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Original Article

Off-label use of stretchable polytetrafluoroethylene: Overexpansion of synthetic shunts

Tom O. Verbelen[1], Nele Famaey[2], Marc Gewillig[3], Filip R. Rega[4], Bart Meyns[4]

[1] Department of Surgery, University Hospital Gasthuisberg, Leuven - Belgium
[2] Department of Mechanical Engineering, Catholic University of Leuven - Belgium
[3] Department of Pediatric Cardiology, University Hospital Gasthuisberg, Leuven - Belgium
[4] Department of Cardiac Surgery, University Hospital Gasthuisberg, Leuven - Belgium

ABSTRACT

Purpose: *To describe our experience with balloon dilatation and stenting of modified systemic-to-pulmonary artery (PA) shunts in relation to an assessment and interpretation of the mechanical properties of thin-walled expandable polytetrafluoroethylene (ePTFE) stretch vascular grafts.*

Methods: *Our pediatric cardiology/cardiac surgery database was reviewed to identify all infants and children with a modified systemic-to-PA shunt who underwent cardiac catheterization. Reports and images were reviewed. Thin-walled stretchable and regular Gore-Tex® vascular grafts were mechanically compared using tensiometry.*

Results: *11 patients underwent dilatation or stenting procedures of a systemic-to-PA shunt. No major complications occurred and none of our patients died during or due to this intervention. High pressures in balloons and stents with diameters larger than the graft were used. Shunt diameters and oxygen saturation levels increased from 2.05 ± 1.25 mm to 4.75 ± 0.88 mm and with 12 ± 6.8%, respectively. In 6 patients re-catheterizations were performed. Four patients died, all with patent shunts. The fail-stress and the fail-strain in the circumferential direction of the stretchable graft were significantly higher than in the non-stretchable graft.*

Conclusions: *Dilatation and stenting of stenosed modified systemic-to-PA shunts is feasible and safe. Dilatation and stenting of these shunts to calibers larger than those provided by the manufacturer is possible. Results of our technical study posit a great advantage for the use of the thin-walled stretch configuration of ePTFE.*

KEY WORDS: *Balloon dilatation, Stents, Shunt, PTFE*

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INTRODUCTION

Systemic-to-pulmonary artery (PA) shunts are created in the neonatal period for various cyanotic heart lesions which are not amenable to correction because of the risk associated with operating on infants with low birth weight. In 1976 Gazzaniga and co-workers introduced the use of polytetrafluoroethylene (PTFE) for the creation of these shunts (1).

Prolonged patency of these PTFE (modified) shunts is essential for long-term relief. However, complete or even partial obstruction to flow is not uncommon, and can result in life-threatening hypoxia (2-6). Therapeutic options include the creation of another systemic-to-PA shunt or, if feasible, correction of the underlying cardiac malformation earlier than planned (7). However in this era, occluded shunts may be crossed with various catheters and guidewires thereby re-establishing patency. Successful balloon angioplasty for shunt stenosis was first described in 1989 (8). Endovascular stent implantation to alleviate shunt ob-

struction was first described in 1997 (9). Subsequently, other reports have mentioned high procedural success rates and low procedural morbidity (4, 7, 10-18).

In our center, thin-walled Gore-Tex® stretch vascular graft is used. As described by the manufacturer, these vascular grafts offer benefits such as ease of implantation and take-down at total correction, as well as good patency and avoidance of excessive shunt flow. The thin-wall stretch configuration is a patented technological advancement which, as described by the manufacturer, provides longitudinal extensibility, allowing easier tailoring and sizing, kink resistance, improved handling, better tissue approximation and a superior anastomotic conformability for use in neonates (19).

This article describes our experience with balloon dilatation and stenting of modified systemic-to-PA shunts. The clinical study is accompanied by a mechanical study of the study material which was performed to assess stretchability as an underexploited mechanical property of Gore-Tex® thin-walled stretch vascular grafts.

MATERIALS AND METHODS

Clinical study

Patients

Approval of the Institutional Review Board (IRB) was not required for this study. We identified all infants and children with pulmonary blood flow depending upon a thin-walled Gore-Tex® stretch vascular graft systemic-to-PA shunt in our pediatric cardiology/cardiac surgery database. Demographic data, indication and type of intervention were collected for those patients who underwent cardiac catheterization for treatment of hypoxemia. Oxygen saturation levels before and after intervention and current clinical condition were noted. Intervals between surgery and cardiac catheterization were calculated.

