⋟ *Original Article* ⋞

Prosthetic Graft Dilation at the Aortic Arch in the Era of Hybrid Aortic Surgery

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Objective: This study aims to evaluate the chronological size changes of the prosthetic graft in the aortic arch, which is used as a landing zone for a subsequent stent grafting in hybrid aortic surgery.
Materials and Methods: Eighty-five patients who underwent total aortic arch replacement followed by computed tomography follow-up for at least 30 months after the surgery were included in the study.
Results: Prosthetic grafts used were Hemashield (Maquet, Rastatt, Germany), J-Graft (Japan Lifeline Inc., Tokyo, Japan) and Triplex (Terumo, Tokyo, Japan). There was an initial increase in diameter compared to package size after implantation (Hemashield, 1.04±0.035 vs. J-Graft, 1.06±0.027 vs. Triplex, 1.04±0.023, p=0.13). Significant difference in graft dilation ratio was observed in Triplex (1.18±0.062) at long-term compared to Hemashield (1.07±0.052, p<0.001) and J-Graft (1.10±0.071, p<0.001). Multivariate analysis showed that age (r=0.002; 95% confidence interval [CI], 0.0001–0.0037; p=0.035), knitted-type prosthesis (r=0.089; 95% CI, 0.0610–0.1163; p<0.0001), and prevalence of cerebral vascular disease (r=0.038; 95% CI, 0.0030–0.0732; p=0.034) were independently associated with graft dilation after surgery.
Conclusion: Prosthetic graft selection and appropriate sizing of the stent graft should be considered for each individual undergoing hybrid aortic surgery to maintain sufficient oversizing of the stent graft.

Introduction

With improvements in endovascular technology, more patients are treated by hybrid technique for extensive aortic arch diseases. The use of a frozen elephant trunk and conventional elephant trunk as a landing zone for subsequent thoracic endovascular aortic repair (TEVAR) is the often-used technique.[1] Hybrid operation types have been classified into three, depending on the need for landing zone reconstruction: type 1, which are those with suitable proximal and distal landing zone; type 2, which are those requiring proximal landing zone reconstruction; and type 3, which are those requiring both proximal and distal landing zone reconstructions.[2]

Although landing zone reconstruction is often performed by prosthetic graft replacement, prosthetic graft dilation after implantation has also been reported. Alimi et al.[3] reported significant increases in prosthetic graft size of up to 12.6% in woven-type graft and 28% in knitted-type prosthetic graft. The expansion rate has also been reported to differ depending on the location of the implanted prosthesis.[4] This phenomenon of graft enlargement may lead to endoleak after subsequent TEVAR treatment for those patients undergoing type 2 or 3 hybrid operation. Residual endoleak after TEVAR should be avoided as it is highly associated with risk for aneurysmal rupture.[5] Choosing the appropriate graft size for an adequate landing zone for subsequent TEVAR should be considered.

This study aims to evaluate the actual degree of graft dilation in the aortic arch and its associated factors in patients undergoing total arch replacement using prosthetic graft available in the era of hybrid aortic surgery.

Methods

From July 2007 to February 2016, 85 patients underwent aortic arch replacement followed by a computed tomography follow-up for at least 30 months after the surgery. For the evaluation of chronological changes in

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prosthetic graft size at the aortic arch, the diameter of the prosthetic graft, distal to the side branches, was evaluated after the surgery at midterm and at long-term on the computed tomography follow-up. The diameter of the graft was calculated from the circumferential length of the prosthetic graft, measured by multi-planar reconstruction view using Ziostation (Ziosoft, Belmont, CA, USA). The degree of size changes was evaluated by calculating a ratio between the diameter of the prosthetic graft at follow-up and the package size (graft dilation ratio). Changes were compared for Hemashield (Maquet, Rastatt, Germany), Triplex (Terumo, Tokyo, Japan), and J-Graft (Japan Lifeline Inc., Tokyo, Japan). The study was approved by the Institutional Review Board of Saitama Medical Center, Jichi Medical University (S19-038).

