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Ann Thorac Surg 2002;74:127-132

Intermediate Follow-Up of a Composite Stentless Porcine Valved Conduit of Bovine Pericardium in the Pulmonary Circulation

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Background. **In the pediatric population, glutaraldehyde-preserved bovine pericardium conduit containing a stentless porcine valve has been proposed as an alternative to homografts for right ventricular outflow tract reconstruction.**

Methods. **Between June 1996 and March 2000, a total of 55 patients, 20 with truncus arteriosus, 21 with pulmonary atresia with ventricular septal defect, and 14 with miscellaneous defects, received this conduit. Median age at implantation was 3.4 months (range, 3 days to 19 years), and 27 patients (50%) were less than 3 months old. Clinical outcome, echocardiographic data, and pathologic analysis were recorded. End points for conduit failure were conduit replacement or dilation. A mean follow-up of 27 months (range, 2 to 46 months) was available for 47 survivors.**

Results. **Procedure for conduit obstruction was required in 13 patients. The most common procedure was operation, and all but 3 patients had an unsuccessful balloon angioplasty before reoperation. Actuarial freedom from conduit dilation or reoperation was 93.6% (95% confidence limits, 82% to 99%), 81.9% (95% confidence limits, 64% to 91%), 77.8% (95% confidence limits, 39% to 78%), and 64.3% (95% confidence limits, 26% to 73%) at 1, 2, 3, and 4 postoperative years, respectively. Univariate analysis identified small conduit size as a risk factor for conduit obstruction.**

Conclusions. **Although this new conduit was not free from progressive obstruction, our clinical results (easy to work and good valvular function) and the availability in small sizes encouraged us to use it as an alternative to small-size homografts when those were not available.**

(Ann Thorac Surg 2002;74:127–32)

Homografts were the initial valved conduit used by Ross and Sommerville in 1966 [1] for right ventricular outflow tract reconstruction, and the development of heterologous substitutes is attributed to Planché and colleagues [2]. Allografts and polyethylene terephthalate fiber (Dacron) valved conduits have been refined during the last 20 years for preservation [3] and Dacron improvement [4]. Despite refinements, when these conduits are implanted in pediatric population, they invariably need to be replaced because of accelerated rate of calcification for homografts and neointima formation in Dacron that could accelerate stenosis of small-diameter conduits. Heterografts are more difficult to implant. They do not conform to the anatomy as easily as homografts. Furthermore, development of early and neonatal repair in the last 10 years for most of the defects has been more demanding for these substitutes, especially in the need of smaller conduits to be inserted in fragile tissues.

Accepted for publication March 25, 2002.

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The Labcor (Sulzer Carbomedics, Austin, TX) glutaraldehyde-preserved bovine pericardial conduit containing a stentless composite porcine aortic valve (Fig 1) has been proposed as an alternative [5]. The aim of this retrospective study was to evaluate the intermediate outcome of the Labcor valved conduit for right ventricular outflow tract reconstruction in a pediatric population.

Material and Methods

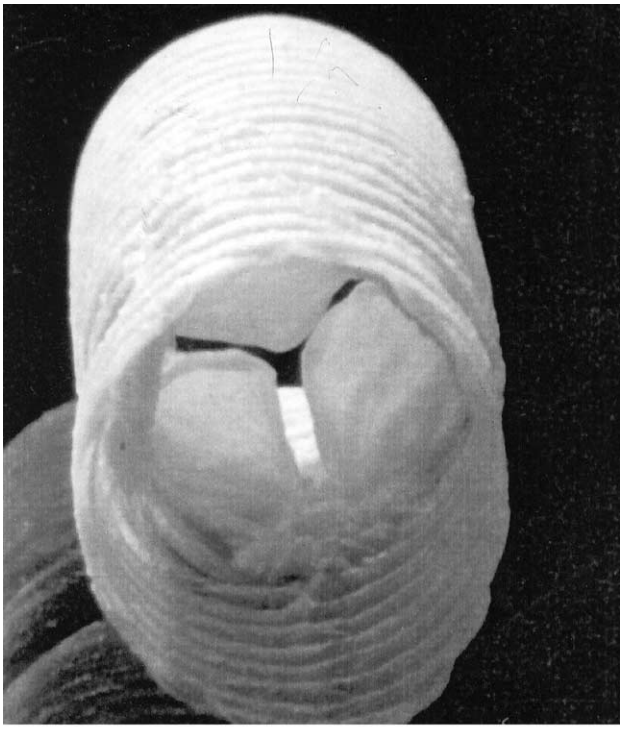
Patients

Between June 1996 and March 2000, 55 patients received the Labcor valved conduit. Patients in this study were all considered for right ventricular reconstruction when valveless reconstruction was not an alternative [6]. The conduit was implanted when suitable homografts were not available.