Catheterizations

Cardiac catheterization reports were reviewed. Catheterization images were re-observed with IMPAX cardio viewer (AGFA Heartlab, Westerly, RI, USA). Calibration was performed by means of the known guiding catheter (French) sizes, followed by measurement of shunt diameters before and after dilatation. These calibrations and measurements were all performed by one person, avoiding operator dependency. All images were studied on high resolution screens. Low profile, high-pressure balloon catheters were chosen, of which the diameters varied from slightly smaller up to 3 mm larger than the original diameter of the shunt. The balloon was inflated with pressures up to 18 atm. If balloon dilation was ineffective or was not considered favorable, endovascular stent implantation was performed. If necessary, these stents were postdilated with a balloon in a secondary phase to obtain better patency.

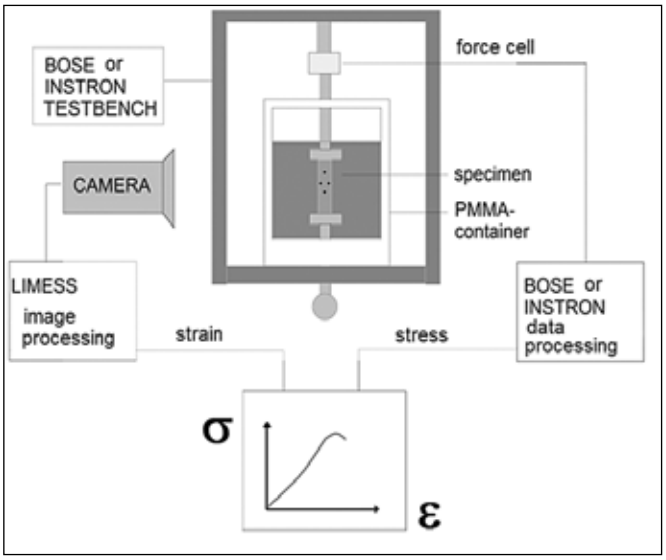


Fig. 1 - *1D tensile test-setup.*

Mechanical study

Thin-walled stretchable and regular Gore-Tex® vascular grafts were compared with respect to their mechanical properties. From each graft type, 6 to 8 axially oriented strips and 6 to 8 circumferentially oriented strips of approximately 10 by 5 mm were cut. These samples were mounted on a uniaxial tensile test bench (INSTRON 5567; Instron, Norwood, MA, USA). Each sample was elongated to 50% extension at a crosshead speed of 1 mm/s and held at this level for 30 seconds. Next, the samples were elongated until rupture occurred. The tests were performed with continuous recording (at 10 Hz) of tensile force with a 1kN INSTRON load cell. Gage length and constriction were recorded with a LIMESS optical measurement system (at 2.5 Hz; Limess, Pforzheim, Germany). Figure 1 shows a