Surgical methods

After a median sternotomy, aortic cannulation was performed at the ascending aorta, and venous drainage was performed from the superior vena cava and inferior vena cava. If the ascending aorta was unsuitable for cannulation, the right axillary artery or left axillary artery was used. The left ventricular venting was inserted from the right upper pulmonary vein. The patient was cooled down to rectal temperature of 25°C. Under a circulatory arrest,

selective cerebral perfusion was started into all three aortic arch branches. Distal anastomosis was performed at the aortic caliber change via intermittent pledgeted suture followed by a running suture with a 4-0 polypropylene. Rewarming was started after distal anastomosis. Open proximal anastomosis was performed in a similar manner, and the aortic clamp was removed. Aortic arch branch reconstruction was performed under beating heart.

Statistical analysis

Normal distribution of the data was assessed using the Kolmogorov–Smirnov test. For continuous variables that were normally distributed, Student's t-test (mean ± standard deviation) and Pearson's correlation were used. For data that were non-normally distributed, analysis was performed using Mann–Whitney test (median, Q1–Q3) and Spearman's correlation. Chi-squared test (n, %) was used for categorical variables, and paired t-test was used for comparing paired data for each individual. For comparing three groups, one-way analysis of variance (ANOVA) with Bonferroni correction was used. Further, preoperative factors were evaluated for their association with graft dilation ratio. Variables with $p < 0.2$ were included in the multivariate analysis. P values less than 0.05 ($p < 0.05$) were considered statistically significant,

Table 1 Demographics of patients who underwent total arch replacement. Patients are divided into the types of prosthesis used in their operation

	Hemashield n=23	J-graft n=22	Triplex n=40	P value
Type of graft	Woven	Woven	Knitted	
Follow-up months (months)	44.5±8.9	40.1±4.9	44.5±7.0	0.055
Age (years)	65.9±12.8	68.2±7.1	70.9±6.7	0.093
Male (%)	16 (69.6%)	18 (81.8%)	30 (75.0%)	0.63
Hypertension (%)	19 (82.6%)	21 (95.5%)	35 (87.5%)	0.22
Hyperlipidemia (%)	9 (39.1%)	10 (45.5%)	12 (30.0%)	0.41
Diabetes (%)	0 (0.0%)	4 (18.2%)	4 (10.0%)	0.11
Cerebral vascular disease (%)	5 (21.7%)	3 (13.6%)	7 (17.5%)	0.77
Hemodialysis (%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	0.57
Ischemic heart disease (%)	3 (13.0%)	3 (13.6%)	1 (2.5%)	0.18
Peripheral arterial disease (%)	1 (4.3%)	0 (0.0%)	0 (0.0%)	0.25
COPD (%)	0 (0.0%)	1 (4.5%)	3 (7.5%)	0.41
Current smoker (%)	2 (8.7%)	6 (27.3%)	11 (27.5%)	0.19
Angiotensin-converting enzyme inhibitor (%)	0 (0.0%)	1 (4.5%)	2 (5.0%)	0.57
Angiotensin II receptor blocker (%)	2 (8.7%)	3 (13.6%)	7 (17.5%)	0.66
Calcium channel blocker (%)	8 (34.8%)	8 (36.4%)	16 (40.0%)	0.94
Beta blocker (%)	15 (65.2%)	13 (59.1%)	24 (60.0%)	0.78
HMG-CoA inhibitor (%)	9 (39.1%)	10 (45.5%)	20 (50.0%)	0.79
Antiplatelet therapy (%)	9 (39.1%)	9 (40.9%)	11 (27.5%)	0.43
Anticoagulation therapy (%)	8 (34.8%)	9 (40.9%)	14 (35.0%)	0.90
Diuresis (%)	2 (8.7%)	1 (4.5%)	5 (12.5%)	0.59
Postoperative systolic blood pressure (mmHg)	110±11.9	107±10.2	109±9.6	0.66
Postoperative mean arterial pressure (mmHg)	79±8.1	76±7.7	79±8.4	0.42

