Behaviour of polyester grafts in adult patients with repaired coarctation of the aorta

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Aims
Whatever the technique used for surgical or endovascular repair of a coarctation of the aorta (CA), long-term complications might occur. Aneurysm formation after patch angioplasty is not uncommon and may lead to a life-threatening condition. Therefore, we were interested in the long-term results of different types of tube grafts, from which a lower degree of dilatation is expected.

Methods and results
All patients, currently older than 16 years, who underwent (redo) surgery for CA, and in whom a tube graft was inserted, were selected from the database of congenital heart disease of our hospital. Follow-up data were collected by reviewing the patients’ files. The degree of graft dilatation was calculated for each patient. Fifty-three patients (41 males, median age 33.1 years, Q1–Q3 29.9–40.2 years) could be included in the study, in which 20 (38%) ‘Gelseal’, 12 (23%) ‘Gelsoft’, 8 (15%) ‘Gelweave’, and 13 (24%) older types of grafts were used. Twenty patients underwent a primary repair and in all others a tube graft was implanted after a previous patch angioplasty. The median graft diameter (manufacturer size) at implantation was 20 mm (Q1–Q3 16–22 mm). The median follow-up time of the grafts was 13.1 years (Q1–Q3 9.0–17.2 years). The graft size increased to a median value of 26 mm (Q1–Q3 22–30 mm) (median 50% increase in diameter, range 0–271%, P < 0.0001). The diameter of six grafts remained unchanged during follow-up. Three deaths occurred, of whom two were cardiac-related. False aneurysms occurred in four patients, graft aneurysm in two, endarteritis in two, and graft stenosis in one.

Conclusion
Nearly, all tube grafts dilated up to 50% of the manufacturer diameter during follow-up. Re-interventions were inevitable in more than 10 per cent of the cases, primarily because of (false) aneurysm formation. Our series illustrates that late complications are not uncommon, so that rigorous follow-up of these CA patients remains mandatory.

Keywords
Coarctation aorta • Dacron • Aneurysm • False aneurysm • Interposition graft • Congenital heart disease

Introduction
Surgery remains the golden standard of the repair of a coarctation of the aorta (CA). But, whatever the technique used and despite excellent early results, long-term complications are not uncommon.1–4 Late aneurysms have been described after each type of surgical repair with increasing incidence throughout the lifespan of these patients. The prevalence seems to vary between 11 and 30%.5–13 Patch repair techniques, such as with ‘Dacron’, are reported to be more prone to develop aneurysms.5,9–11,13,14 The latter is present typically at the opposite site from or nearby the patch.

Therefore, several centres decided to use prosthetic tube grafts in CA repair. However, all ‘Dacron’ grafts have a tendency to expand after insertion in the ascending or descending aorta.15–18 ‘Dacron’ is a polyester fibre and obtained as a condensation polymer from ethylene glycol and terephthalic acid. It was designed for its high tensile strength, high resistance to stretching and good resistance to degradation by chemicals and to abrasion. Contemporary vascular
grafs are made of knitted and woven ‘Dacron’ fibres. Woven-type grafts such as ‘Gelweave’ (Vaskutek Ltd, Inchinnan, Renfrewshire, Scotland) and ‘Hemashield’ (Boston Scientific Corp, Natick, MA, USA) are expected to dilate less than knitted types such as ‘Gelseal’ and ‘Gelsoft’ (Vaskutek Ltd, Inchinnan) grafts.19–21

Because we used several types of interposition grafts in patients with CA repair, we were interested to describe the graft behaviour at late follow-up.

Methods

Patients’ selection and database characteristics

All patients older than 16 years, who underwent repair with a polyester interposition graft for CA, were selected from the database of congenital and paediatric cardiology University Hospital Gasthuisberg, Leuven, Belgium. The database was started in 1988 by congenital cardiac surgery and extended in 1991 by the Department of Pediatric Cardiology. All patients with a congenital heart defect, who are evaluated and/or treated by a paediatric and/or congenital cardiologist of our hospital, are included in the database. It runs on Filemaker Pro 4.1 software (FileMaker Inc., Santa Clara, CA, US) and is updated each time a patient had a contact with paediatric or congenital cardiologist of our hospital, are included in the database. The first patch angioplasty in our study cohort was performed on 8 May 2008, with the keywords ‘Gelseal’, ‘Gelsoft’ ‘Gelweave’ and ‘interposition graft’. In the selection, no exclusion criteria were present.