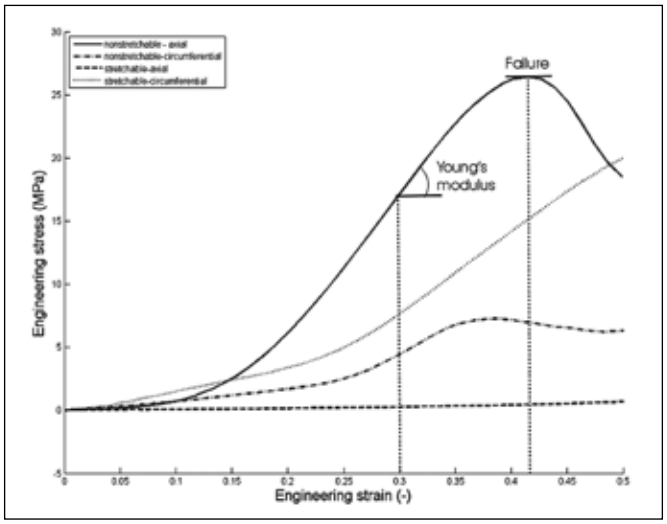
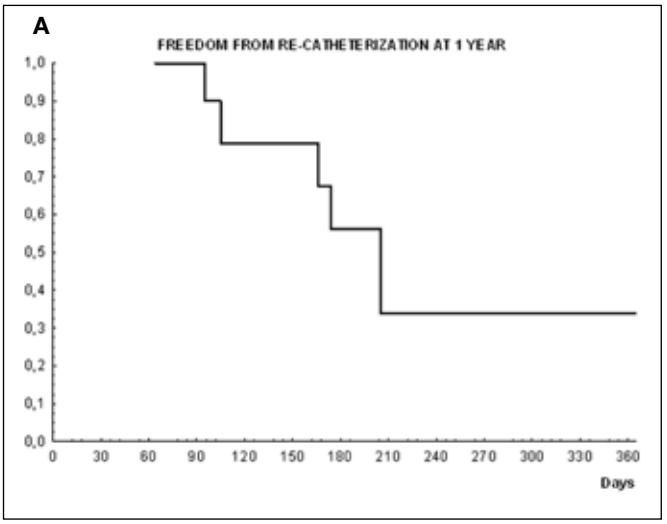


Fig. 2 - *Stress-strain curve for both grafts in circumferential and axial direction.*



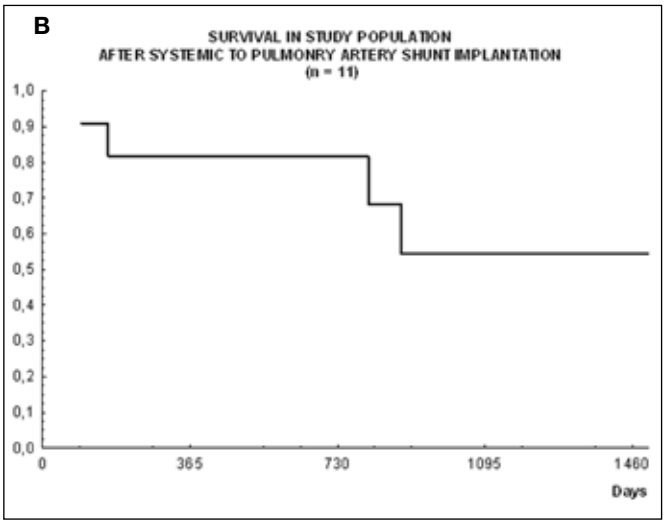


Fig. 3 - *Survival analysis:* **A:** *Freedom from re-catheterization at 1 year;* **B:** *Survival function in study population after systemic-to-PA shunt implantation (n=11).*

schematic overview of the test setup. The initial dimensions of each sample, namely thickness, width and length, were measured with a digital caliper. The acquired data were processed to obtain the engineering stress, σ_{ii} (i.e., force normalized to the initial sample width and thickness) and the engineering strain, ε_{ii} (i.e., displacement normalized to the initial sample length). The material was approximated as tranversely isotropic, with a bilinear stress-strain curve in the circumferential and axial directions. To describe this behavior from the uniaxially collected data in the deformation range relevant for this application, different parameters were extracted from each experimental data set. These were the Young's modulus (E_{ii}), i.e., the tangent of the stress-strain curve at 30% elongation, Poisson's ratio (ν_{ii}), i.e., the average ratio of constriction versus elongation, and the stress and strain at which gross plastic deformation or failure occurred, as shown in Figure 2.

Statistical analysis

Data are represented as mean ± standard deviation or as median (Min - Max) data where appropriate. MS Excel 2007, Matlab 7.0 and STATISTICA 8.0 statistical software were used to analyze data.