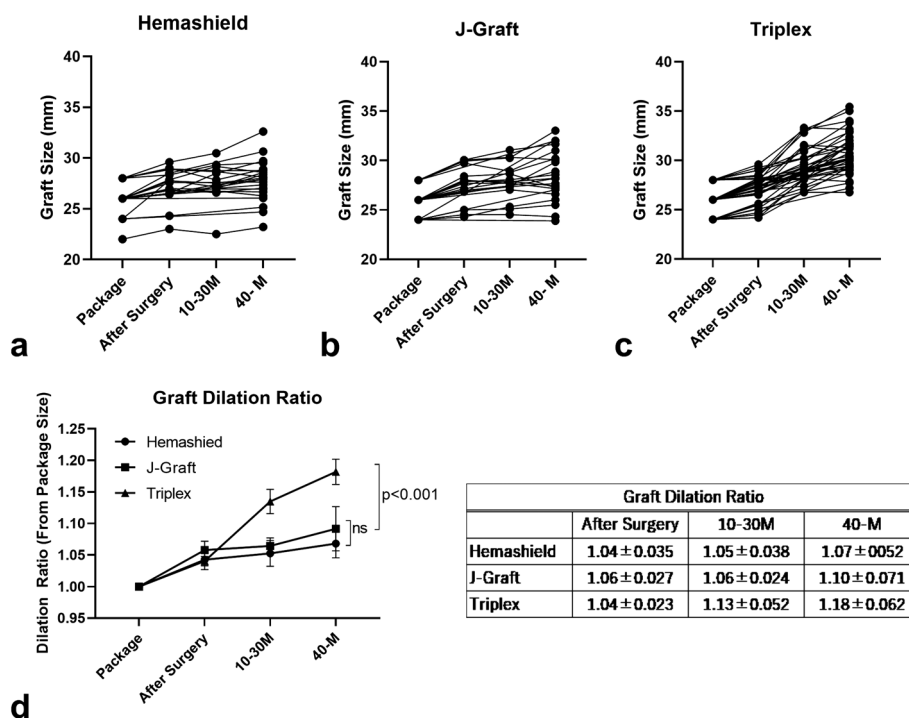COPD: chronic occlusive pulmonary disease

Fig. 1 Prosthetic graft size: package size, after surgery, midterm, and long-term follow-up. Hemashield (**a**); J-Graft (**b**); and Triplex (**c**). Graft dilation ratio was compared among the three groups (**d**).
Mean period of midterm follow-up was 26±5.3 months, and the long-term follow-up was 43±7.3 months.

and the analysis was performed using Stata (version 13.1, Stata Corp., College Station, TX, USA) and Prism (version 8.0.2, GraphPad, La Jolla, CA, USA).

Results

The demographics of patients are shown in **Table 1**. Twenty-three patients were treated by Hemashield (Maquet, Rastatt, Germany), twenty-two by J-Graft (Japan Lifeline Inc., Tokyo, Japan), and forty by Triplex (Terumo, Tokyo, Japan). Postoperative computed tomography was performed 1 week after the surgery. The mean follow-up with computed tomography at midterm was 26 ± 5.6 months (Hemashield), 27 ± 5.3 months (J-Graft), and 25 ± 5.2 months (Triplex) (p=0.52), and the mean follow-up at long-term was 45 ± 8.9 months (Hemashield), 40 ± 4.9 months (J-Graft), and 45 ± 7.0 months (Triplex) (p=0.055). There were no significant differences in patient age (p=0.093), gender (p=0.63), and other comorbidities including hypertension (p=0.22), hyperlipidemia (p=0.41), diabetes (p=0.11), and peripheral arterial disease (p=0.25). Further, there were no significant differences in medication among the three groups (**Table 1**).

There was a significant increase in graft size in all three types of prosthetic grafts after surgery compared to package size (Hemashield [package, 26.0 ± 1.48 mm vs.

after surgery, 27.2 ± 1.55 mm; p<0.001], J-Graft [package, 26.0 ± 1.41 mm vs. after surgery, 27.6 ± 1.81 mm; p<0.001], and Triplex [package, 26.0 ± 1.36 mm vs. after surgery, 27.1 ± 1.40 mm; p<0.001]) (**Figs. 1a–1c**). There was no significant increase in diameter at midterm compared to graft size after implantation in patients receiving Hemashield (after surgery, 27.2 ± 1.55 mm vs. midterm, 27.6 ± 1.75 mm, p=0.15) and J-Graft (after surgery, 27.6 ± 1.81 mm vs. midterm, 27.8 ± 1.83 mm, p=0.29) (**Figs. 1a** and **1b**). However, there was a significant increase in graft diameter in patient receiving Triplex (after surgery, 27.1 ± 1.40 mm vs. midterm, 29.6 ± 1.83 mm, p<0.001) (**Fig. 1c**). At long-term, there was a significant increase in graft size in all types of prosthetic graft compared to size after implantation (Hemashield [after surgery, 27.2 ± 1.55 mm vs. long-term, 27.8 ± 1.99 mm, p=0.004], J-Graft [after surgery, 27.6 ± 1.81 mm vs. long-term, 28.7 ± 2.36 mm, p=0.048], and Triplex [after surgery, 27.1 ± 1.40 mm vs. long-term, 30.7 ± 2.01 mm, p<0.001]) (**Figs. 1a–1c**).

