Ann Thorac Cardiovasc Surg 2022; 28: 255–261
Online February 26, 2022
doi: 10.5761/atcs.oa.21-00261

*Original Article*

# Extensive Arch Repair with a Novel Two-Branched Stent Graft in Acute Type A Aortic Dissection

Zhao An,[1,2] Yang-Yong Sun,[2] Rui-Xin Fan,[3] Shi-Qiang Yu,[4] Jun-Ming Zhu,[5] Qing-Qi Han,[2] and Lin Han[2]

**Purpose: In this study, we compared the early results between the extensive arch repair with a novel two-branched stent graft (TSG) and the traditional technique.**
**Methods: Between 2013 July and 2015 March, 63 acute type A aortic dissection (ATAAD) patients from four cardiac centers with indications for extensive arch repair were included in this study. Finally, 28 patients were involved in the traditional procedure (TP) group (23 males with the age of 49.75 ± 9.26 years) and 35 patients were involved in the TSG group (29 males with the age of 53.82 ± 8.17 years).**
**Results: The operation was successful in all patients. The selective cerebral perfusion time, total operation time, and chest drainage within 24 hours after the operation in the TSG group were significantly less than those in the TP group (P ≤0.05). The mean follow-up time was 11.17 ± 1.74 months in the TP group and 11.94 ± 4.29 months in the TSG group. No statistical differences were found in aortic diameter, false lumen diameter, and true lumen diameter at the diaphragmatic level during the follow-up.**
**Conclusion: Our technique with a novel TSG simplified the extensive arch repair procedure and was an effective way for the treatment of ATAAD.**

**Keywords:** arch repair, acute type A aortic dissection, branched stent graft

[1]*Department of Thoracic Surgery, Shanghai Pulmonary Hospital, Tongji University School of Medicine, Shanghai, China*
[2]*Department of Cardiovascular Surgery, Changhai Hospital, Naval Medical University, Shanghai, China*
[3]*Department of Cardiovascular Surgery, Guangdong General Hospital, Guangdong Academy of Medical Sciences, Guangzhou, China*
[4]*Department of Cardiovascular Surgery, Xijing Hospital, Fourth Military Medical University, Xi'an, China*
[5]*Department of Cardiology, Beijing Anzhen Hospital, Capital Medical University, Beijing, China*

Received: December 5, 2021; Accepted: January 25, 2022
Corresponding author: Lin Han. Department of Cardiovascular Surgery, Changhai Hospital, Naval Medical University, 168 Changhai Road, Shanghai 200433, China
Email: linhan1@yeah.net



## Introduction

Acute type A aortic dissection (ATAAD) is the most lethal aortic condition with high mortality, and emergency surgical repair remains an effective treatment for ATAAD patients.[1)] Surgical repair is inevitable for ATAAD; however, surgical strategy in the arch is still controversial. Hemiarch replacement is a simple and safe way for arch repair, but this procedure was associated with an increased incidence of reoperation and decreased incidence of false lumen thrombosis.[2,3)] Compared with hemiarch replacement, extensive arch repair is related to a higher operative risk since this procedure needs to anastomose brachiocephalic arteries, which makes it more complex and prolongs selective cerebral perfusion (SCP) time, although extensive arch repair improves postoperative survival and avoids reintervention.[4–6)]

The complex procedure of extensive arch repair limited its application. Some attempts were made to overcome this deficiency. Chen et al. adopted the open placement of triple-branched stent graft technique to simplify the arch replacement.[7,8] In another study, the conventional four-branched vascular prosthesis and stented elephant trunk used in extensive arch repair were replaced by a four-branched frozen elephant trunk prosthesis.[9] Zhu et al. reported that they preserved the autologous brachiocephalic vessels to simplify the arch replacement procedures.[10] However, compared with the conventional surgery, results of these studies showed that the SCP time was not significantly decreased, which meant further improvements on the extensive arch repair technique were needed.

Recently, we adopted a novel two-branched stent graft (TSG) and delivery system to simplify the extensive arch repair procedure.[11] In this prospective, randomized, multicenter study, we reported that the early results of 35 patients received this new technique.

## Patients and Methods

### Patients

Between 2013 July and 2015 March, 64 ATAAD patients from four cardiac centers with indications for extensive arch repair were included in this study. Patients were randomly divided into two groups; patients in one group received extensive arch repair with TSG and patients in the control group received extensive arch repair with the traditional procedure (TP). One patient in the TP group was excluded because the patient required to drop out before the operation.

Finally, 35 patients in the TSG group received TSG implantation under direct vision during the operation. A total of 28 patients in the TP group received traditional extensive arch repair with stented elephant trunk implantation. Patients were included in this study because they satisfied the following indications: 1) 18 ≤age ≤65 years, 2) diagnosed with ATAAD, 3) the aortic arch has no anatomical aberration, 4) no surgical contraindication like hepatic or renal insufficiency, and 5) did not receive cardiac surgery before.

Patients with Marfan syndrome, other connective tissue diseases, or severe brachiocephalic arteries dissection were excluded. All patients received emergency operation once ATAAD was diagnosed. Details of patients' preoperative data are shown in **Table 1**. This study was approved by the Institutional Review Board of the four hospitals in this study, and informed consent was signed by the patients or their direct relatives.