RESULTS

Clinical study

Fifty-three patients were treated with a systemic-to-PA shunt between October 1999 and May 2007. From December 2001 to September 2008, 11 out of 53 patients underwent a dilatation and/or stenting of the shunt during one or more procedures before definitive surgical repair of the congenital cardiac anomaly. Patients presented raising dyspnea, falling exercise capacities and decreases in

TABLE I - PATIENTS DEMOGRAPHICS

Patient	Gender	Cardiac diagnosis	Genetic disorder/syndrome	Age at shunt (days)	Weight at shunt (kg)
1	M	TF, DORV, PA, extreme hypoplasia of central AP. Multiple MAPCA's	46, XY de novo deletion 22q11; CATCH 22: syndrome of Shprintzen	402	7.86
2	M	DORV, TGA, VSD, PS		1466	14.3
3	M	TGA, VSD, PS		50	4.79
4	M	TA, UVH, VSD, PS		127	6.3
5	M	TF, PA		8	3.27
6	F	UVH, TA, VSD		59	3.73
7	F (+)	UVH, VSD, DORV, PS, left atrial isomerism	46, XX Left abdominal isomerism	420	8.44
8	F	TF, PA	Syndrome of Alagille	574	MD
					MD
9	M	AI 1/4, UVH, DILV, TGA, PA, hypoplasia central AP, VSD		5	3.04
10	M (+)	Mesorcardia, atrial situs inversus, DORV, PA, TGA	Abdominal situs inversus	14	3.8
11	M (+)	Right atrial isomerism, dextrocardia, UVH, DIRV via AVSD, DORV, TGA, PA	Ivemark syndrome	92	4.33
Median				58	4.56

Abbreviations: TF = tetralogy of Fallot, DORV = double outlet right ventricle, PA = pulmonal valve atresia, AP = arteria pulmonalis, TGA = transposition of the great arteries, VSD = ventricular septum defect, PS = pulmonal valve stenosis, TA = tricuspid valve atresia, UVH = univentricular heart, DILV = double inlet left ventricle, AI = aortic valve insufficiency, DIRV = double inlet right ventricle, AVSD = atrioventricular septum defect, BT = Blalock-Taussig, ePTFE = expanded Polytetrafluoroethylene, MD = missing data.

systemic arterial oxygen saturation. Demographics are listed in Table I. Diagnosis of a stenosed modified systemic-to-PA shunt was put forward after transthoracic echocardiography and cardiac catheterization.

An overview of procedural data is listed in Table II. The median interval between shunt placement and the first catheterization was 390 days (1-981). In those patients who underwent several interventions, the median interval between these interventions was 126 days (35-1033). Intervention was initially successful at re-establishing modified systemic-to-PA patency in 21/22 (95.5%) of the cases based on repeated shunt angiography immediately after dilatation. One intervention resulted in suboptimal flow due to persistent stenosis, although rising post-intervention oxygen saturation levels were noticed. Freedom from re-catheterization is shown in Figure 3A. Shunts remained patent after the first transcatheter recanalization until definitive corrective surgery in 3 patients. Survival analysis is shown in Figure 3B. Six patients successfully underwent definitive corrective surgery; one patient is awaiting definitive corrective repair; all 4 patients who died had a patent shunt at time of death. We collected the resulting diameters on 13 interventions and peri-operative oxygen saturation levels on 12 interventions. Figure 4 illustrates diameters measured before and after interventions. Intra-operative complications occurred only in 2 cases: 1 blockage of a 4 mm stent in another stent, which was solved by inserting and expanding a 3 mm balloon in this second stent, and 1 temporary occlusion of the superficial femoral artery. Bleedings or deaths did not occur during the procedures.

Mechanical study

The mechanical parameters are shown in Table III. Figure 2 shows an average curve for both grafts in the circumferential and axial directions. The Young's modulus of the stretchable graft in the axial direction is by far the lowest, thus showing the highest compliance or stretchability. The moduli of the other non-stretchable graft and of the axial direction of the stretchable graft are similar in range, while the non-stretchable graft is the stiffest in the axial direction. To calculate the pressure needed to obtain a certain circumferential strain, Laplace's law can be used to approximate the circum-