There was no significant difference in graft dilation ratio after surgery between the grafts (Hemashield, 1.04 ± 0.035 vs. J-Graft, 1.06 ± 0.027 vs. Triplex, 1.04 ± 0.023, p=0.13) (**Fig. 1d**). Significant difference in graft dilation ratio between Hemashield and Triplex was observed at midterm (Hemashield, 1.05 ± 0.038

vs. Triplex, 1.13±0.052; p<0.001) and at long-term (Hemashield, 1.07±0.052 vs. Triplex, 1.18±0.062; p<0.001) (**Fig. 1d**). Similarly, significant difference in graft dilation ratio was observed between J-Graft and Triplex at midterm (J-Graft, 1.06±0.024 vs. Triplex, 1.13±0.052; p<0.001) and at long-term (J-Graft, 1.10±0.071 vs. Triplex, 1.18±0.062; p<0.001) (**Fig. 1d**). However, there was no significant difference in graft dilation ratio between Hemashield and J-Graft at midterm (Hemashield, 1.05±0.038 vs. J-Graft, 1.06±0.024; p=1) and at long-term (Hemashield, 1.07±0.052 vs. J-Graft, 1.10±0.071; p=0.28) (**Fig. 1d**).

There was a significant difference in the ratio between the diameter at the distal anastomosis and the graft size (Hemashield, 0.88±0.093 vs. J-Graft, 0.87±0.109 vs. Triplex, 0.95±0.111; p=0.011). However, this was not associated with graft dilation ratio at long-term (Hemashield, r=−0.11; 95% confidence interval [CI], −0.51–0.34; p=0.65; J-Graft, r=−0.03; 95% CI, −0.55–0.51; p=0.92; Triplex, r=0.16; 95% CI, −0.17–0.46; p=0.34). There also was a significant difference in the ratio of the diameter at proximal anastomosis

to the graft size (Hemashield, 1.05±0.099 vs. J-Graft, 1.01±0.144 vs. Triplex, 1.13±0.102; p=0.001). However, the diameter at the proximal anastomosis was larger than the prosthetic graft used (**Supplement A**).

Of the 85 patients enrolled in the study, 38 patients (44.7%) received postoperative pulse wave velocity (PWV) measurements. Although the follow-up rate was limited, there was a trend toward positive correlation between the graft dilation ratio and postoperative PWV (**Supplement B**).

Risk factors for graft dilation at long-term were evaluated. For continuous variables, age (r=0.32; 95% CI, 0.12–0.50; p=0.003) was correlated with graft dilation ratio. However, the initial graft size was not associated with graft dilation ratio (p=0.45) (**Table 2**). For categorical variables, there were no significant correlations between medication and graft dilation ratio. However, knitted-type prosthetic graft compared to woven-type was associated with greater graft dilation ratio at long-term (woven, 1.08±0.064 vs. knitted, 1.18±0.063; p<0.001) (**Table 3**). Multivariate analysis for graft dilation showed that age (r=0.002; 95% CI, 0.0001–0.0037;

Table 2 Univariate analysis of continuous variable in relation to graft dilation ratio

	Correlation ratio	95% confidence interval	P value
Age (years)	0.323	0.118–0.501	0.003
Initial graft size (mm)	−0.0834	−0.291–0.132	0.45
Postoperative systolic blood pressure (mmHg)	−0.029	−0.240–0.186	0.79
Postoperative mean arterial pressure (mmHg)	0.045	−0.170–0.256	0.68

Table 3 Univariate analysis of graft dilation ratio for each categorical variable listed on the table

