

# Stent expansion of restrictive Fontan conduits to nominal diameter and beyond

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## Abstract

**Background:** Mechanical factors may cause bottlenecks in a Fontan circuit. Extracardiac conduits (ECC) are placed at a young age, but the materials do not allow growth. Restriction in ECC dimensions may deteriorate the function of the circuit.

**Aims:** This study aimed to evaluate the feasibility and safety of stent expansion of an ECC to the nominal dimension at the time of implant and, if possible, beyond nominal.

**Methods:** Retrospective, single-center observational review of all ECC Fontan patients who received a stent to expand a previously placed surgical conduit.

**Results:** A total of 44 restrictive conduits were stented over a 14-year study period with a median of 11.8 (interquartile ranges [IQR]: 9.1–13.8) years after ECC placement. Cross-sectional areas were a median of 30% (IQR: 21–42) smaller than the originally placed ECC; there was no gradient in 23/44 patients and in 21/44, a minimal gradient of  $1.3 \pm 0.5$  (range 1–3 mmHg). All conduits could be enlarged with a significant ( $p < 0.0001$ ) increase in diameter from  $13.6 \pm 1.8$  to  $19.2 \pm 1.2$  mm, corresponding to a median cross-sectional area increase of 171% (IQR: 153–220). In three patients where the conduits were not contracted, expansion of between 127% and 165% was obtained. There were no conduit ruptures and only one minor complication.

**Conclusions:** ECC in some Fontan patients become smaller than nominal over time, usually without overt symptoms. The dimensions of ECC's can be safely and significantly increased to nominal or even beyond employing stenting. It allows adjustment of ECC dimensions to compensate for somatic growth.

## KEYWORDS

cross-sectional area, expansion, extracardiac conduit, growth, stent

## 1 | INTRODUCTION

The Fontan circulation comprises several components in series, and multiple physiological and mechanical factors may cause bottlenecks with various consequences in the circuit.<sup>1,2</sup> Extracardiac conduits (ECC) are now favored over atriopulmonary connections due to improved flow dynamics and better outcomes.<sup>3,4</sup>

Preferred ECC's consist of Gore-Tex<sup>®</sup> in diameters ranging from 14 to 22 mm, but other materials such as homograft tissue and Dacron<sup>®</sup> have been used. All materials have different properties that may impact the long-term efficiency of the circuit: homografts tend to calcify and crimp, while Dacron has been associated with severe stenosis as a result of intimal ingrowth and thromboembolism.<sup>5-8</sup> Gore-Tex<sup>®</sup> is now widely used since expanded polytetrafluoroethylene is inert and relatively biocompatible with less fibrosis, as well as being strong, conformable, and easy-to-handle.<sup>9,10</sup> The drawback of all these conduits is that they have no growth potential.

The Fontan operation is now performed in children as young as 2–4 years old. However, selecting the ideal diameter to compensate for growth is challenging. Theoretically, if a too large or too long conduit is inserted, surrounding structures may be compressed. On the other hand, a too-large conduit may potentially result in increased dead space and thrombus formation. However, placing a smaller conduit at a young age may result in a disproportionately small conduit in adolescence and adulthood. Usually, the surgeon will place the most significant conduit allowed by the anatomy at the time of surgery.

Restriction of ECC dimensions over time is increasingly being recognized and may occur in up to 13%–33% of cases.<sup>11</sup> Studies have shown that ECC cross-sectional area may decrease as early as 6 months after surgery and between 10% and 33% after a couple of years.<sup>10,12,13</sup> The effects of these dimension changes over time are presently not apparent. However, in our current understanding of the mechanics of the total cavopulmonary connection, it is evident that even small regional increases in resistance in the critical bottleneck can impair the flow mechanics of the whole circuit due to upstream and downstream changes.<sup>2</sup> It thus stands to reason that even minor restrictions in the circuit should be treated. In a study by Mets et al. in 50 patients with a clinically significant narrowed lateral tunnel Fontan, only 35% of patients who required stents had measurable gradients.<sup>14</sup> This is supported by an magnetic resonance imaging (MRI)-based computational model, which showed that cavopulmonary resistance might be high at rest even though no or minimal gradients are measured. Increased resistance and gradients only became evident during exercise.<sup>5</sup> Surgical replacement is possible but requires major surgery; percutaneous optimization, therefore, appears to be an appealing alternative.