Diagnoses included 20 truncus arteriosus, 21 pulmonary atresia with ventricular septal defect, and 14 miscellaneous. Overall clinical characteristics of the patients are displayed in Table 1. Median age at implantation was 3.4 months (range, 3 days to 19 years), and 27 patients (50%) were less than 3 months old. Median weight at implantation was 5.5 kg (range, 2 to 36 kg). Eight patients

Published by Elsevier Science Inc

0003-4975/02/$22.00
PII S0003-4975(02)03639-1



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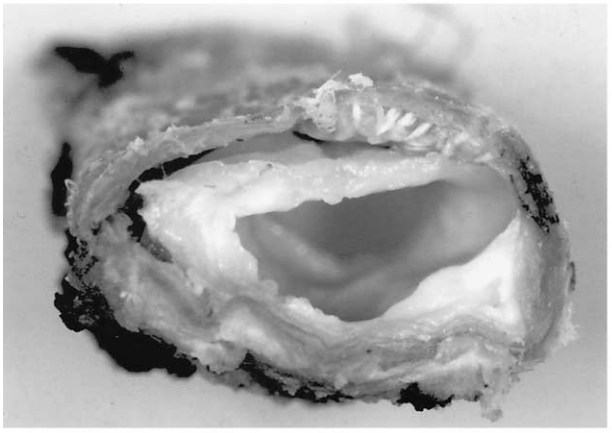

B

Fig 1. General view of the conduit before implantation (A) and 26 months after implantation (B) for right ventricular outflow tract reconstruction in truncus arteriosus (11 mm).

received an 11-mm diameter conduit, 23 a 13-mm, 8 a 15-mm, and 15 received a 17-mm diameter conduit.

The median age and weight according to conduit diameter are displayed in Figure 2.

Conduit and Surgical Procedure

Labcor stentless pulmonary conduit is made of bovine pericardium, treated with 0.4% glutaraldehyde in a phosphate-buffered solution at pH 7.4% and crimped to achieve the stable tubular configuration. A stentless tricomposite porcine valve is assembled inside the pericardium tube. Storage solution is 0.2% glutaraldehyde. Valve diameter is 2 mm less than conduit dimension (9 mm for 11-mm conduit). Before implantation the conduit must be rinsed three times using fresh physiologic saline solution in a minimum of 500 mL and 5 minutes each time.

Table 1. Initial Diagnosis in 55 Patients Related to Late Deaths and Results

Initial Diagnosis	No. of Patients	Late Deaths	Reoperation for Obstruction for 47 Survivors
Truncus arteriosus	20	...	8
TOF-PA	21	1	4
DORV	4	...	...
TGA-VSD-PS	2	...	...
TGA-VSD-IAA	1	...	...
CTGA	1	...	
APVS	1	...	1
CAS (Ross procedure)	2	...	
SV	1	...	
Complex cardiopathy	2	...	
Total	55	1	13

APVS = absent pulmonary valve syndrome; CAS = critical aortic stenosis; CTGA = corrected TGA; DORV = double-outlet right ventricle; IAA = interrupted aortic arch; PS = pulmonary stenosis; SV = single ventricle; TGA = transposition of great arteries; TOF-PA = tetralogy of Fallot and pulmonary atresia; VSD = ventricular septal defect.