Preoperative variables	Graft dilation ratio for each variable		P value
	Without	With	
Male gender	1.13±0.090	1.13±0.077	0.69
Knitted-type graft	1.08±0.064	1.18±0.063	<0.001
Hypertension	1.10±0.064	1.13±0.081	0.29
Hyperlipidemia	1.13±0.081	1.14±0.079	0.66
Diabetes	1.13±0.081	1.14±0.076	0.86
Cerebral vascular disease	1.12±0.068	1.16±0.119	0.15
Ischemic heart disease	1.13±0.082	1.13±0.049	0.97
COPD	1.13±0.079	1.17±0.093	0.32
Current smoker	1.13±0.078	1.12±0.088	0.63
Angiotensin-converting enzyme inhibitor	1.13±0.079	1.16±0.111	0.54
Angiotensin II receptor blocker	1.13±0.081	1.13±0.075	0.93
Calcium channel blocker	1.13±0.078	1.13±0.083	0.71
Beta blocker	1.13±0.074	1.13±0.083	0.81
HMG-CoA inhibitor	1.12±0.086	1.14±0.070	0.16
Antiplatelet therapy	1.12±0.070	1.14±0.095	0.41
Anticoagulation therapy	1.13±0.077	1.13±0.084	0.86

"With" represents dilation ratio of the patient with variable listed on the table, while "Without" represents graft dilation of patients without variable listed on the table.
COPD: chronic occlusive pulmonary disease

Table 4 Multivariate analysis for graft dilation ratio

	r	Standard error	95% confidence interval	P value
Age (years)	0.002	0.0008	0.0001–0.0033	0.035
Knitted-type prosthesis	0.089	0.0139	0.0610–0.1163	<0.001
Cerebral vascular disease	0.038	0.0176	0.0030–0.0732	0.034
HMG-CoA inhibitor	0.014	0.0139	−0.0137–0.0418	0.32

p = 0.035), knitted-type prosthesis (r = 0.089; 95% CI, 0.0610–0.1163; p < 0.0001), and cerebral vascular disease (r = 0.038; 95% CI, 0.0030–0.0732; p = 0.034) were independently associated with graft dilation at long-term (**Table 4**). PWV was not entered in the multivariate analysis due to small sample size.

Discussion

There was a significant increase in graft size at the aortic arch in all three types of prosthetic graft used (Hemashield, J-Graft, and Triplex). Multivariate analysis showed that age, prevalence of cerebral vascular disease, and use of knitted-type prosthetic graft were independent risk factors for graft dilation.

Gelseal graft dilation has been reported previously. Takami et al. reported 26% increase in graft size compared with the package size in Gelseal graft used in the ascending aorta. This was further dilated to up to 10.5%, 5 years after the surgery.[6] Mattens et al. reported Gelseal graft dilation in the descending aorta, which was dilated to up to 31.4%, 2 years after the surgery.[7] Similar to these results, Etz et al. reported Dacron graft dilation in the ascending and descending aorta, which showed a slight difference in the dilation rate.[4] In their study, the ascending aorta was more likely to dilate at a median rate of 2.8% per year, while descending aorta dilation was limited to 1.1% per year.[4] Our study has also shown that there was an initial increase in diameter after implantation compared to the package size for Hemashield, J-Graft, and Triplex. Although graft size continued to increase within the median observation period of 43 months, Triplex showed the most increase in diameter among the three grafts.

There are two types of prosthetic graft in the market based on how the fibers are assembled: woven graft, which is made of over and under patterned structure, and knitted graft, which is structured by looping fibers in an interlocking chain pattern. Due to its structure, woven-type is stronger and has less porosity compared to knitted-type graft. However, it is less compliant and may fray when cut. On the other hand, knitted-type is soft and more stretchable than the woven-type graft.[6] Among the three prosthetic grafts used in our study, Hemashield and J-Graft are classified as woven-type prosthetic graft. On the other hand, Triplex is a three-layer structured graft in which the inner and outer layers are made of knitted graft and the middle layer is made of self-sealing elastomeric membrane. The nonbiological elastomeric membrane has been reported to minimize bleeding and inflammatory response after surgery.[8,9] Although it consists of knitted-type graft, Triplex has been assembled to prevent graft dilation. However, similar to the previous results, our study has shown that degree of graft dilation was larger in knitted Triplex graft compared to the woven-type prosthetic graft in the aortic arch. Although there was no correlation between the narrowing of the anastomosis site to the graft dilation ratio, Triplex showed the least reduction in the diameter of the anastomosis. This may be due to the stiffness of the three-layered structure preventing it from graft folding from the intermittent suture. Larger diameter at the proximal anastomosis may be due to our surgical strategy in which proximal graft is cut at a 45-degree angle for anastomosis.