The Ethics Committee approved the selection procedure and the review process of the patients’ records. The search for this study was performed on 8 May 2008, with the keywords ‘Gelseal’, ‘Gelsoft’ ‘Gelweave’ and ‘interposition graft’. In the selection, no exclusion criteria were present. The Ethics Committee approved the selection procedure and the review process of the patients’ records.

Follow-up strategy and review process of patients’ records

Demographic, clinical and graft characteristics were obtained by reviewing the records from all patients who were included in the study. For most of them, a yearly checkup was scheduled. In the case of non-compliance, the patients were re-invited within 3 months for a routine visit.

This visit included a clinical examination, an electrocardiogram and imaging [transthoracic echocardiography, magnetic resonance imaging (MRI)], or both). Depending on the echogenicity of the patient and/or the complexity of the repair, at least every 3 years, and in most patients every year, an MRI was performed.

Despite the retrospective design of the study, MRI data from all patients were available close to the latest follow-up date. Therefore, MRI images of the aorta were used to evaluate tube graft behaviour. The MRI size of the ascending aorta, transverse arch and descending aorta, immediately before graft implantation (only for the group that underwent first a patch angioplasty) was reviewed. The manufacturer size of the tube graft was used as the reference point to determine graft behaviour and graft diameters within 1 year after implantation and at latest follow-up were noticed for analysis.

Statistical analysis

All continuous variables were tested for normality. If present, mean ± standard deviation was used. If the distribution of the variables was not normal, median and first and third quartiles (Q1–Q3) were reported. Proportions were described with numbers (n) and percentages (%). To detect changes in continuous variables with normal distribution, a paired t-test was performed. For changes in variables with no normal distribution, a Wilcoxon signed-rank test was performed. Pearson or Spearman correlation coefficients were calculated to determine which variables could correlate with the degree of graft dilatation. The degree of graft dilatation was calculated by the following ratio: the diameter of the graft at latest follow-up minus the manufacturer graft diameter/the manufacturer graft diameter. All tests were two-sided, and \( P < 0.05 \) was considered to be statistically significant. In the case of multiple testing, a Bonferroni adjustment was applied. The statistical analysis was performed with SPSS for Windows (version 15.0).

Results

Patients’ characteristics

Fifty-three patients, repaired for CA with a tube graft, could be selected from the database of congenital and paediatric cardiology (41 males, median age 33.1 years, Q1–Q3 29.9–40.2 years). The corresponding mean body weight and height at latest follow-up were 78 ± 14 kg and 175 ± 9 cm, respectively. At tube graft implantation, the median age of the patients’ cohort was 19.8 years (Q1–Q3 16.3–26.1 years). The changes in clinical characteristics are summarized in Table 1. At the end of the study period, 17 patients (32%) were treated for increased blood pressure (2 with diuretics, 15 with beta-blockers, and 9 with angiotensin-converting enzyme-inhibitors or angiotensin receptor blockers). In 19 patients (36%), a concomitant bicuspid aortic valve was present, of whom only 8 patients suffered from a moderate valve dysfunction (aortic valve stenosis). In 11 patients (21%), left ventricular hypertrophy was noticed on the latest transthoracic echocardiography.

Aorta and tube graft characteristics

Twenty patients underwent a primary repair for CA. In the remaining 33 patients, angioplasty with a ‘Dacron’ patch preceded the tube graft implantation. In these patients, the tube grafts were inserted because of aneurysmal dilatation at the previous repair site. The first patch angioplasty in our study cohort was performed in 1958, the last one in 1988. In 1970, the first tube graft was implanted, in 2002 the last one. ‘Gelseal’ and ‘Gelsoft’ (knitted-type) grafts were used in 20 (38%) and 12 (23%) patients, respectively. In 8 (15%) patients, a ‘Gelweave’ graft (woven-type) was used, whereas in 13 (14%) patients, older types such as double-velour grafts were implanted.