This study aimed to evaluate the feasibility and safety of stent expansion of an ECC to at least the nominal dimensions at the time of implant and, if possible, beyond nominal to be more appropriate for the adult patient following somatic growth.

## 2 | METHODS

The study was a retrospective, descriptive review of all extracardiac conduit Fontan patients who received a stent intending to enlarge a previously placed ECC to nominal or beyond from October 2007 to September 2021. Anonymized data and demographics were captured from the institutional congenital cardiac database, including clinical and surgical notes, catheterization reports, and angiograms.

Routine cardiac catheterization was performed if patients were near the end of somatic growth, required closure of a fenestration, or were symptomatic. Before the catheterization, different optimization options were discussed (embolization collaterals, closing residual fenestrations, stenting stenosis or mismatch of conduits, anastomosis or branch pulmonary arteries, and lymphosclerosis) with the patient and the parents outlining the known and unknowns, proven and theoretical advantages, as well as possible complications.

The main indications for stent expansion were either a markedly crimped or compressed conduit compared to the nominal diameter of the original surgically placed ECC (41/44), marked visual disproportion of the conduit compared to nearest normal vessel dimensions (inferior caval vein [ICV] or pulmonary artery) (44/44) or the presence of any gradient between ICV and/or pulmonary artery (21/44). The absence of a gradient was no contraindication for stent expansion of the ECC.

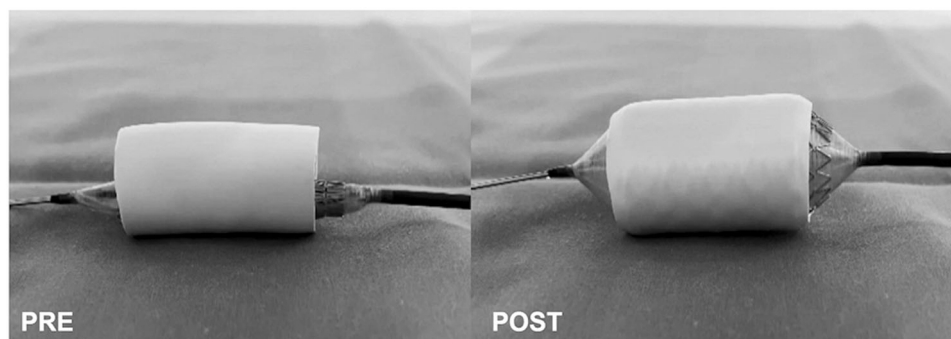
### 2.1 | Cardiac catheterization

Informed consent was obtained in all cases. Procedures were performed under general anesthesia with routine anticoagulation and antibiotics administered per standard operating protocol (heparin 100 u/kg and cefazolin 50 mg/kg [max 2 g] IV).

### 2.2 | Technical aspects

A bench test was performed in a 16 mm Gore-Tex<sup>®</sup> conduit using an Atlas<sup>®</sup> Gold balloon (BARD) at high pressure and a bare-metal stent. The conduit was expanded to 20 mm without the outer layer ripping apart or any tears (Figure 1).

