetrical growth of hypoplastic central and hilar pulmonary vessels. Consequently, iatrogenic pulmonary injury and pulmonary arterial stenosis are seen less frequently with this shunt [Amato 1988]. Therefore, we have performed central shunt

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Figure 1. Photograph of graft.

operations in infants and neonates and have used the modified Blalock-Taussig shunt operation in older children.

## PATIENTS AND METHODS

Systemic pulmonary shunt operations were performed in 20 patients between May 2005 and April 2006. The study protocol was reviewed and approved by the School of Medicine Ethics Committee. We used biological tubular

grafts with a tapered design that consisted of bovine internal mammary artery treated with glutaraldehyde and the Shelhigh No-React process (Figure 1). Patients ranged in age from 20 days to 7 years, and 55% were female. All patients had congenital heart disease with low pulmonary blood flow diagnosed by echocardiography or by echocardiography and cardiac catheterization. Nine patients (45%) had tetralogy of Fallot, 3 patients (15%) had pulmonary stenosis, 3 patients (15%) had tricuspid atresia, 3 patients (15%) had transposition of the great arteries plus pulmonary stenosis, and 2 patients (10%) had pulmonary atresia (Table). Before the operation, all of the patients had significant cyanosis and hypoxia (evident from arterial blood gas and pulse oximetry readings). Eight patients underwent operation under emergency conditions. Preoperative heparin (50-100 IU/kg) was given to all patients. In the initial 24 hours after the operation, we administered heparin at a maintenance dosage of 25 IU/kg per hour, and we followed this treatment with an aspirin regimen of 3 to 5 mg/kg per day. All patients had mild or serious signs of hypoxia and cyanosis, both of which were caused by congenital heart disease with decreased pulmonary blood flow. Monitoring of hypoxia was achieved by continuous monitoring of arterial PO<sub>2</sub> and oxygen saturation. In the 1 case of patent ductus arteriosus, we infused prostaglandin to keep the ductus arteriosus open and planned an elective operation. Echocardiographic evaluations were carried out for all patients on postoperative day 1, week 1, and month 6. Patent turbulent flow was seen in patient shunts (Figure 2). At postoperative month 6,

### Patient Characteristics Immediately Postoperatively and 6 Months Postoperatively\*

Age	Sex	Diagnosis	Shunt Type	Graft Diameter, mm	Graft Diameter (Month 6), mm	Discharge Day	Preoperative O <sub>2</sub> Saturation, %	Postoperative O <sub>2</sub> Saturation, %
5 mo	M	TOF	AORTA MEAN Pa	4.5	4.20	13	46	89
4 mo	M	TOF	AORTA L Pa	4.5	4.38	11	63	95
1 y	M	TOF	AORTA MEAN Pa	4.5	4.30	10	58	91
3.5 y	F	TOF	AORTA L (BT) Pa	5-6	4.36	9	52	93
3.5 mo	F	TOF	AORTA MEAN Pa	4.5	4.54	18	42	91
3 mo	F	TOF	AORTO R Pa	4.5	4.68	21	43	95
3.5 mo	F	TOF	AORTA L Pa	4.5	4.80	16	65	97
2 mo	F	TOF	AORTA MEAN Pa	4.5	4.72	9	44	90
20 d	M	TA	AORTA MEAN Pa	4.5	4.45	28	38	90
30 d	M	TA + PA	AORTA MEAN Pa	4.5	Ex		44	88
3 d	F	TA + PS	AORTA MEAN Pa	4.5	Ex		48	96
40 d	F	PA + MA, ASD	AORTA MEAN Pa	4.5	4.90	29	58	97
7 y	M	TGA + VSD + PS	AORTA L Pa (BT)	5-6	5.85	7	71	95
4 y	F	TGA + VSD + PS	AORTA L Pa (BT)	5-6	5.81	8	40	84
2 y	M	PA + DILV	AORTA L Pa (BT)	5-6	5.78	16	30	87
1 y	F	PS + DILV	AORTA MEAN Pa	4.5	4.89	11	20	86
4 y	M	PS + AVSD	AORTA L Pa (BT)	5-6	5.53	8	71	96
11 mo	F	PS + AVSD	AORTA MEAN Pa	4.5	4.83	20	66	100
2 y	F	TGA + AVSD, DORV	AORTA L Pa (BT)	5-6	5.74	11	68	94
2 mo	F	TOF	AORTA MEAN Pa	4.5	4.84	18	44	90

\*TOF indicates tetralogy of Fallot; AORTA MEAN Pa, aorta mean pulmonary artery; Pa, pulmonary artery; L, left; BT, Blalock-Taussig; R, right; TA, tricuspid atresia; PA, pulmonary atresia; Ex, died; PS, pulmonary stenosis; MA, mitral atresia; ASD, atrial septal defect; TGA, transposition of the great arteries; VSD, ventricular septal defect; DILV, double-inlet left ventricle; AVSD, atrioventricular septal defect; DORV, double-outlet right ventricle.