At implantation, the ascending aorta and the transversal arch measured on MRI were 32 ± 5 and 18 ± 6 mm, respectively. The diameter of the repair site of the patients who underwent first patch angioplasty was 46 ± 10 mm. The implanted grafts had a median manufacturer diameter of 20 mm (Q1–Q3 16–22 mm), were followed for a median period of 13.1 years (Q1–Q3 9.0–17.2 years), and increased to a median graft diameter of 26 mm (Q1–Q3 22–32 mm) \( P < 0.0001 \) diameter vs.
manufacturer diameter) at 1-year follow-up and to 26 mm (Q1–Q3 22–30 mm) \( (P < 0.0001 \text{ diameter vs. manufacturer diameter}) \) at latest follow-up. The latter corresponded with a median increase of 50% of the tube graft manufacturer diameter, range 0–271% (Table 1). Six grafts remained unchanged during the entire follow-up period. In summary, the changes in the graft size diameter are plotted in Figure 1A for woven and Figure 1B for knitted grafts.

**Occurrence of pseudo-aneurysms**

In one ‘Gelseal’ patient, two small pseudo-aneurysms occurred, one at the proximal and one at the distal suture line of the graft, 7 years after graft implantation. Although the dimension of this pseudo-aneurysm remained stable (<5 mm), the patient developed a rapid progression with a false aneurysm diameter up to 30 mm 7 years after its occurrence. The patient was scheduled for semi-urgent elective surgery, but developed an acute rupture of the false aneurysm, for which urgent implantation of three endoprostheses was needed. In a second patient, also treated with a ‘Gelseal’ interposition, a pseudo-aneurysm occurred 9 years after graft implantation. In this patient, the pseudo-aneurysm remained small, but 4 years after its occurrence, it caused an asymptomatic dissection of the descending aorta. This patient was scheduled for elective endoprosthesis implantation. In another patient, two small pseudo-aneurysms (<5 mm) occurred 4 years after ‘Gelseal’ graft interposition. In this patient, the size of one of the pseudo-aneurysms increased minimally (<10 mm) during follow-up. All three patients underwent previously a ‘Dacron’ patch angioplasty. False aneurysms did not occur in patients who underwent primary repair with a Gelseal, Gelseft or Gelweave graft; one patient presented with a very large pseudo-aneurysm 31 years after interposition with a woven Dacron graft and was treated with covered stents. The risk for developing a pseudo-aneurysm after coarctation repair with a tube graft could be calculated as high as 10% after 10 years of follow-up (Figure 2).

**Survival and re-intervention**

There were three deaths during follow-up: two were cardiac-related (endarteritis and sudden death). A third patient died because of malignancy.

**Table 1** Patients’ and tube grafts’ characteristics at graft implantation and at latest follow-up

<table>
<thead>
<tr>
<th></th>
<th>At tube graft implantation</th>
<th>At latest follow-up</th>
<th>( P )-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number ((n))</td>
<td>53</td>
<td>53</td>
<td></td>
</tr>
<tr>
<td>Age (years, median, Q1–Q3)</td>
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<td>33.1, 29.9–40.2</td>
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<tr>
<td>Height (cm, mean ± SD)</td>
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<td>175 ± 9</td>
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</tr>
<tr>
<td>Weight (kg, mean ± SD)</td>
<td>66 ± 13</td>
<td>78 ± 14</td>
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</tr>
<tr>
<td>BMI (kg/m(^2), mean ± SD)</td>
<td>22 ± 3</td>
<td>26 ± 4</td>
<td></td>
</tr>
<tr>
<td>Clinical BP gradient (mmHg, median, Q1–Q3)</td>
<td>8, 0–40</td>
<td>0, 0–20</td>
<td>0.18*</td>
</tr>
<tr>
<td>Tube graft diameter (mm, median, Q1–Q3)</td>
<td>20, 16–22**</td>
<td>26, 22–30</td>
<td>&lt;0.0001*</td>
</tr>
</tbody>
</table>

SD, standard deviation; BP, blood pressure.

* Wilcoxon signed-rank test.