Interventions were conducted in a standard manner using moderate hypothermic extracorporeal circulation and cold blood cardioplegia. For conduit implantation, distal anastomosis was made after intracardiac repair, while the aorta was still cross-clamped. When necessary, it was easy to cut the distal part of the tube in an oblique shape to enlarge a proximal hypoplastic pulmonary artery or to restore configuration of the bifurcation. The proximal anastomosis was made just after removal of the aortic cross-clamp, on a beating heart. The valve segment of the conduit was placed as close as possible to the pulmonary artery. No reinforcement of the ventricular

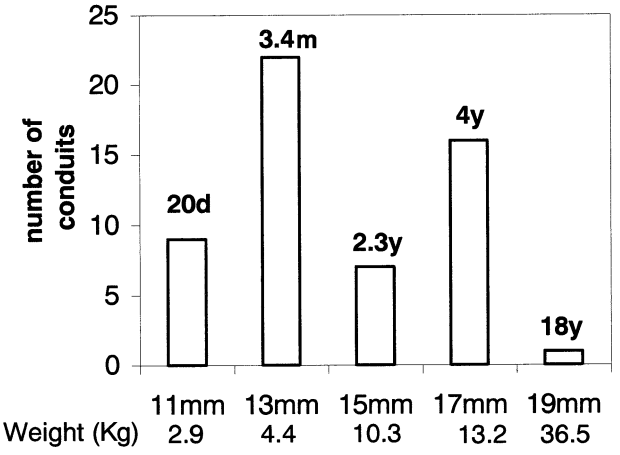

Fig 2. Distribution of conduit diameter, weight, and age (median values at implantation). Valve diameter is 2 mm less than conduit dimensions.

anastomosis, using pledgets or pericardium, was required.

Follow-Up

Early mortality was defined as perioperative death. The postoperative evaluation consisted of regular clinical follow-up and serial echocardiography assessment. Thus 43, 34, and 29 echocardiography studies were available at a mean period of 15 days, 8 months, and 2 years after operation, respectively.

All survivors (n = 47) but one (lost to follow-up) were followed for a mean period of 2.25 years postoperatively, with the end point being March 2000.

Histologic analysis was performed on two explanted conduits (tissue fixation with hematoxylin-eosin-safranin and orcein coloration).

Statistical Analysis

Median and range were calculated for all descriptive variables. Actuarial data were analyzed using the actuarial Kaplan-Meier estimation of the probability of freedom from obstruction and conduit-related events. Dilation or reoperation was used as the end point for obstruction. Risk factors for reoperation, including age and weight at operation and conduit diameter were analyzed using the logistic regression analysis for analysis of conduit obstruction. All statistical analyses were completed using SAS statistical software (SAS Institute, Cary, NC).

Results

Patient Survival and Perioperative Morbidity

Early postoperative mortality and morbidity were not related to the conduit. There was no postoperative reoperation for bleeding or mediastinitis. One patient was reexplored for compression of the conduit by the sternum caused by misplacement.

Echocardiography Study

Elevation of Doppler-estimated peak systolic gradient through the conduit was progressive during the study: 25 ± 16, 37 ± 22, and 61 ± 29 mm Hg at 2 weeks, 8 months, and 2 years after implantation, respectively. The exact site of conduit obstruction was difficult to determine because of the small sizes of conduits or low echogenicity. However, neither proximal nor distal stenosis was observed. Valvar function was good without progressive regurgitation (moderate valvar regurgitation in some cases). Pulmonary regurgitation was three times mild and two times moderate at a mean follow-up period of 15 days and five times mild and two times moderate at a mean period of 8 months.

Conduit-Related Events

There was one infective endocarditis of the conduit. Seven months after initial operation, echocardiography revealed a proximal infective aneurysm associated with a peak systolic gradient of 60 mm Hg. The conduit was replaced with a 17-mm allograft, and the postoperative outcome was uneventful.

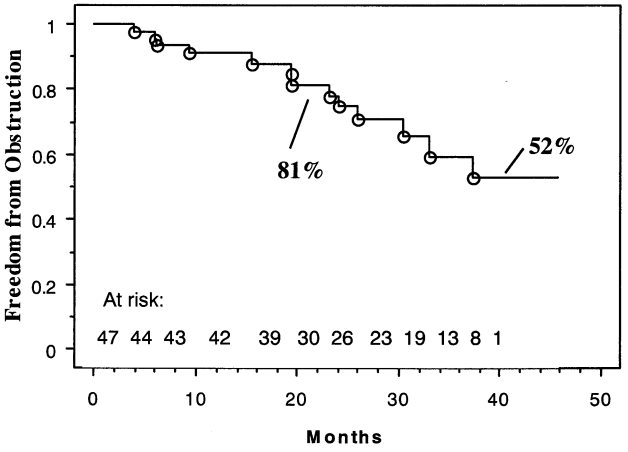

Fig 3. Kaplan-Meier freedom from conduit obstruction.

