Long-term size follow-up of knitted Dacron grafts (Gelseal™) used in the ascending aorta

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Abstract

There is limited information about the size change of a knitted Dacron graft (Gelseal™) used in the thoracic aorta. We evaluated the diameters of the Gelseal™ grafts at a long-term follow-up for 3.7 ± 1.3 years (1–5.9 years; median, 4.0 years), which were used for replacement of the ascending aorta in 59 patients with acute aortic dissection. The early and late dilatation rates (LDRs) of the prosthetic grafts were calculated retrospectively based on the graft diameter at the level equivalent to the ascending aorta on the pre-discharge computed tomography (CT) scans and follow-up CT scans performed every year after surgery. Immediately after surgery (15 ± 7 days), the early dilatation of the Gelseal™ grafts was 26.0 ± 6.0% with significant correlations with the number of post-operative days (R = 0.500, P = 0.003). At the follow-up for 3.7 ± 1.3 years, the LDR was 10.5 ± 6.6%, which was also significantly correlated with the number of the post-operative years (R = 0.608, P = 0.001). Linear regression analysis indicated that the annual dilatation rate was ~3.23%. During the follow-up, we have experienced no redo surgery due to graft fracture or false aneurysm formation at the anastomosis sites associated with the graft dilatation. In conclusion, the Gelseal™ graft used in the ascending aorta demonstrates a small but continuous increase in the diameter, up to 5 years after implantation, without any adverse events.

Keywords: Knitted Dacron graft • Gelseal • Ascending aorta • Diameter

INTRODUCTION

Since DeBakey first introduced in 1957 [1], Dacron, a highly durable polyester, thermoplastic polyethylene terephthalate, has been extensively processed into synthetic prostheses for the arterial reconstruction of the thoracic and abdominal aorta. Historically, weaving and knitting have been the two common techniques for fabrication of Dacron fibres into a tubular conduit. The knit structure involves looping fibres in an interlocking chain, which yields a soft and stretchable fabric. In contrast, a woven structure assembles the yarn in an over-and-under pattern in the lengthwise and circumferential directions [2]. Woven grafts are stronger and less porous than knitted grafts but are less compliant and may fray when cut. Since highly porous knitted Dacron grafts typically required ‘preclotting’, most commercial knitted grafts are currently impregnated with gelatin [3], collagen [4] or albumin [5].

As for the reconstruction of the thoracic aorta, woven Dacron grafts are generally recommended due to expected longer durability associated with higher porosity than the knitted ones. However, we have preferably used a gelatin-sealed knitted Dacron graft (Vascutek™ Gelseal™, Terumo Cardiovascular Systems Co., Ann Arbor, MI, USA) for the thoracic aorta, based on its improved handling characteristics and its expected potential to promote tissue integration. Several investigators [6–10] have observed dilatation over time of the knitted Dacron prostheses used as the replacement material in the abdominal aorta. However, few reports are available on its long-term behaviour when used for the thoracic aorta [11, 12]. The purpose of the present study was to evaluate the degree of dilatation of the Gelseal™ grafts, at a long-term follow-up, for the replacement of the ascending aorta in patients with acute aortic dissection to uniform the haemodynamic effects.

MATERIALS AND METHODS

Patients

Between January 2003 and January 2009, 68 consecutive patients with Stanford type A acute aortic dissection underwent aortic reconstruction using Gelseal™ grafts on an emergency basis. Among them, we included 59 patients (39 men and 20 women; mean age at surgery, 63 ± 13 years) who survived the emergency surgery and followed with the computed tomography (CT) scans. Table 1 summarizes the demographic and clinical characteristics of the patients. The diagnosis of type A acute aortic dissection was confirmed with enhanced CT scans, indicating the involvement into the ascending aorta.

Patients routinely underwent surgery under cardiopulmonary bypass (CPB). After systemic cooling, CPB was discontinued at the rectal or bladder temperature of 25°C, and the aorta was...
opened to identify the location of the intimal tear during the deep hypothermic circulatory arrest. Our surgical strategy for type A acute aortic dissection has been to eliminate the primary entry. Using selective antegrade cerebral perfusion, open distal anastomosis was performed. Finally, when this procedure was completed, cerebral perfusion was stopped and antegrade systemic perfusion was re-instituted though the prosthesis. The proximal anastomosis was performed during re-warming.

**Computed tomography follow-up**

Immediate post-operative CT scans were performed just before discharge, and follow-up CT scans were performed at our outpatient clinic once a year. The CT examinations were performed with contrast material enhancement except for when the patients had renal insufficiency or an allergy to the contrast medium. On every CT scan, the diameter of the Gelseal™ graft was measured at the level equivalent to the ascending aorta. The early dilatation rate (EDR) of the prosthetic graft was calculated as follows: difference in diameter between the package size (D1) and the measurement at hospital discharge (D1) on the CT scan divided by the package size: that is EDR (%) = 100 (D1 − P)/P. Similarly, the late dilatation rate (LDR) was also indicated for the difference between D1 and the finally measured diameter at follow-up (D2): that is LDR (%) = 100 (D2 − D1)/D1.