Stents were delivered as previously described mounted on BIB<sup>®</sup> balloons (NuMED) at low pressure through a 12–14 F Mullins sheath (COOK).<sup>15</sup> Balloon diameter was at least the nominal value of the ECC, but as our experience evolved over time, we elected to use an 18 or 20-mm balloon depending on the desired final diameter of the conduit. Care was taken to cover the whole conduit from the cranial pulmonary anastomosis to just beyond the caudal ICV anastomosis, thereby avoiding the possibility of late stent compression by the liver. In cases where two stents were required to cover the whole length of the conduit, the cranial stent was placed first and then overlapped at least 30% by the caudal stent. Both bare metal and covered stents were used. The latter when a residual fenestration needed to be closed, the danger of conduit rupture (calcified homograft) was considered, or when the device in the fenestration was bulky or potentially might puncture the delivery BIB



**FIGURE 1** Bench testing. Left: 16 mm Gore-Tex<sup>®</sup> conduit before expansion with a 20 mm Atlas<sup>®</sup> Gold high pressure balloon. Right: Conduit after expansion to 20 mm. Note no fabric tears.

balloon. When further expansion was desired, this was done by high-pressure balloon expansion (Atlas Gold; Bard) with pressures up to 26 atmospheres or more until the desired final diameter of 18–20 mm or more was reached.<sup>16,17</sup>

### 2.3 | Measurements

For this report, the conduits were measured using calibrated standard image measuring software of the angiographic system (IMPAX<sup>®</sup> viewer; Agfa Heartlab<sup>®</sup>). Before stenting, conduits were measured in both anteroposterior and lateral views in the same positions: cranially at the narrowest aspect of the pulmonary anastomosis, the middle of the conduit and caudally at the narrowest segment of ICV anastomosis. The three measurements for each plane were then averaged to derive a single diameter for each plane. The cross-sectional surface area of the oval-shaped tube was calculated:  $3.14 \times \text{radius Anteroposterior} \times \text{radius Lateral}$ . ICV was measured at the widest diameter, just below the conduit. Post stenting, only one measurement was used to calculate area and surface since this was now assumed to be a perfectly round tube.

### 2.4 | Ethics and statistics

Permission was obtained from the institutional ethical review board (ref S66331). Continuous variables, when asymmetrically distributed, are expressed as median and interquartile ranges (IQR) 25% and 75%, otherwise as mean  $\pm$  standard deviation. A *t*-test was used to compare normally distributed data. *p* Values of  $<0.05$  were considered statistically significant. Statistical analysis was performed using SPSS<sup>®</sup> (IBM<sup>®</sup>).

## 3 | RESULTS

A total of 44 patients with restrictive conduits were stented over the study period representing the total experience. Demographics and baseline characteristics can be viewed in Table 1. Extracardiac conduit Fontan was performed at a median age of

**TABLE 1** Baseline characteristics

	Fontan			Stent expansion		
	Median	Q25	Q75	Median	Q25	Q75
Age (year)	3.7	3.2	4.9	15.9	13.7	17.9
Weight (kg)				55.3	40.7	63.0
ECC	n					
Homograft	2					
Gelseal	1					
Goretex	41					
Implant diameter (mm)	n	%				
14 mm	4	9				
16 mm	17	39				
18 mm	12	27				
20 mm	9	20				
22 mm	2	5				
Preexpansion	Postexpansion					
Pulmonary artery pressure (mm Hg)	16	15	19	16	15	19
Gradient IVC-pulmonary artery (mm Hg)	1	0	1	-	-	-

*Note:* Baseline characteristics at Fontan, pressures before and after extracardiac conduit (ECC) stenting. Pressures are in mm Hg. Gradient after stent expansion not performed.