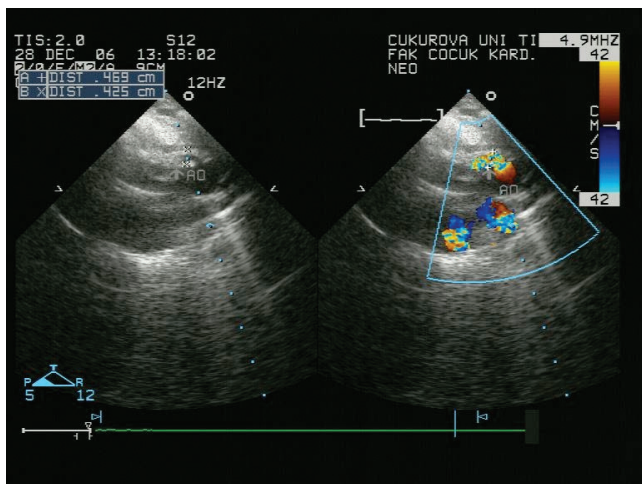


Figure 2. Echocardiography evaluations indicated patent turbulent flow in shunts.

we measured graft diameters and found all shunts to have patent flow (turbulent or laminar).

**Operation Technique**

Central shunt operations were performed in 14 patients (70%), and modified Blalock-Taussig shunt operations were performed in 6 patients (30%). All patients underwent their operations without cardiopulmonary bypass (ie, off pump). Patients were administered 100% oxygen under general anesthesia. The central shunt operations were performed by the same team described by Amato and colleagues [1988]. Following median sternotomy, the thymus was extracted, and the pericardium was partially opened. The pulmonary artery was freed from the ascending aorta. Heparin (50-100 IU/kg) was then administered intravenously before placing of the side clamp on the pulmonary artery. After placing this clamp, we performed an arteriotomy and anastomosed the larger-diameter distal end (5 mm or 6 mm) of the biological graft treated with the No-React process to the pulmonary artery with a continuous-suture technique using 7/0 Prolene suture (Ethicon/Johnson & Johnson, Somerville, MA, USA). We then removed the side clamp, placed the side clamp on the ascending aorta, and anastomosed the smaller-diameter proximal end (4 mm or 5 mm) of the biological tubular graft to the aorta with a continuous-suture technique using 7/0 Prolene suture. We then removed the side clamp (Figure 3).

The same team also carried out the modified Blalock-Taussig shunt procedure. After performing a left thoracotomy, we opened left thoracic cavity from the fourth intercostal space. The left subclavian artery and the left pulmonary artery were explored and rotated with a tape band. Following heparinization, we performed an arteriotomy by placing a side clamp on the pulmonary artery and anastomosing the larger-diameter distal end of the tubular graft with 7/0 Prolene suture. Next, we placed the clamp on the left subclavian artery, performed an arteriotomy, and anastomosed the proximal end of the tubular graft with a continuous-suture

technique using 7/0 Prolene suture. After completion of all of the anastomoses, we followed up with palpation over the graft and observing the normal limits. Following completion of anastomoses, pulse oximetry readings indicated that oxygen saturation had increased significantly.

**RESULTS**

In this study, we evaluated 20 patients with congenital heart diseases. One patient died on postoperative day 6 because of prolonged respiratory problems unrelated to the shunt. A second patient died following a sudden cardiac arrest in the intensive care unit while on the ventilator. Preoperative and postoperative oxygen saturation values ranged from 20% to 72% (mean  $\pm$  SD, 51.95%  $\pm$  14.77%) and 84% to 100% (92.40%  $\pm$  4.41%), respectively. Patients were discharged between 7 days and 29 days after the operation. None of the patients underwent reoperation for acute graft occlusion, thrombosis, and/or kinking. One patient underwent reoperation at postoperative hour 3 because of bleeding, and the investigative surgical intervention revealed that the shunt was working and that the source of the bleeding was residual thymus tissue. No bleeding was observed from the graft or from the anastomosis sites. Drainages from the other patients were within acceptable limits. We performed echocardiography evaluations for all of the patients, and the shunts exhibited patent turbulent flows. At postoperative month 6, echocardiographic evaluations verified patent turbulent flows for all shunts. The diameters of the grafts (5.11  $\pm$  0.89 mm) as measured by echocardiography revealed that there were no graft obstructions. Postoperative angiography and cardiac catheterization procedures were performed in 3 patients.

