Original Studies

Stent Expansion of Stretch Gore-Tex® Grafts in Children With Congenital Heart Lesions

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Objective: To evaluate the efficacy and safety of expanding vascular shunt grafts beyond original nominal diameter using stents. Methods: Bench testing confirmed the expandability of 3.5 mm and 4.0 mm vascular Gore-Tex® stretch grafts. A retrospective analysis included eleven systemic to pulmonary artery shunts with diminished flow which were stented with the aim of increasing the original nominal diameter of the shunts. Results: During bench testing, the grafts could be expanded to 4.5 mm and 5.8 mm, respectively. Fourteen stents were implanted in 11 stretch grafts a median of 18.9 months (3.2; 21.6 months) after shunt surgery. There was a median increase in diameter of 1.4 mm (0.9; 1.7 mm) [*P* = 0.001, 95% CI: 0.47; 1.7) from original nominal to final stented diameter of the shunts with a median gain of 28%. A simultaneous improvement in saturations from a median of 73% (66; 77%) to 87% (84; 89%) [*P* = 0.015; 95% CI: 3; 22] was observed. No complications were experienced during the procedures. Conclusion: In our limited experience, stretch Gore-Tex vascular grafts can be safely expanded beyond nominal diameters using high pressure vascular stents. This leads to improvement in saturation and pulmonary blood flow. It allows the clinician to tailor pulmonary flow in relation to pulmonary artery size and growth, ensuring best possible timing for the next surgical procedure.

Key words: shunt; dilatable shunt; stent; palliative-expansion

INTRODUCTION

Systemic to pulmonary artery shunts are effective palliation for infants with congenital heart disease associated with critical reduction of pulmonary artery blood flow [1–3]. Most shunts allow no compensation or increase in flow associated with growth. A modified Blalock-Taussig shunt allows some flow control: the orifice of the subclavian artery acts as the initial limitation and later as the child grows, the diameter of the shunt itself becomes the limiting factor [4].

When creating a shunt, the surgeon has the choice of several grafts made of different materials. Thin walled stretch Gore-Tex® vascular grafts (W.L. Gore & Associates, Flagstaff, AZ) are made of polytetrafluoroethylene (PTFE) and are extensively used in our centre. These grafts offer benefits such as ease of implantation and takedown during surgery and are purportedly more forgiving for length mismatch during implantation; they are relatively kink resistant and have superior anastomotic conformability whilst maintaining good patency. Stretch is available longitudinally but no radial stretch is claimed.

Stenoses and occlusions of shunts can be safely and effectively managed by balloon angioplasty and stenting [5–13]. It would be advantageous if the size of a shunt could be increased beyond the nominal

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diameter at initial implantation, allowing manipulation of pulmonary blood flow. The aim of this study was to determine whether the original nominal diameter of stretchable vascular grafts could be increased effectively and safely by means of percutaneous stent implantation and whether this would lead to an improvement in systemic saturation.

METHODS

During the study period, bench testing was performed to prove that increase in original nominal diameter of Gore-Tex stretch grafts was possible and to determine the limits of expansion. A 4.0 mm and a 5.0 mm stent were inflated in two pieces of 3.5 mm and 4.0 mm stretch Gore-Tex grafts respectively, at 8–10 atmospheres of pressure to obtain complete expansion. Both stents were subsequently further dilated using a 6 mm balloon at 12 atmospheres.

A retrospective analysis of our institutional pediatric cardiology database was performed to identify all children who had undergone stenting of a stretchable vascular graft with the aim of increasing the shunt diameter beyond the original nominal diameter at surgery. Eleven stretch grafts were stented with the intention of increasing diameter during a period ranging from December 2001 to June 2009. The predominant indications for interventions were arterial desaturation, inadequate pulmonary arterial flow or insufficient pulmonary artery growth, increasing the risk (and sometimes even excluding the possibility) of corrective surgery. Patient records were used to obtain catheterization and follow-up data. Digital measurements of catheterization data were performed using an IMPAX viewer (Agfa Heartlab®). The study was conducted in accordance with local ethical committee guidelines.