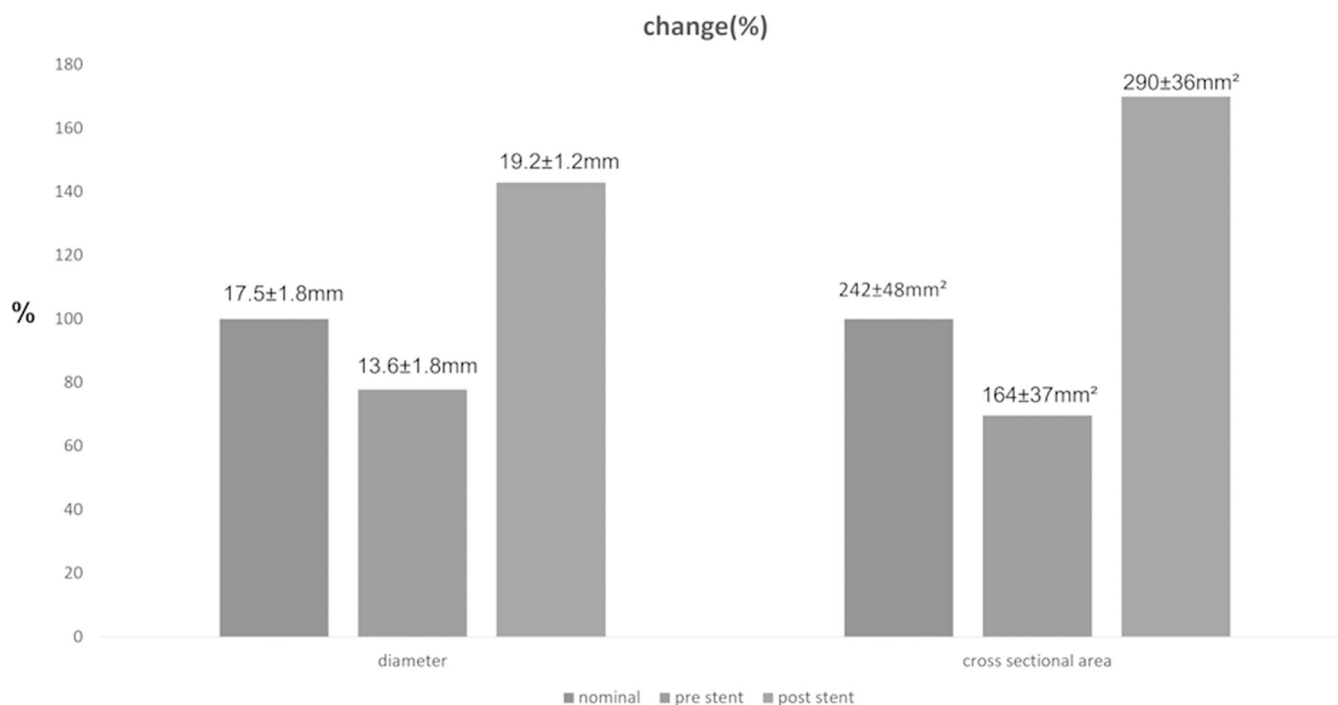
3.7 (quick response 3.2; 4.9) years and consisted of 24 males and 20 females. Initial surgical conduits consisted mainly of 16, 18, and 20 mm diameters, but 14 and 22 mm were used in a minority (Table 1). In the vast majority (41/44, 93%) of conduits, Gore-Tex<sup>®</sup> (Gore Medical) was used. One Gelseal<sup>®</sup> graft (16 mm) (Vascutek; Sulzer Medica) and two homografts (14 and 16 mm) were implanted in the late 90s and early 2000s, but these and 14 mm grafts ( $n = 4$ ) are now no longer used in our institution. The series included one patient of 35 years who had a reconversion of a classical right atrium to pulmonary artery Fontan to a Gore-Tex<sup>®</sup> ECC (22 mm) in 2014.