**Figure 1** Diameter of woven (A) and knitted (B) tube grafts at implantation (manufacturer), at 1-year follow-up, and at latest follow-up. Each line represents the changes in the tube graft diameter of an individual patient. Dots represent the median tube graft diameter, and the vertical lines represent the interquartile range. \( P \)-values refer to Wilcoxon signed-rank test.

Eight patients needed a re-intervention after graft interposition: three were treated for pseudo-aneurysms, two for endarteritis, and one for severe tube graft stenosis. The latter was related with a non-invasive systolic brachial-ankle blood pressure gradient of >40 mmHg. In all other cases, this clinical gradient was not more than 12 mmHg. Two patients with double velour interposition were referred for elective endoprosthesis implantation.
because of the development of large graft aneurysms (>5 cm) after 24 and 25 years, respectively. No large aneurysms could be detected at present in the groups in which Gelseal, Gelsoft or Gelweave graft was used.

**Potential determinants for graft size progression**

When divided into subcategories according to the type of the graft used, a significant difference in graft size progression could be documented between Gelsoft (knitted) and Gelweave grafts (woven) and between Gelseal (knitted) and Gelweave grafts (woven) (48 ± 24 vs. 5.5 ± 5 and 50 ± 26 vs. 5.5 ± 5%, respectively, P < 0.0001 for both groups). Changes in tube graft diameters are presented in Figure 1A for woven and Figure 1B for knitted grafts. Graft size progression was not related to the size of the aortic arch at tube graft insertion (Pearson’s correlation coefficient 0.2, P = 0.29). No significant relationship could be found between the presence of a bicuspid aortic valve and the degree of graft dilatation (Spearman correlation coefficient −0.2, P = 0.21). There was also no difference in graft progression between patients who were first treated with a ‘Dacron’ angioplasty and those who underwent primary repair with a graft interposition (graft progression 45 ± 28 vs. 48 ± 79%, P = 0.90). Also, the use of antihypertensive agents did not influence the progression of the graft size.

**Discussion**

We found that in patients with CA repair, nearly all interposition grafts dilated up to 50% of their original size for a follow-up period of more than 10 years. The development of true aneurysms necessitated re-intervention in two patients. In addition, pseudo-aneurysms occurred in four patients, for whom also a re-intervention was required. Therefore, late complications are not uncommon (11%), so that rigorous follow-up remains mandatory.

Whatever the technique used for surgical repair of CA, long-term complications might occur. The incidence of aneurysm formation is increasing with time and reaches 17% after subclavian flap angioplasty, 6% after tube graft repair, and 3% after end-to-end anastomosis. However, the highest incidence of aneurysm formation is reported in patients with a ‘Dacron’ patch angioplasty (up to 38%). In these patients, the risk for a rupture-related death reaches 7%.

The underlying pathophysiological mechanisms are still under debate. Aneurysm formation of the native wall may be preconditioned by congenital related (aortic wall weakness or cystic media necrosis) or acquired atherosclerotic changes. It has also been attributed to altered haemodynamics due to systemic hypertension and increased blood flow turbulence. In particular, a compliance mismatch between the patch used for angioplasty and the native wall could release local forces on the native wall, which leads to the typical aneurysms at the opposite site of the patch. It has also been suggested that a concomitant hypoplastic transverse arch or older age at initial repair would predispose to a similar aneurysm formation at the repair site.

The first important finding in this study was that the tube grafts dilated up to 50% (range 0–271) of the original size, as given by the manufacturer, and this for a follow-up period of nearly 14 years.
Most of the enlargement seemed to occur within the first post-operative year,\textsuperscript{21,27,28} and the degree of dilatation was more pronounced in knitted (Gelseal and Gelsoft) than in woven (Gelweave) type. The mechanisms underlying this phenomenon are less clear and remain still hypothetic. Several reports state that the dilatation of the polyester graft is caused by progressive stretching of the fibre loops by pressurization of the graft.\textsuperscript{16,17,29} This might be confirmed by the observation that the most pronounced enlargement occurred within the first post-operative year. However, several imaging studies have even documented that dilatation already starts per-operatively, immediately after declamping the aorta.\textsuperscript{21,27,28} We had no data on immediate perioperative changes of the graft size, but in accordance to the findings of others, we also found that the most prominent change in graft diameters occurred within the first year after implantation.