TECHNIQUE

All procedures were performed under general anesthesia. A retrograde femoral arterial approach, using size 4–6F guiding sheaths, was used in the case of systemic to pulmonary artery shunts, whilst the femoral vein (7F) was used for cannulation in one case of a right ventricle to pulmonary artery conduit. Standard methods and techniques were employed. In short, once the shunt was identified, it was crossed using a 0.014 inch guidewire. Angiography was subsequently carried out and appropriate measurements were performed. Some shunts were difficult to cross, and maintaining stable guidewire position was problematic; in these cases, we often used a co-axial system as previously described [14]. If possible, a 6F guiding catheter was preferred for stent delivery. However, if patient size proved to be problematic, only a 4F short femoral introducer sheath was used. Only premounted stents were used. Once the stent was in position, it was completely expanded using a pressure manometer. The balloon was inflated at least up to recommended nominal pressure. Depending on the clinical result, the delivery balloon was overinflated or a larger, high pressure balloon was used. Antibiotics and heparin (50–100 U/kg) were administrated intravenously during the procedure, followed up by oral aspirin (2 mg/kg/day) at discharge. Success was defined as any increase above the nominal diameter of the original shunt at implantation. Improvements in percutaneous saturations in room air before and after the procedures were also recorded where possible.

STATISTICAL ANALYSIS

Data was captured using excel spreadsheets, and statistical analyses were performed using Graph Pad Prism version 5.00 for Windows (Graph Pad Software, San Diego, CA). A P value <0.05 was considered statistically significant. Results were given as median with quartiles (25th; 75th) and 95% confidence intervals (non-parametric for median change).

RESULTS

Bench Test

Results of bench testing showed that after full expansion with a 6 mm balloon at 18 atmospheres, a 3.5 mm graft could be expanded up to 4.9 mm (40%), and a 4.0 mm graft up to 5.8 mm (45%) (Fig. 1). No rupture or tear occurred.

Patients

In 11 stretch grafts, 14 stents were implanted in 10 patients a median of 18.9 months (3.2; 21.6 months) after shunt surgery. Median age and weight at the time of the procedure was 1.7 years (0.3; 5.3 years) and 9.4 kg

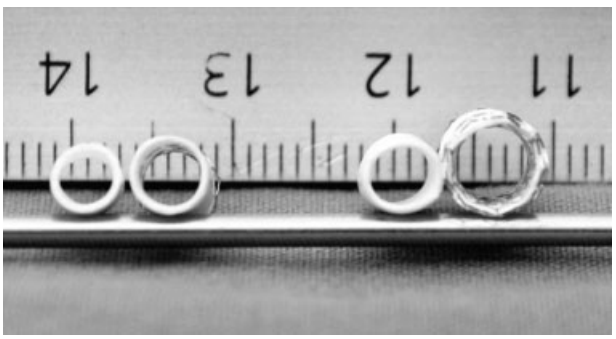

Fig. 1. Bench test of 3.5 and 4.0 stretch Gore-Tex® vascular graft. Left: 3.5 mm stretch Gore-Tex vascular graft expanded up to 4.9 mm diameter; right: a 4.0 mm stretch Gore-Tex vascular graft expanded up to 5.8 mm. See text for details.

TABLE I. Patient Characteristics

Diagnosis	Type shunt	Original nominal diameter shunt	Stent diameter	No stents	Stent length	Type of stent	Max ball	Diameter post	Percentage increase[a]
TGA-PS	MBT	3.5	4.5	2	18, 12	Driver®	6	4.9	41
PA-VSD	Sano	6	7	1	18	Herculink®	8	7.7	28
PA-VSD	c	3.5	4	1	8	Coroflex Blue®	4	4.9	40
TA	MBT	6	7	1	18	Herculink®	7	7.7	28
PA-VSD	MBT	3.5	4.5	1	24	Driver®	4.5	3.9	11
	c	3.5	5	1	16	Liberté®	5	4.8	36
DORV-PA	c	3.5	4.5	1	16	Liberté®	4.5	4.4	25
PA-VSD	MBT	5	7	2	18, 18	Herculink®	7	6.0	20
Tet	c	3	3.5	2	18, 12	Driver®	7	3.5	16
UVH	c	4	6	1	40	Cordis Precise®	6	5.5	38
UVH	c	4	5	1	18	Multi-link Visionr®	5	5.7	43

Diameter and lengths in mm.