Reports on the risk factors have also been presented. Etz et al. reported that arterial hypertension was associated with graft growth in the descending aorta, but not in the ascending aorta. Further, smaller grafts had proportionally greater increases in diameter.[4] However in their report, probable risk factors including age, sex, or history of smoking were not associated with graft dilation.[4] Other studies have also reported that age, hypertension, and initial diameter were not associated with graft dilation.[7] On the contrary, our study has shown that age and history of cerebral vascular disease was associated with graft dilation independent of types of prosthetic graft used.

The concept of aortic compliance and compliance mismatch after graft implantation has been documented in several reports. The absence of elasticity of the native aorta after graft replacement results in subsequent flow changes to the vascular wall, which has been suggested to enhance graft enlargement.[10] Aortic stiffness and compliance is associated with atherosclerosis, which has also been reported to increase with age.[11] Our findings of increased age and prevalence of cerebral vascular disease may be associated with greater compliance of the vascular system, which may result in enhanced enlargement of the prosthetic graft.[10] Although limited in sample size, our data has also shown a possible correlation between the graft dilation ratio and postoperative PWV measurement, which is a measure for aortic stiffness.

Long-term freedom rate from aneurysm-related com-

plication after endovascular repair of the descending thoracic aortic aneurysm has been reported to be 96.2% at 11.8 years. However, endovascular reintervention was required in 7.3% due to endoleak.[12] With hybrid approach, Melissano et al.[13] examined type 1 endoleak at incidence rate of 7.1% in stent graft coverage from zone 0, 0.33% from zone 1, and 7.9% from zone 2. In another report by Kanaoka et al. risk factors for early type 1 endoleak after TEVAR included landing zone 0–1, large proximal neck, large stent graft diameter, and excessive oversizing.[14] Undersizing of the stent graft can also cause endoleak due to insufficient attachment of the stent graft to the landing zone and further to stent graft migration.[15,16] Due to changes in the diameter of the landing zone, insufficient oversizing of the stent graft at the time of surgery could lead to undersizing of the stent graft at long-term. Consideration of appropriate oversizing of the stent graft is needed to prevent stent graft-associated complications in a hybrid operation. In the previous report, decrease in expansion rate from 2% to 3% per year for the first 2 years to 1% year after 18 months has also been reported.[3] Although further investigation is needed, our study showed continuous increase in graft dilation during the median observation period of 43 months for the three grafts used. Two-stage hybrid surgery may be a better option for patients who have allowance for time, as enlargement of the prosthetic graft was continuous; thus, the measurement of oversizing could be more accurate and appropriate for preventing undersizing of the stent graft at long-term.

This study has several limitations. First, this is a retrospective study with a limited sample size. Follow-up study with a larger sample size is preferable to determine independent risk factors. Second, J-Graft and Triplex are only used in Japan; thus, expansion rate for other grafts should be further evaluated. Third, radial force of a stent graft differs with its graft size. In hybrid surgery, radial force of a larger device may have more profound influence on the graft dilation. It is also suggested that radial force of a stent graft itself differs with its opening diameters; thus, different sizes in landing zone may also have influence on the emerging radial force of an implanted stent graft. Although multivariate analysis in our study showed that graft size was not an independent factor for graft dilation, further study is needed for confirmation. Fourth, graft dilation ratio may be affected by the difference in the manufacturing line for each graft. However, dilation patterns observed in our study were similar in most grafts used for each graft type. Further, grafts used in our hospital were not particularly selected by the company, and it is unlikely that the data observed in this study is specific to our hospital. Finally, data on PWV was limited in this study. Further study is needed to confirm the effect of PWV on graft dilation.

Conclusion

The types of prosthetic graft used for landing zone reconstruction, patient demographics, oversizing of the stent graft, and the timing of endovascular approach should be considered in prevention of probable endoleak and migration in patients undergoing hybrid surgery for extensive aortic disease.

Disclosure Statements

Atsushi Yamaguchi serves as a consultant to Japan Lifeline Inc. All other authors have no conflict of interest.

Author Contributions

Study conception: DH
Data collection: DH, SK, TS
Analysis: DH
Investigation: DH, SK, TS
Writing: DH
Critical review and revision: all authors
Final approval of the article: all authors
Accountability for all aspects of the work: all authors

Supplementary Materials

Supplementary materials are available at the online article sites on J-STAGE and PMC.

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