Although it had been suggested that the presence of an hypoplastic arch could determine graft size progression, we could not document a significant correlation between the size of the aortic arch and the degree of graft dilatation. Indeed, graft enlargement was similar in patients with former ‘Dacron’ patch angioplasty and an hypoplastic arch and in those with primary CA repair and normal sized arches. Tube graft dilatation is probably inherent to the type of the prosthetic material used, in particular knitted grafts, and seems not to be influenced by the anatomic features of the aortic arch, as commented by Schepens\textsuperscript{30} on our previous work.

Except for the type of the prosthetic grafts used, we could not identify other predictors of graft size progression. Although a clear correlation between the presence of a bicuspid aortic valve and a higher incidence of aneurysm formation of the native aortic wall is well described in the literatures,\textsuperscript{31–35} no relationship could be documented in our patients’ cohort. This finding seems to confirm that graft dilatation is related to the type of the prosthetic material used. In other series, a history of systemic hypertension was associated with higher growth rates.\textsuperscript{15,18} We could not find a correlation between hypertension and the progression of the graft size; however, high blood pressure was rigorously controlled in our series, which might have neutralized this variable as a predictor of graft size increase.

The second important finding was that four of our patients (8%) developed false aneurysms at the suture lines. These false aneurysms did not remain uncomplicated. In one patient, rupture occurred and another patient developed a focal dissection. This warrants for strict long-term follow-up on a regular basis with accurate imaging techniques, preferentially magnetic resonance with three-dimensional reconstruction of the thoracic aorta. These false aneurysms emerged rather late and raise questions about their aetiology: the lesions could be related to a surgical suture problem or continuous traction on the suture lines might induce false aneurysms. Why the false aneurysms did not occur in patients with primary CA repair is unclear, but it might be related to technical and surgical issues. Preventive insertion of a vascular endoprosthesis could be an option in those patients who develop false aneurysms late after graft interposition.

Within 20 years of follow-up, no aneurysms occurred in our patients with tube graft implantation. However, two of our patients required elective repair because of severe aneurysmatic dilatation after a double velours interposition, which was performed more than 20 years ago. Late graft failure and rupture have been described.\textsuperscript{36–39} The mechanism has been attributed to the breaking of the ‘Dacron’ fibres or yarn. Berger and Sauvage\textsuperscript{40} identified two types of broken fibres. First, due to chronic stretching, fibres may deteriorate slowly and break in a way with tapered and frayed ends. Secondly, some damaged fibres were noted to have square ends, suggesting a sudden increase in stretch causing the fibres to snap. Under chronic hydrostatic forces, ‘Dacron’ fibres can slowly stretch or creep until breaking. Remarkably, in several reports, no correlation could be found between the degree of graft dilatation and graft failure.\textsuperscript{16,17} However, we experienced that graft failure might become more frequent when the follow-up period of interposition grafts will exceed 20 years.

However, it remains difficult to estimate the clinical impact of graft failure in a patient. Aneurysms and false aneurysms of the thoracic aorta have a rather insidious course, but might lead to life-threatening situations such as rupture or fistulization to surrounding structures.

Finally, only one patient suffered from tube graft stenosis. We hypothesized that this rather low incidence of restenosis is probably due to the older age at tube graft implantation, where relatively larger tube graft diameters were selected.

Finally, our study has some limitations. First, the study is single-centred, and this may lead to an important selection bias. Secondly, numbers are limited, which implicates that the study might be under-powered for some statistical analysis. Thirdly, the data were collected from an accurate follow-up database, but the study design remains retrospective with its inconvenient disadvantages.

In conclusion, significant, but clinically acceptable, tube graft dilatation is found in CA patients after redo surgery, as well as in patients after primary CA repair. Gelweave grafts (woven-type) dilate significantly less than Gelseal or Gelsoft grafts (knitted types). Late post-operative complications as false aneurysms are observed and necessitate a persistent strict follow-up of these patients.

Conflict of interest: none declared.

References