Manufacturers: Driver®, Medtronic Inc., Minneapolis, MN; Herculink®, Abbott Lab, IL; Coroflex Blue®, B. Braun, Netherlands; Liberte®, Boston Scientific, Natick, MA; Cordis Precise®, Cordis, Warren, NJ; Multi-Link Vision®, Abbott Lab, IL.

Max ball, maximum diameter of balloon used to expand stent; TGA-PS, transposition with sub pulmonary stenosis; PA-VSD, pulmonary atresia with ventricular septal defect; TA, tricuspid atresia; DORV, double outlet right ventricle; PA, pulmonary atresia; TOF, tetralogy of Fallot; UVH, univentricular heart complex; MBT, modified Blalock-Taussig shunt; c, central shunt.

[a]Percentage increase from original shunt (nominal) diameter.

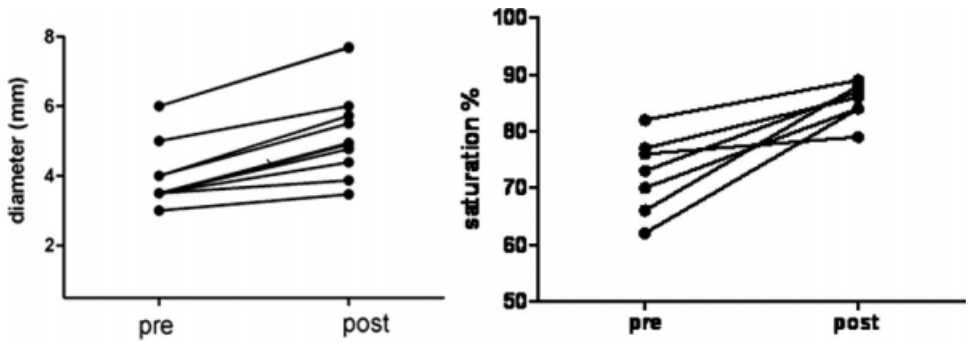

Fig. 2. Diameters and oxygen saturations before (pre) and after (post) stent implantation.

(3.8; 15.1 kg), respectively. Stented grafts consisted of modified Blalock-Taussig ($n = 4$), central ($n = 6$), and one Sano shunt. Further details can be viewed in Table I.

There was a median increase in diameter of 1.4 mm (0.9; 1.7 mm) [$P = 0.001$, 95% CI: 0.47; 1.7) from original nominal to final stented diameter of the grafts representing a median gain of 28% (Fig. 2). A noteworthy improvement in saturations from a median of 73% (66; 77%) to 87% (84; 89%) [$P = 0.015$; 95% CI: 3; 22] was also observed (Fig. 2). In two patients, the increase in diameter was obtained only after a second dilatation with high pressure balloons: 6 mm Maverick® (Boston Scientific, Waterton, MA) and 8 mm UDT® (Boston Scientific, Waterton, MA) for patients 1 and 2, respectively. One virtually occluded shunt was recanalized during the procedure. Angiographic examples can be viewed in Fig. 3. Some narrowing at the proximal anastomosis was observed in six shunts, at the distal anastomosis in nine shunts and at the mid area of one shunt before stent implantation. No complications were experienced during the procedures.

Follow-Up

The median follow-up time since last visit was 10.2 months (4.4; 41.9 months). During this period four patients were re-catheterized: three required re-stenting and one required angioplasty of the stents because of stenoses and/or peel formation. In the latter the shunt completely thrombosed eleven months later, but the patient proceeded uneventfully to surgery since there was a patent cavopulmonary connection. Five children proceeded to surgical repair, 6 months to 5 years after graft expansion. Two are still being followed up with good saturations, and three died from problems related to co-morbidities. The deaths occurred two, four, and eleven months after shunt expansion in patients with Alagille, Kartageners, and right atrial isomerism syndromes, respectively. All shunts were patent at the time of death.