### 3.1 | Catheterization and stenting

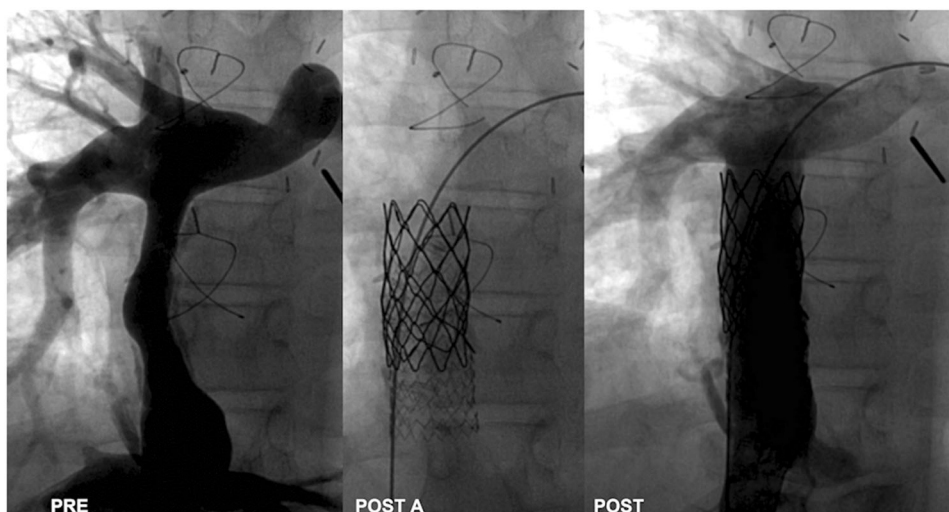
Cardiac catheterization and stenting were performed in these patients at a median period of 11.8 (IQR: 9.1–13.8) years after the initial Fontan operation with median age and weight of 15.9 years and 55.3 kg, respectively (Table 1). Fifty percent ( $n = 22/44$ ) complained of effort intolerance, five were cyanosed and had a fenestration, two patients presented with protein-losing enteropathy and 1 with plastic bronchitis. In 18 ( $n = 18$ ) patients fenestrations were previously closed with devices:

various types of Amplatzer® devices ( $n = 9$ ) and PFO Star® ( $n = 9$ ). There was a gradient of  $\geq 1$  mmHg in 21 patients, but in 23/44, no gradients were measured. Before conduit expansion, median pulmonary artery pressures were 16 mmHg (IQR: 16–19) and demonstrated no change postexpansion (Table 1).

Observable conduit contraction/compression was present with a transverse diameter decreasing to a median of 70% (IQR: 58–79) and cross-sectional area shrinkage to 78% (IQR: 70–88) compared to nominal at surgery (Figure 2). In three ( $n = 3$ ) patients, conduits were



**FIGURE 2** Average diameters and cross sectional area changes before and after stenting. Transverse diameter (mm) and cross sectional area (mm<sup>2</sup>) of conduits (see text for formula) at implantation, before, and after stent expansion.



**FIGURE 3** Two stents in homograft ECC. Pre: Angiogram of shrunken conduit (9 mm) before stent expansion of previously placed 16 mm homograft. Post: (A) Overlapping of 2 stents can be seen: 45 mm covered CP and Intrastent expanded to 18 mm. Angiogram showing expanded ECC. CP, cheatham platinum; ECC, extracardiac conduits.

found to have the same diameter as at implant, but the pulmonary artery and ICV were markedly larger than the conduit. The ICV appeared dilated in most patients, and the average ratio of ICV to conduit diameter was  $2.2 \pm 0.4$ .

Conduits could be expanded using a single stent in 39 patients; two stents were needed in 5 patients. A total of 49 stents were implanted, consisting of 23 covered cheatham platinum<sup>®</sup> (39–65 mm), 23 Andrastent XXL<sup>®</sup> (26–57 mm), 2 Optimus XXL<sup>®</sup> (38–48 mm), and one 45 mm Intrastent<sup>®</sup>. Additional procedures in 19 patients included left pulmonary artery stenting in 5, closing a residual fenestration with a covered stent in 5 (Figures 3–5), closure of collateral vessels in 5, transhepatic periportal lymphosclerosis in 2, and stenting of residual

coarctation in another patient was performed. As part of the optimization process but unrelated to the stent procedure, one patient received an epicardial pacemaker some days after the catheterization, another plication of the diaphragm, and one patient was put on a hypocaloric diet.