TABLE II - PROCEDURAL DATA

Patient	Type of shunt	No	Interval to intervention (days)	Indication	Diameter (mm) shunt before intervention	Diameter (mm) shunt after intervention	% change in diameter	% diameter original placed shunt	Saturation (%) before intervention	Saturation (%) after intervention	% increase of saturation	Outcome + interval from shunt (years)
1	Left BT ePTFE 5 mm	1	981	K + SAd	MD	MD	MD	MD	68,6*	84,1*	15.5	Waiting for definitive repair
		2	1863	ShS	MD	MD	MD	MD	77	86	9	
		3	2906	StS	3.89	4.84	(+) 24.4	(-) 3.2	MD	92	MD	
2	Central ePTFE 5 mm	1	366	SAd	1.86	5.73	(+) 208.1	(+) 14.6	MD	87	MD	Fontan 5.94
		2	532	StS	2.04	5.53	(+) 171.1	(+) 10.6	MD	89	MD	
		3	679	StS	0	MD	MD	MD	MD	83	MD	
		4	714	SAp	MD	MD	MD	MD	MD	MD	MD	
3	Right BT ePTFE 3.5 mm	1	649	ShS	2.93	4.20	(+) 43.3	(+) 20	76	79	3	Waiting for Rastelli or Nikaidoh
4	Central ePFTE 4 mm	1	203	K + ShS	MD	MD	MD	MD	MD	MD	MD	Fontan 3.08
5	Central ePTFE 3.5 mm	1	1	Sad	MD	MD	MD	MD	68,3*	82,5*	14.2	Repair TF 0.74
		2	96	K + ShS	3.30	5.87	(+) 77.9	(+) 67.7	82	89	7	
6	Right BT ePTFE 4 mm	1	370	ShS	1,68	4,12	(+) 145.2	(+) 3	70	86	16	Glenn 1.19
7	Left BT ePTFE 4 mm	1	562	ShS	MD	MD	MD	MD	MD	85	MD	† 2.21
		2	736	StS	MD	MD	MD	MD	81	85	4	
8	Right BT ePTFE 3.5 mm	1	568	ShS	0	4.77	/	(+) 36.3	62	84	22	† 2.43
		2	773	StS	2,5	5,41	(+) 116.4	(+) 54.6	MD	MD	MD	
	Central ePTFE 3.5 mm	3	515	ShS	2.03	4.77	(+) 135	(+) 36.3	62	84	22	† 2.28
		4	720	StS	3,77	4,14	(+) 9.8	(+) 18.3	MD	MD	MD	
9	Central ePTFE 4 mm	1	410	ShS	MD	MD	MD	MD	81	85	4	Fontan 3.22
10	Central ePTFE 3.5 mm	1	35	SAd	1.13	4.00	(+) 254	(+) 14.3	67,1*	77,2*	10.1	† 0.44
		2	140	ShS	1.46	2.81	(+) 92.5	(-) 19.7	MD	MD	MD	
11	Central ePTFE 4 mm	1	28	ST	0.00	5.50	/	(+) 37.5	66,3*	83,7*	17.4	† 0.27
Mean ± SD					**2.05 ± 1.25**	**4.75 ± 0.88**	**116.2 ± 76.6**	**22.3 ± 23.8**	**71.8 ± 7.3**	**83.8 ± 3.1**	**12 ± 6.8**	

Abbreviations: PTFE = polytetrafluoroethylene K = kinking, SAd = Stenonis of anastomosis distal, SAp = Stenosis of anastomis proximal, ShS = Shunt Stenosis, StS = Stent Stenosis, ST = Shunt Trombosis, TF = Tetralogy of Fallot, BD = balloon dilatation, SD = stent dilatation, MD = missing data. *arterial oxygen saturations, other saturation values are measured during procedure in the Aorta.

ferential or hoop stress in a thin-walled tube (20),

$$\sigma_{circ} = \frac{pd}{2t}$$

with *p* as the internal pressure of the graft, *d* the diameter of the graft and *t* the graft thickness. This can be combined with Hooke's law $\varepsilon = \sigma / E$, to obtain $p = \frac{2Et}{d}\varepsilon$.

For example, in a stretchable graft with an internal radius of 3 mm and a thickness of 0.2 mm, circumferential strain of 40% can be reached by applying an internal pressure of 1.0 ± 0.1 MPa, which is equivalent to approximately 10 atm. According to Hooke's law, this corresponds to a circumferential stress of 15.5 ± 1.5 MPa. Combining these parameters with Poisson's ratio leads to an estimation of the building up of axial stress or strain, namely 0.029 ± 0.023 MPa and 2.0% ± 0.8%, respectively. The same amount of circumferential strain for a non-stretchable graft can be reached with an internal pressure of 0.55 ± 0.10 MPa and will lead to a circumferential stress of 8.53 ± 1.47 MPa. In the axial direction, this corresponds to a similar amount of strain (2.8±1.2%), but a considerably higher amount of stress (1.84±1.35 MPa).