DISCUSSION

In patients with shunt dependant pulmonary flow, ''premature'' dysfunction of the shunt may occur

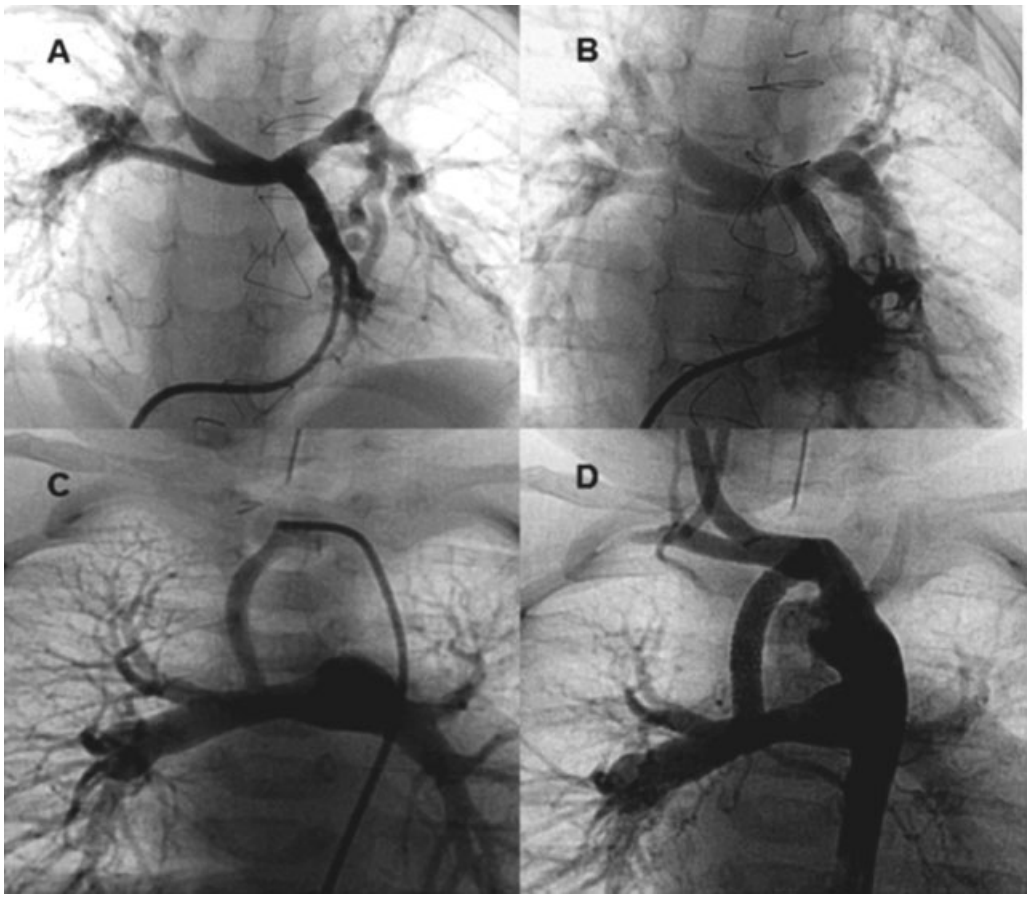

Fig. 3. Stent placement of stretch Gore-Tex® vascular graft. A and B: 6 mm Sano shunt before (A) and after stent expansion (B) up to 7.7 mm. C and D: 3.5 mm central shunt pre (C) and post (D) stent expansion up to 4.9 mm.