### 3.2 | Poststent dimensions

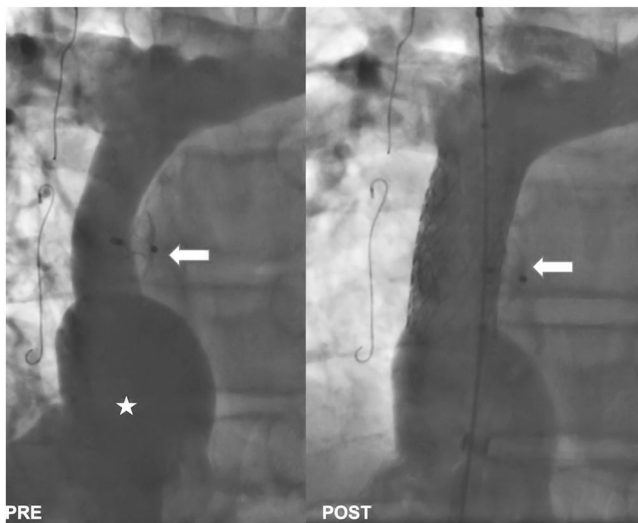
A significant increase from baseline at catheterization in median diameter and cross-sectional area of 143% (IQR: 126–157) and 171% (IQR: 153–220), respectively, could be achieved in all patients ( $p < 0.0001$ ). In the three patients where the conduits were not contracted but small in relation to adjacent vessels, expansion of between 127% and 165% beyond nominal was obtained.

### 3.3 | Complications

No conduit tear nor contrast extravasation was observed. In a few Gore-Tex<sup>®</sup> patients, a “tearing” sound was heard during the dilation; this was not observed during bench testing. The authors speculate that this is probably the result of conduits rigidifying in the body after implantation. Only one adverse event occurred in a patient where the superior caval vein was inadvertently dilated, resulting in transient sinus arrest with slow junctional escape rhythm, which required no intervention. No other complications were experienced. It should be noted that patients with devices previously placed for fenestration closure did not present any difficulty or experienced more complications.

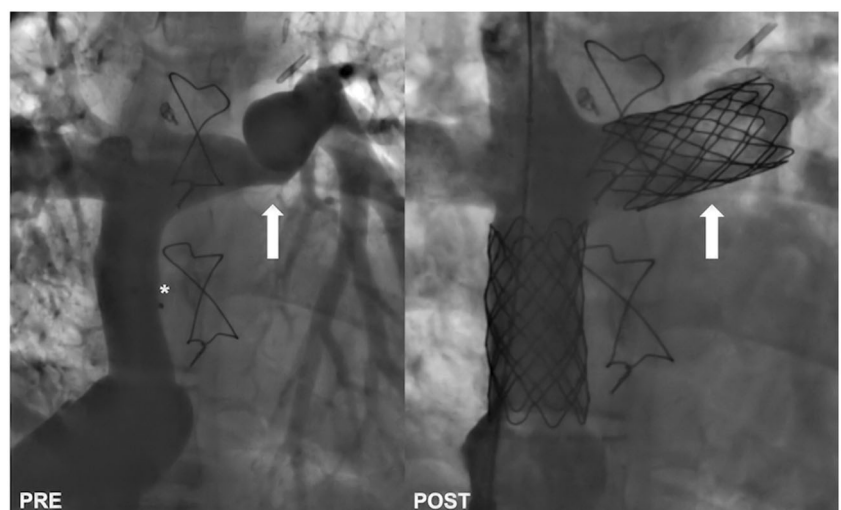
### 3.4 | Follow-up

All patients remained on their standard anti-aggregation with aspirin 1–2 mg/kg/d ( $n = 42$ ) or coumadin ( $n = 2$ ). All patients were



**FIGURE 4** Fenestration device in situ. Pre This initial 18 mm Gore-Tex<sup>®</sup> conduit measured 12 mm in transverse diameter; a 4 mm Amplatzer<sup>®</sup> atrial septal defect device used to close a fenestration previously (shown by white arrow). Note marked dilation of inferior caval vein (star). Post Conduit expanded with a 39 mm Optimus XXL stent to 20 mm.