Procedures for conduit obstruction were required in 13 patients (Fig 3); the gradient across the conduit before the procedure was 84 ± 12 mm Hg at a mean period of 20 months. There were 8 with truncus arteriosus, 4 with pulmonary atresia ventricular septal defect, and 1 with absent pulmonary valve syndrome. Ten patients were younger than 1 month at initial operation. Conduit diameter was 11 mm in 4 cases, 13 mm in 6 cases, and 17 mm in 3 cases. The most common procedure was operation, and all but 3 had an unsuccessful balloon angioplasty before reoperation (6 conduit replacement and 4 patch augmentation). Three obstructions were managed by dilation (n = 2) or balloon expendable stenting (n = 1). One patient was reoperated on for proximal aneurysm, a consequence of previous conduit dilation, and died at reoperation (1 year after implantation).

To differentiate the impact of child growth and conduit structural degeneration on obstruction, the diameter of the conduit (valvar level) was compared with the expected pulmonary valve dimension normalized to the patient's body surface area at the time of obstruction. A Z value for each obstructed conduit was extrapolated from nomogram [7]. Z value was −3,5 (n = 3), −3 (n = 2), −2 (n = 2), −1 (n = 4), and zero (n = 2) for the 13 obstructed patients.

Actuarial freedom from conduit angioplasty or reoperation was 93.6% (95% confidence limits [CL], 82% to 99%), 81.9% (95% CL, 64% to 91%), 77.8% (95% CL, 9% to 78%), and 64.3% (95% CL, 26% to 73%) at 1, 2, 3, and 4 postoperative years, respectively (Fig 3). Reoperation was required in 7 patients at a mean period of 75 days (range, 3 to 256 days) after balloon dilation. The remaining 3 patients continue to benefit from the relief of obstruction 210, 270, and 674 days after dilation. One of these patients was dilated twice before requiring stent implantation with satisfactory result. Success was considered as a 50% gradient diminution for at least 3 months.

The logistic regression analysis (univariate analysis) identified small conduit size as a risk factor for conduit

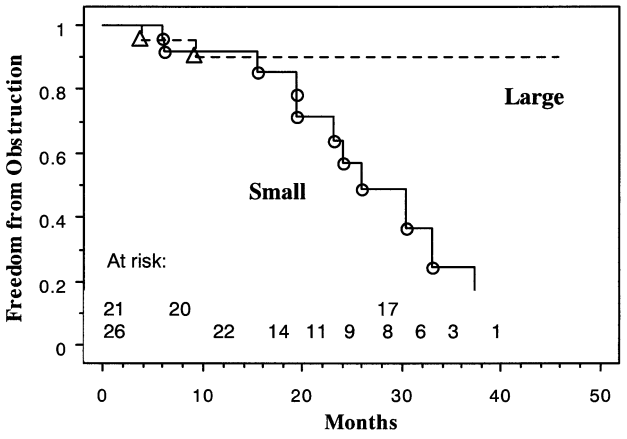

Fig 4. Kaplan-Meier freedom from conduit obstruction stratified according to conduit diameter (small, 11 to 13 mm; large, 15 to 17 mm). Log-rank test, p = *0.0015.*

obstruction ($p < 0.001$). Age at operation, weight, and immediate postoperative gradient were not risk factors for obstruction ($p > 0.05$). This was confirmed when comparing log-rank test from Kaplan-Meier analysis for conduit size (Fig 4) and age (Fig 5).

Histology

Two specimens (both 11 mm, in place for 24 and 27 months) were examined after decalcification. One had been dilated before explantation. Gross features included that the porcine valves were thick and retracted and the cusps were stenotic and adherent to the conduit. The luminal peels were all less than 3 mm thick. In the dilated conduit the peel could be stripped away easily from the underlying conduit (Fig 1) and was fenestrated near the valve, allowing contact between blood and the pericardial surface. Microscopic features were that the peel was a dense collagen tissue with myofibroblasts (hematoxylin-eosin-safranin O). Glutaraldehyde stabilization of biologic material is effective, and its clinical use needs careful tissue detoxification. One distal anastomotic stenosis associated with tissue scaring, leading to necrosis of the pulmonary artery media in one explanted specimen, may be related to excess free aldehyde radicals in the implanted conduit. Some calcifications were noted in the pericardial wall.