Interpretation of the failure stresses in Table III shows that the axial direction of stretchable and non-stretchable grafts has the highest failure strength and no significant difference is noticeable between the two types. The circumferential direction is significantly weaker in both cases, however, the stretchable version is still significantly stronger than the non-stretchable version.

DISCUSSION

Clinical study

Occlusion or stenosis of a modified systemic-to-PA shunt can be due to a sudden occlusion or a "chronic"

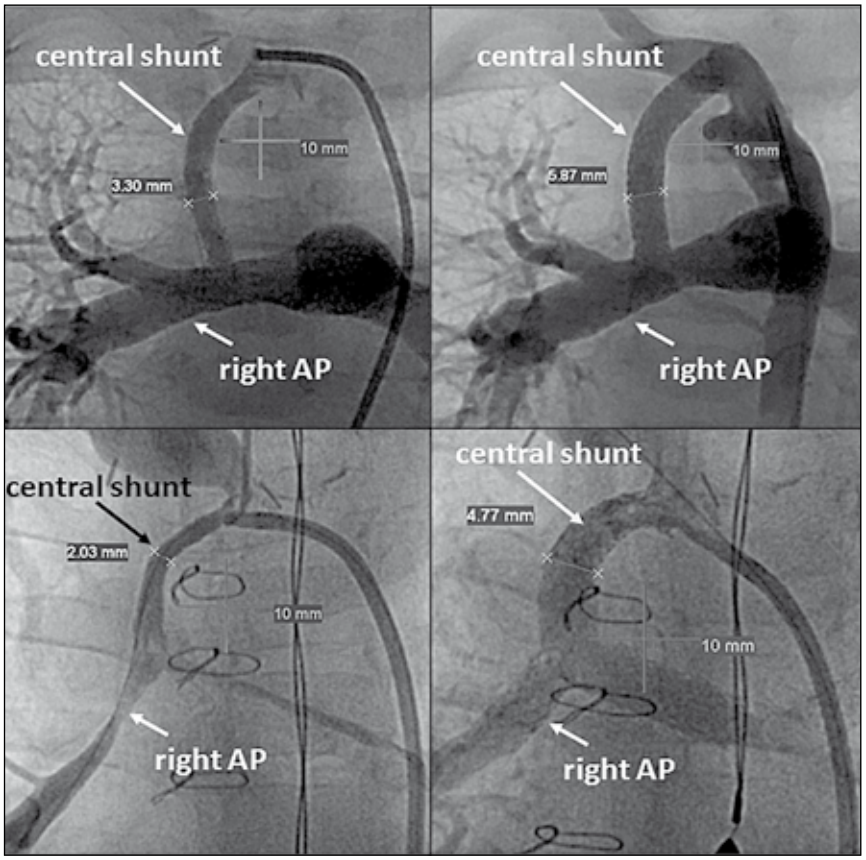


Fig. 4 - *Angiographic illustrations of balloon dilatation/stenting of systemic-to-PA shunts:* ***A:*** *Patient 5, status before second intervention, kinking + shunt stenosis of central shunt;* ***B:*** *Patient 5, status after second intervention (3 stents);* ***C:*** *Patient 8, status before first intervention, shunt stenosis central shunt;* ***D:*** *Patient 8, status after first intervention (2 balloon dilatations + 1 stent).*

TABLE III - MECHANICAL PARAMETERS

		Young's modulus (MPa)	Poisson's ratio	Yield strain (-)	Yield stress (MPa)
Stretchable	axial (n=6)	1.15±0.70	0.05±0.02	1.20±0.16	18.72±1.23
	circumferential (n=7)	38.25±3.94	0.26±0.04	0.49±0.08	13.68±1.62
Non-stretchable	axial (n=8)	55.09±24.69	0.07±0.03	0.44±0.06	22.34±2.27
	circumferential (n=7)	20.82±4.36	0.79±0.23	0.36±0.03	7.44±1.08

shunt failure. A sudden occlusion may constitute a medical emergency (10). We found two sudden occlusions in our series, i.e., one shunt thrombosis and one kinking. The use of thrombolytic agents is unpredictable and associated with complications in early postoperative patients (21). Therefore it was decided to directly attempt recanalization of the shunt by performing an embolectomy in the first case, followed by balloon dilatation and stenting in both cases.