**FIGURE 5** Stent of conduit and left pulmonary artery. Pre 20 mm Gore-Tex<sup>®</sup> conduit measured 16 mm pre stent expansion. Stenosis of the left pulmonary artery (arrow) and a previously placed 5 mm Amplatzer<sup>®</sup> atrial septal defect device (asterisk) in fenestration can be seen. Post Conduit expanded to 20 mm using a 45 mm covered cheatham platinum stent. Stent relief of left pulmonary artery during the same procedure.



discharged the day after the catheterization. When reassessed clinically 1–3 months later, 55% ( $n = 24/44$ ) patients reported a subjective improvement in exercise tolerance, which partly could be attributed the additional procedures performed in 19 patients. After an average follow-up of  $4.2 \pm 2.5$  years, no complications were observed and no additional procedures were required.

## 4 | DISCUSSION

An increasing body of evidence shows that over time, a Fontan conduit may become restrictive due to (eccentric) compression, shrinkage, elongation, kinking, protrusion of fenestration closure devices, and peel or thrombus formation and somatic growth.<sup>8,18</sup> The pathology is diverse, and anatomy varies with no clear guidelines for treatment especially in mild to moderate cases. The study's main finding showed that the dimensions of these conduits could be significantly enlarged by stent placement. A decrease in diameter of these predominantly Gore-Tex<sup>®</sup> conduits was observed to occur uniformly over the whole length of the conduit over time. However, using stent placement, the diameter could be increased back to nominal and even beyond with negligible complications. This finding demonstrated the feasibility and safety of percutaneous stent treatment for patients with small, presumably restrictive conduits.

Conduit dimensions could be enlarged up to 165% of the original conduit years after the Fontan operation. Successful enlargement of conduits by percutaneous stent implantation has been demonstrated in several studies up to 13 years after initial placement.<sup>11–13,19–22</sup> This series comprises of an extensive collection of contracted Gore-Tex<sup>®</sup> ECCs ( $n = 44$ ) in current literature. In contrast to the studies conducted by Hagler and ten Cate, which included small numbers of Gore-Tex<sup>®</sup> conduits ( $n = 6$ ) and where mainly localized stenosis and obstructions were treated, we expanded the whole length of the conduit.<sup>11,13</sup>

The aim was to return the dimensions of the conduit at least to nominal diameter and where possible up to 18–20 mm in all our patients. Stents could easily be delivered in position since patients were mainly older and access was generally adequate. The ECC could easily be opened to nominal value when delivering the stent at low pressure (less than 4 atmospheres). Furthermore, we could stretch the conduit with high-pressure balloons beyond nominal with virtually no complications. In a previous study and our bench test, we demonstrated that Gore-Tex<sup>®</sup> could be safely expanded beyond nominal.<sup>23</sup> This allows the ability to adjust conduit dimensions for somatic growth or clinical needs.

Only one adverse event occurred because of an inadvertent dilation of the superior caval vein. Specifically, no conduits ruptured despite expanding conduits to or beyond nominal. This is in agreement with other reports where minimal complications were observed during stenting and dilation of ECC's.<sup>11,13,19</sup> As an additional benefit, where required, a fenestration may be closed simultaneously as we have done in five patients. A potential drawback of stenting is that access for electrophysiological studies