Comment

Allografts and Dacron conduits are widely used to create continuity between the right ventricle and pulmonary circulation in many congenital heart lesions. However, most of these prosthesis will require replacement. Suitability of homografts [8, 9], calcification, and obstruction are persistent problems, and Dacron conduits are relatively rigid and develop rapid obstruction in small sizes [9–12]. The surgeon must select the conduit most likely to fit the anatomy of the pulmonary artery, to be easy to handle, and to provide long-term performance, thus, freedom from reoperation. Because of the continuing problems associated with these conduits, especially when used in the neonate, the Labcor conduit was investigated as an alternative for right ventricle to pulmonary artery reconstruction.

This series of patients included a wide spectrum of congenital heart defects including truncus arteriosus, tetralogy of Fallot, pulmonary atresia, and numerous miscellaneous defects. The age range was limited to very young patients; half of the cohort was younger than 3 months. Therefore, this study is representative of the outcomes that can be expected for right ventricular outflow tract reconstruction in a pediatric population.

Echocardiography follow-up revealed a progressive transconduit gradient elevation. Valvular function remains good, and regurgitation was not observed either in the postoperative period or during follow-up. The early occurrence of pulmonary valve insufficiency is most commonly unrelated to valve degeneration. In the present study, structural valve deterioration led to a predominance of valvular obstruction rather than regurgitation. Because of better acceptance than catheterization in the pediatric population, routine echocardiography became the standard for conduit follow-up. Therefore, catheterization was not performed routinely.

There is no consensus in the literature for conduit replacement. In the present study, conduit replacement or dilation was used as an indicator of valve failure. The use of conduit replacement as an indicator of conduit failure should be imprecise and may fail to detect important conduit dysfunction in older patients [13] in whom elevated right sided-pressures are better accepted. The relatively young age of the population in this study minimized the imprecision of using replacement or dilation for analysis of conduit failure. Reoperation or conduit dilation was performed when valvular gradient was close to systemic value (70% to 80%) or was associated with the first sign of pulmonary ventricular dysfunction. Reoperation for conduit stenosis was required in 27% of the patients at a mean period of 20 months. This was disappointing, but not excessive considering the young age of this cohort. The presented results are very similar

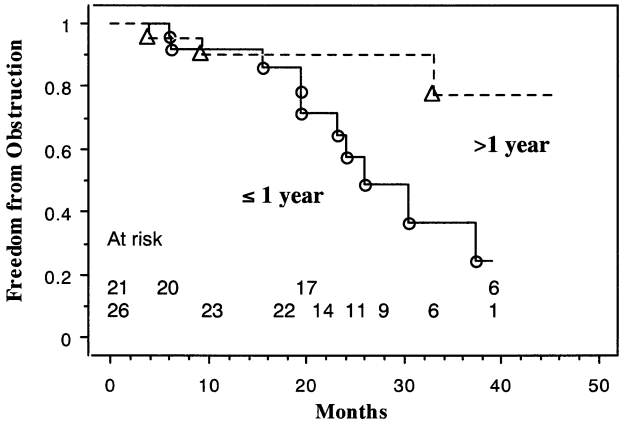

Fig 5. Kaplan-Meier freedom from conduit obstruction stratified according to age (≤1 year or >1 year). Log-rank test, p = *0.0126.*

to those of previous studies [10–12], and our actuarial freedom from conduit-related obstruction of 93.6% (95% CL, 82% to 99%), 81.9% (95% CL, 64% to 91%), 77.8% (95% CL, 39% to 78%), and 64.3% (95% CL, 26% to 73%) at 1, 2, 3, and 4 postoperative years, respectively, are similar to series using small conduits [9–11]. Furthermore, better longevity should be attributed to markedly different patient populations. Young age at initial operation (less than 2 years) and conduits smaller than 15 mm correlate with an increased risk of early conduit failure in many reports [13, 14].

Although surgical conduit replacement can be performed at low risk, balloon dilation of bioprosthetic conduits has been used to delay surgical procedure [15–17]. Standard balloon dilation angioplasty has had limited success in our series, the same as in the literature for other conduits [15]. These poor results of low-pressure angioplasty encouraged some authors to perform prolonged high-pressure inflation [16] or to associate balloon angioplasty with stent implantation [17]. We believe that isolated balloon angioplasty should be deleterious with risk of peel dissection and embolization or suture leakage. Despite attendant problems with stent implantation (stent fracture, displacement, and embolization), consistent successes have been reported for stenosis at the valvar level mainly with homografts [17]. One stent had been successfully implanted in our series. However, after the follow-up was closed, five stents were implanted with success. Limitations of the interventional procedure should be multiple locations of stenosis and rigid and calcified conduits. At the time of conduit replacement, valved or valveless substitutes were considered on the basis of clinical conditions for each case.