**Statistical analysis**

This retrospective study was approved by the Institutional Review Board of our hospital, and the Board waived individual patient consent for the study patients. All values are expressed as the mean ± standard deviation. Spearman’s correlation coefficient (two-tailed) and simple regression analysis were used to evaluate whether the dilatation rate of the Gelseal™ graft was correlated with the time interval between the surgery and the diameter measurement on CT scans. All statistical analyses were performed with StatView 5.0 (Abacus Concepts Inc., Berkeley, CA, USA). A P-value of <0.05 was considered significant.

**RESULTS**

We performed graft replacements of the ascending aorta in 39 patients (66%), the hemi-arch in 6 (10%) and total arch in 12 (20%), as shown in Table 1. The modified Bentall procedures (the aortic root replacement with a composite graft and re-implantation of both coronary arteries) were performed on two patients (3%). Fifteen patients (25%) underwent concomitant procedures, including commissural re-suspension of the aortic valve (n = 10), coronary artery bypass grafting (n = 4) and replacement of the abdominal aorta (n = 1). The sizes of the Gelseal™ grafts used for the replacement of the ascending aorta were 22 mm in 7 patients (12%), 24 mm in 36 patients (61%), 26 mm in 10 patients (17%) and 28 mm in 6 patients (10%), as also shown in Table 1.

On the CT scans just before discharge (mean, 15 ± 7 days), the EDR of the Gelseal™ grafts was 26.0 ± 6.0%. The dilatation rate at discharge was significantly correlated with the number of post-operative days (R = 0.500, P = 0.003), as demonstrated in Fig. 1. At follow-up for 3.7 ± 1.3 years (1–5.9 years; median, 4.0 years), the LDR was 10.5 ± 6.6%. The dilatation rate at follow-up was significantly correlated with the number of the post-operative years (R = 0.608, P = 0.001), as demonstrated in Fig. 2. Linear regression analysis indicated that the annual dilatation rate was approximately 3.23%. During the follow-up, we have experienced no redo surgery due to graft fracture or false aneurysm formation at the anastomosis sites associated with the graft dilatation.

**DISCUSSION**

The present study provides three major findings. First, the diameter of the Gelseal™ graft used in the ascending aorta increases by ∼26%, compared with the package size, immediately after implantation. This EDR coincided with the previous data reported in the abdominal aorta [6–10]. Second, the Gelseal™ graft further dilates ∼10.5%, compared with the diameter at discharge, up to 5
years after surgery. Third, the Gelseal™ graft dilates gradually at 3.23% per year in diameter after implantation.

To our knowledge, the present study is the first to describe the long-term follow-up of the diameter of the Gelseal™ graft used in the ascending aorta in a larger number of study patients. In addition, we focused on the graft diameter in the limited position, ascending aorta, in the patients with acute aortic dissection. There are two reasons for our exclusion of the patients with degenerative aortic aneurysms. First, we tried to evaluate the size change of the graft in the position of the proximal ascending aorta, where the haemodynamic energy may be the largest in the aorta. Second, the ascending aorta is completely replaced in all patients with acute type A dissection, while it is partially replaced in some patients with aortic aneurysm, especially with arch aneurysm. Third, the anatomical positions of the aorta and its cervical branches are not usually changed in the patients with acute type A dissection, while the extremely dilated and elongated aorta and dilated cervical branches may affect the anatomical position of the graft in some patients with aortic aneurysm.

We think that the exclusive approach helped to uniform the anatomical and haemodynamic effects on the graft dilatation.

In the previous reports [11, 12], we can find that the follow-up duration was short, the study group was small and the position for grafting was not necessarily an ascending aorta. Goossens et al. [11] demonstrated that the size of the Gelseal™ graft used in the thoracic aorta increased by 16.2% in diameter compared with the package size within 4 weeks of surgery in 18 patients and that this initial dilatation attributes to the loss of crimpage. Mattens et al. [12] reported that the diameter of the Gelseal™ graft increased by 31.4% at 2 years after implantation for the descending thoracic aorta in 12 patients. This dilatation rate at 2 years coincides with our results, as demonstrated in Fig. 2. Our results suggest further increase in the graft diameter at 3.23% per year, up to 5 years, after the initial dilatation due to the loss of crimpage. This small but continuous increase in the diameter may attribute to yarn slippage or yarn deterioration, as suggested previously [12, 13]. However, we have experienced no redo surgery due to graft fracture or false aneurysm formation at the anastomosis sites in the study patients. Therefore, we do not think that the continuous dilatation even 5 years after implantation support the contraindication of the use of the Gelseal™ graft for the thoracic aorta. Out results potentially provide useful information when we follow the patients with the Gelseal™ graft in the thoracic position, using the CT scans.

One imitation of the present study is that there are no evidences that dependence of the graft dilatation upon the elapsed year is linear. We should examine the diameter measurements at several points for each patient. Another limitation is that our results can mislead into the conclusion that the graft dilatation is unlimited, although the dilatation rates were 50% and more in five patients in this study. We need further follow-up investigation to determine when the graft dilatation is diminished and negligible because the graft dilatation may potentially predispose to transgraft haemorrhage through a Dacron graft, although Gelseal™ is not a standard knitted Dacron graft but has a triaxial structure.

CONCLUSIONS

The present study provides important information on long-term size change of the Gelseal™ graft used in the ascending aorta. The graft diameter increases by ~26%, compared with the package size, immediately after implantation. The Gelseal™ graft further dilates ~10.5%, compared with the diameter at discharge, at 3.23% per year up to 5 years after surgery without any adverse events.

REFERENCES