**DISCUSSION**

Although the indications for a systemic pulmonary shunt are variable, the indications are generally a cyanotic complex defect, a hypoplastic pulmonary artery, hypoplasia of the

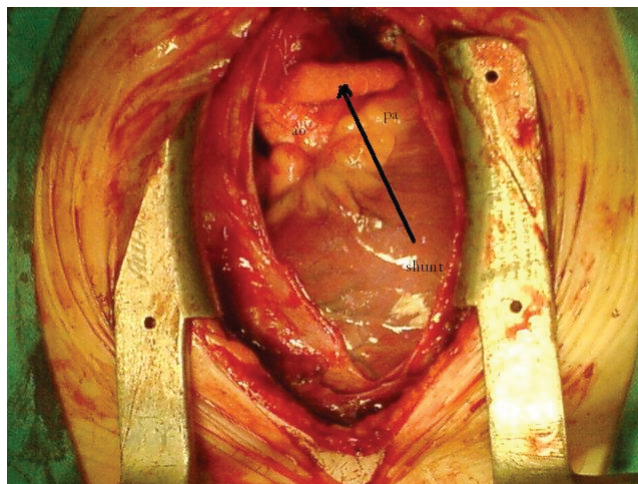


Figure 3. Operative view. ao indicates aorta; pa, pulmonary artery.

pulmonary artery annulus, neonates with tetralogy of Fallot and pulmonary atresia, and tricuspid atresia [Gladman 1997; Gates 1998]. In such cases, the early-mortality rate for a total correction is greater than that for a 2-phase correction. Recent studies have found that the use of a central shunt is more advantageous than a Blalock-Taussig shunt, especially in neonates, infants, and young children, because a central shunt gives the pulmonary artery a chance to develop and causes less pulmonary injury, especially for the aforementioned operations. Therefore, in our study we performed a central shunt in 14 neonate and infant patients. Another 6 patients underwent a modified Blalock-Taussig shunt operation. Traditionally, PTFE grafts have been used worldwide for systemic pulmonary shunt operations; in our clinic, shunt operations with PTFE tubular grafts of various sizes have been performed in nearly 500 patients. In this study of shunts performed between May 2005 and April 2006, we used tubular grafts obtained from bovine internal mammary artery that had been treated with the Shelhigh No-React process as an alternative to PTFE grafts. The early-mortality rate for these biological tubular grafts in our 20-patient series was 10% (2 patients). Compared with mortality rates of 13% [Potapov 2001] and 6% [Fermanis 1992] previously reported for PTFE grafts, our results are satisfactory. The Shelhigh grafts are also used for peripheral vascular procedures in our center. Shelhigh biological grafts are treated with the No-React process, which renders them biocompatible; consequently, they are resistant to infection, in-graft calcification, and absorption by tissue [Abolhoda 1996]. No sign of infection was seen in any of our cases. Because the Shelhigh device is a biological graft and more flexible to handle than a PTFE graft, it is more easily implanted and anastomosed. In this study, the decreased bleeding from anastomosis lines and the decreased need for additional sutures compared with PTFE grafts indicate an advantage of these biological grafts over synthetic grafts. In one series, the rate of postoperative leakage of serous fluid (seroma) from such grafts because of their structural features was reported to be 12% [Berger 1998]. Such leakage was not observed for the Shelhigh biological grafts that we used.

We have encountered PTFE graft kinking in our clinical experience, although such cases are very rare; however, we observed no kinking with biological grafts treated with the Shelhigh No-React process. We suggest that the proportion of grafts that are not occluded and the absence of decreases in graft diameters during the 6 months of follow-up are evidence for the superior performance of the Shelhigh grafts. Because our experience with PTFE grafts is more extensive, however, more clinical studies and longer follow-up periods are needed. The Shelhigh biological internal mammary artery

graft is a good alternative to the PTFE graft, and we believe that it can replace PTFE grafts in the future.

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