during somatic growth. The clinician is faced with the following options: perform a second shunt, proceed to surgical correction accepting the risk of small pulmonary arteries and low body mass, or maintain the status quo (risking progressive cyanosis, poor pulmonary artery growth, and shunt thrombosis). Stent expansion of a stretchable graft becomes an attractive alternative in this scenario. The possibility of elective percutaneous graft enlargement broadens treatment options: lifespan of a shunt could be prolonged until satisfactory weight gain and/or pulmonary size are reached. A second surgical systemic to pulmonary artery shunt can be avoided and could allow the surgeon to create a smaller shunt at birth, especially in low birth weight infants and certain types of univentricular hearts where protection from volume overloading is important (hypoplastic left heart syndrome, unbalanced atrioventricular septal defect with right ventricle dominance). The shunt can electively be expanded in the first weeks or months after placement to manage pulmonary blood flow and keep track with growth. Furthermore, access to a catheterization laboratory is quick and easy, should the patient suddenly or unexpectedly become progressively cyanosed (especially in units where long waiting lists for surgery exist).

Results of this study show that the nominal diameter of stretch Gore-Tex vascular grafts can be significantly and safely increased with stents by means of transcatheter techniques. This was associated with a clinically significant 14% median increase in arterial oxygen saturations. Surgery could be delayed for a minimum of 6 months and for two patients not yet operated, satisfactory saturations were present during follow-up of 10 and 60 months. Percutaneous stent implantation allows a relatively predictable, durable, and safe expansion of vascular grafts.

Some aspects regarding the intervention need to be highlighted:

- Guidewire stability cannot be overemphasized: a coaxial system was frequently needed not only for shunt access, but also to achieve stable guidewire position. The intervention often required more than

two pairs of experienced hands to maintain catheter positions and guidewire positions [14].
- A 6F arterial sheath is preferred since it will allow a 6F guiding catheter (right coronary guiding catheter or internal mammary guiding catheter in case of central shunts with acute angles). The guiding catheter also allows for hand injection angiography to facilitate perfect stent positioning.
- Premounted stents and, for smaller shunts, coronary stents were almost exclusively used (Table I). The great variety of stents were due to the fact that the review spanned a period of almost 8 years—coronary balloons available in the catheterization laboratory at the time were selected on the basis of diameter and high pressure tolerance. On average, we chose stents with a diameter 1 mm (range: 0.5–2 mm) larger than the nominal diameter of the original shunt. If required, an additional increase could be obtained using the delivery balloon or another larger, high pressure balloon. Although stent foreshortening was not observed in our patients, it remains a theoretical possibility especially if oversized balloons are used. No distortion of the pulmonary arteries was noticed on angiography.
- As reported in the literature [6], stenoses occur frequently at the anastomotic sites of the shunts and should be managed simultaneously. In general, the whole graft was stented up to the anastomoses; some protrusion into the lumen of surrounding vessels is not important, as long as there is no contact with the opposite side, except for the proximal end, especially if later re-entry is anticipated.
- We also stent expanded three larger grafts (based on our experience with the smaller diameter grafts) with a favorable increase in diameter. In these we used balloon pressures aiming for at least a 1 mm increase in diameter.

Some older children were included, consisting of complex lesions where early repair was not possible. Adequate pulmonary growth was obtained, and two patients with pulmonary atresia with ventricular septal defect (PA-VSD) proceeded to complete repair. One patient, not amenable to repair, is still being followed up with acceptable saturations.

Studies have shown that risk factors for stent thrombosis are longer length, smaller diameter, and wall abnormalities [15–17]. In this small series, low dose oral aspirin seemed to be effective in preventing stent (shunt) occlusion, as thrombosis occurred in only one stent expanded graft 11 months after intervention. No complications occurred, although dissection or aneurysm formation has been described during transcatheter management of shunts [18].

STUDY LIMITATIONS

This is a small, retrospective study and comparisons with other treatment regimens were not made. However, the primary aim of the study was to ascertain whether successful graft expansion was possible. Follow-up studies are indicated and should focus on pulmonary arterial growth.

CONCLUSION

In our limited experience, stretch Gore-Tex® vascular grafts can be safely expanded beyond original nominal diameters by percutaneous stents implantation, enhancing pulmonary blood flow as well as improving oxygen saturations. This may potentially allow the clinician to tailor shunt size to growth and pulmonary flow requirements, adding new management options.

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