In "chronic" shunt failure, occlusion occurs within months/years after shunt placement. This may result from scar formation at the anastomotic site, or from either fibrous neointimal peel formation or thrombosis in the PTFE tube (11). Dilatation of the shunt can be performed semi-electively. We dilated 20 (91% of cases) chronically occluded shunts.

With a mean increase from 2.05 ± 1.25 mm to 4.75 ± 0.88 mm by using stents, our shunts are significantly expanded.

Gillespie and co-workers describe an implantation with stents sized to fit the original diameter of the shunt (22). For balloon angioplasty only, on the other hand, some authors advocate higher than luminal diameters varying from 1 mm to 150% of the balloon shunt ratio (14, 22, 23). However, other authors have recommended caution in using such a ratio for dilating prosthetic materials and advise the use of adequately sized balloons, since overexpansion may lead to aneurysm formation, ruputure of sutures, vessel and graft (18, 24).

Peuster et al performed his balloon catheter dilatations with inflation pressures of 9 to 10 atm. Stents were carefully expanded with 4 atm (18). Wang et al applied pressures of 3 to 8 atm to inflate the balloons (14). Much higher pressures up to 18 atm were used in our study. The use of higher pressures in balloons and stents with larger diameters is a reasonable explanation for our higher resulting diameters and was not associated with any complications, despite warnings and complications found in literature.

Fortunately we did not face major procedure-related complications and few are described in the literature (4, 14, 17). In contrary to other studies, additional surgical procedures prior to definitive repair were avoided in all patients (4, 17, 24).

Mechanical study

A study of the mechanical properties of Gore-Tex® vascular grafts was performed to gain insight into the extent that shunts can be dilated. The known axial extensibility of the thin-walled stretch vascular graft was confirmed by the corresponding Young's modulus, which was by far the lowest compared to the moduli of circumferential and non-stretchable samples. This property implies that the development of axial stress due to circumferential expansion will be much lower in this type of grafts. This has implications on the effect of graft expansion on the anastomosis sites and the surrounding tissue. Although the development of stress will not be maximal due to the compliance of the native tissue, it is clear that the loading on the anastomosis will be significantly higher in the case of a non-stretchable graft.

Moreover, the failure strain and stress of stretchable grafts in the circumferential direction are significantly higher than those of the non-stretchable graft in the same direction. This implies that a stretchable graft will be able to withstand higher dilatations than a non-stretchable graft. Both statements count as a justification for the use of stretchable over non-stretchable grafts.

Study limitations

The retrospective nature of this analysis results in certain limitations. Apparently oxygen saturation levels were not accurately noted in the catheterization reports. Several catheterization images were lost. The accuracy of shunt diameter measurements can be questioned. However by using high resolution images and by having the calibrations and measurements performed by one person, we have aimed for the highest accuracy possible. The small patient population limited our ability to perform statistical analysis to determine predictors of success as well as our ability to apply risk-adjustment to the study population.

CONCLUSIONS

We believe that dilatation of stenosed modified systemic-to-PA shunts, when performed with high pressures and with balloons and stents with a significant higher diameter than the original shunt, is feasible and safe. The procedure can be performed with low morbidity and high success rates, especially when considering the resulting shunt diameters and oxygen saturation levels. Moreover it is a successful alternative to fibrinolytic therapy or operative shunt revision in selected patients. With a view to further research, the results of our technical study posit a great advantage for the use of the thin-walled stretch configuration of ePTFE.

Conflict of interest statement: None of the authors has any disclosures concerning financial support or proprietary interest to add.

Address for correspondence:
Tom O. Verbelen, MD
Department of Cardiac Surgery
University Hospital Gasthuisberg
Herestraat 49
B - 3000 Leuven, Belgium
e-mail: tom.verbelen@student.kuleuven.be

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