Stentless valve deterioration was identical to standard bioprosthetic valve, and intimal peel formation was observed inside the Labcor conduit (Fig 1) similarly to Dacron [18]. Predominant obstruction was observed at the valve level. Furthermore, in dilated conduit the peel could be stripped away from the lumen; isolated dilation must be imperatively avoided because of potential critical stenosis associated with conduit dissection. There was some parietal and valvular calcifications but never of clinical significance.

A commonly held opinion is that younger patients have decreased conduit durability because they are receiving smaller implants during a period of rapid growth and accumulation of body mass [10]. Outgrowth is an important impact in this young population and seems to be directly related to obstruction in 5 cases (Z value < -3). On the one hand, outgrowth does not rely on most of the obstructed conduits, but on the other, even a minimal diminution of internal conduit diameter (fibrous intima peel, prosthesis degeneration) should precipitate outgrowth and major obstruction in small conduits.

Pulmonary xenografts have demonstrated a high incidence of supravalvular obstructions [19]. In the present study, at the time of conduit explantation pulmonary branch arteries were neither retracted nor stenotic. Furthermore, easier intraoperative handling allowing distal cutting to bypass proximal pulmonary stenosis when needed and excellent hemostasis at the suture lines had been demonstrated by the near zero postoperative morbidity. The biologic characteristics of the pericardial tissue match well with the pulmonary artery, which makes it particularly suitable for neonate implantation. The concern that the surgical technique is of importance is raised by a postoperative gradient of 25 ± 16 mm Hg, perhaps slightly higher than if homografts were used. Traction on suture lines and geometric concordance are factors not always easy to manage when considering ventricle to pulmonary connections, and homografts probably provide easier distal insertion. However, handling and clinical characteristics should permit us to consider the Labcor as an alternative when homografts are not available in small sizes.

The limitations of this study are its retrospective nature and the single institution bias that make comparisons with other reports difficult [19].

In conclusion, this new conduit was not free from progressive obstruction, but our clinical results and the availability in small sizes encouraged us to use it as an alternative to small-size homografts when they are not available. Thus, homografts and Dacron conduits [20] remain the conduits of choice in larger pediatric patients at our institution.

We are grateful to André Capderou for his statistical assistance and to the following pediatric cardiologists who provided continuous follow-up of the patients: Claude Almange (Rennes), Gèrard Blaysat (Rouen), Alain Chantepie (Tours), François Godart (Lille), Veronique Gournay (Nantes), Nedeljko Krevs (Slovenia), Angelo Livolsli (Strasbourg), Suzelle Magnier (Paris), Patrice Morville (Reims), Anne Marie Worms (Nancy).

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Mark your calendars for the Thirty-ninth Annual Meeting of the Society of Thoracic Surgeons, which will be held in San Diego, California, January 31–February 2, 2003. The program will provide in-depth coverage of thoracic surgical topics selected to enhance and broaden the knowledge of practicing thoracic and cardiac surgeons. Traditional abstract presentations as well as topic-specific ancillary sessions and courses will make up the continuing medical education opportunities that will be offered at the Thirty-ninth Annual Meeting.

Advance registration forms, hotel reservation forms, and details regarding transportation arrangements, as well as the complete meeting program, will be mailed to Society members. Also, complete meeting information will be available on The Society's Web site located at http://www.sts.org. Nonmembers wishing to receive information on attending the meeting may contact The Society's Secretary, Gordon F. Murray.

Abstracts for the meeting must be submitted electronically. The electronic submission form may be accessed at http://www.ctsnet.org/abstracts/sts. There is no charge for submitting your abstract electronically. The electronic abstract submission deadline is August 5, 2002, at 12 Midnight, CDT. If interested authors are unable to access the electronic submission forms, they may contact the Society headquarters at least 3 weeks prior to the abstract due date. Otherwise, all abstracts must be submitted using the electronic forms located at http://www.ctsnet.org/abstracts/sts. Any questions may be directed to the STS headquarters.

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