may be hampered. Clinicians caring for Fontan patients might argue that stent expansion of a conduit without a significant gradient might not be useful. Fontan physiology is complex and still not completely understood. The absence of a gradient across a conduit during general anesthesia does not guarantee unrestricted flow during exercise, when the flow in the ICV may increase by 300% or more during moderate exercise.<sup>24</sup> An MRI study of 57 asymptomatic patients with ECC's with a median cross-sectional area reduction of only 9% compared to the ICV showed an ICV-conduit velocity mismatch factor of more than one during expiration in 90% of patients.<sup>25</sup> It was further demonstrated that the highest ICV-conduit velocity mismatch was present in patients with smaller conduits and that it increased during exercise. The authors speculated that 16–20 mm conduits might be inadequate in late adolescence in a Fontan patient, indicating the importance of at least maintaining conduit dimensions or adjusting them for growth. Should a conduit-ICV mismatch be allowed to persist, the critical Fontan detriments will be aggravated: more venous congestion and less output both at rest and during exercise.<sup>26</sup> The Fontan state predisposes the ventricle to become less compliant, which is detrimental for the Fontan circuit as it impedes good runoff from the lungs. Prevention and avoidance of decreasing ventricular compliance, which is hard to reverse, is extremely important.<sup>27,28</sup> By optimizing the conduit size, a Fontan patient can, with exercise, maximally recruit his pulmonary vasculature and “stretch” his ventricle by providing an adequate preload, which may slow down the long-term decline of the circuit as a whole. However, it may take years, if not decades, to prove all these aspects. In the meantime, the patient and the clinician must devise the best possible strategy. Stent expansion of apparently restrictive conduits combined with frequent exercise appears to be the most promising option.

It is evident that some ECC's may become smaller over time (years). In our series, the diameter of the conduits at stent placement was up to 30% smaller compared to nominal at the time of implantation. This was observed in all diameters (14–22 mm) of the conduits, similar to findings of other studies.<sup>12</sup> Lateral external compression and longitudinal stretching of the Gore-Tex<sup>®</sup> conduit during somatic growth are likely causes as the conduits were constricted in a diffuse tubular manner over the whole length. Other authors have also postulated this mechanism.<sup>11,13,19</sup> As a result of somatic growth, this is expected to worsen during adolescence and may result in gradually increasing resistance to flow in the conduit over time.<sup>29</sup> As expected, the majority of patients had no symptoms at rest. Still, in a series of Ten Cate et al. as many as 76% of patients with severe obstructions requiring stent treatment had no symptoms, and only minor gradients of 1–2 mmHg in their conduits.<sup>11</sup> In a Fontan circulation, even these “minor” resistances may have marked clinical effects, and symptoms of obstruction such as hepatic cirrhosis, ascites, edema, and protein-losing enteropathy may ensue.<sup>11,13,30</sup>

In all our patients the ICV appeared large to grossly dilated compared to surrounding structures and à priori compared to the conduit. A previous study demonstrated that the critical conduit to ICV ratio should be less than 1.5.<sup>17</sup> This supports our observations

that ICV-conduit mismatch may potentially be used as one marker for intervention in asymptomatic or mildly symptomatic patients.

To identify patients with mild ECC impairment, it seems prudent to follow the American Heart Association recommendation to perform cardiac catheterization once a child reaches adolescence.<sup>31</sup>

## 5 | LIMITATIONS

Consideration is warranted for the potential limitations of this study due to its retrospective nature and the fact that it was a relatively small study population. Serial evaluation of functional parameters such as flows, VO<sub>2</sub> measurements at baseline and maximal exercise levels, or exercise-induced changes of stroke volume would have added benefit but was not available in most patients. Clinical effects on Fontan complications not evaluated as this is only an early study. These should be considered in future studies.

## 6 | CONCLUSION

The diameter of the extracardiac conduit decreases over time in some patients with a Fontan circulation. The dimensions of ECC's can be safely and significantly increased to nominal or even beyond using stenting. It allows adjustment of ECC dimensions to compensate for adult somatic growth.

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### CONFLICT OF INTEREST

The authors declare no conflict of interest.

### DATA AVAILABILITY STATEMENT

Data are available from the corresponding author

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