### Description of the device

The device was a TSG, which comprised a main graft and two branches. It was designed and manufactured by Lifetech Scientific (Shenzhen, China). The device consisted of three parts: 1) the stent frame was constructed by self-expandable nitinol, 2) polytetrafluoroethylene covered the inside and outside of the stent to construct a sealed lumen, and 3) a Dacron tube was on the proximal end of the main graft to provide a suture zone between the device and the vascular prosthesis. To fit closely to the vascular wall, both the main and branched grafts were tapered on the distal ends. Besides, the device was flexible enough to conform the aortic arch curve. The device is shown in **Fig. 1**.

**Table 1 Patients details**

| | TP (N = 28) | TSG (N = 35) | P |
|---|---|---|---|
| Age | 49.75 ± 9.26 | 53.82 ± 8.17 | 0.17 |
| Gender (male) | 23 (82.14) | 29 (82.86) | 1.00 |
| BMI | 26.02 ± 6.13 | 25.52 ± 3.48 | 0.74 |
| Hypertension | 15 (53.57) | 18 (51.43) | 0.87 |
| Dyslipidemia | 2 (7.14) | 0 (0.00) | 0.19 |
| Diabetes | 1 (3.57) | 0 (0.00) | 0.44 |
| LVEF (%) | 58.38 ± 7.51 | 57.27 ± 7.26 | 0.61 |
| MD of ascending aorta (mm) | 42.11 ± 10.05 | 41.48 ± 4.82 | 0.78 |
| Aortic regurgitation | | | |
| Mild | 4 (14.29) | 11 (31.43) | 0.11 |
| Moderate | 4 (14.29) | 2 (5.71) | 0.39 |
| Severe | 5 (17.86) | 4 (11.43) | 0.49 |

Data presented as mean ± standard deviation or n (%). TP: traditional procedure; TSG: two-branched stent graft; LVEF: left ventricular ejection fraction; MD: maximum diameter

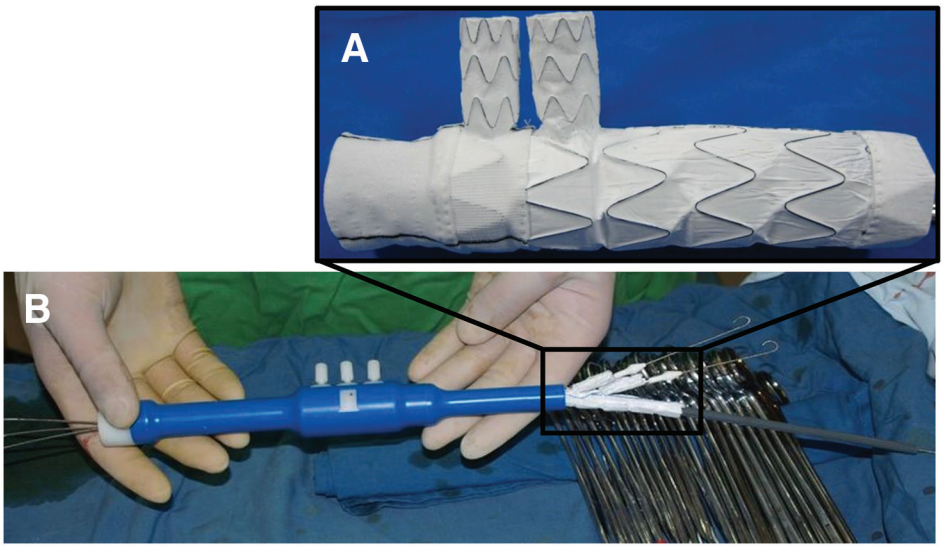


**Fig. 1** The TSG and delivery system. (**A**) The expanded TSG. (**B**) The delivery system with the fold TSG. TSG: two-branched stent graft

### Description of the delivery system

The double-branched stent graft was mounted on three hollow fixed rods in our delivery system by silk strings, individually. Each fixed rod contained a guide wire, which was used to guide the rod into the true lumen of the artery under direct vision. Besides, control module on the handle of the delivery system linked three control cables, which were used to release the graft during operation. The delivery system is shown in **Fig. 1**.

### Operation technique

The operation was under general anesthesia and deep hypothermia in all patients. We monitored the arterial blood pressure of both the upper and the lower limbs, and transesophageal echocardiographic was used to monitor the cardiac function during the operation.

Median sternotomy was performed in all patients. The left femoral artery, right axillary artery, and superior and inferior vena cava were cannulated for cardiopulmonary bypass (CPB) and unilateral antegrade SCP. During the operation, CPB flow was maintained at 2.2 to 2.4 L/min/$m^2$. After cross-clamp at the root of the innominate artery, ascending aorta was dissected from the sinotubular junction and cold blood cardioplegia was perfused through the coronary ostia to protect myocardium. During cooling, the aortic root procedure was done if necessary. Besides, aortic root was anastomosed to a one-branched vascular prosthesis.

When the rectal temperature reached 25°C, CPB was arrested and SCP started at a flow of 5 to 10 mL/kg/min. The cross-clamps in the aorta, left common carotid artery, and left subclavian artery were removed. The guide wires were inserted in the true lumen of the descending aorta, left common carotid artery, and left subclavian artery under direct vision. Then the fixed rod of the delivery system was inserted in these arteries under the guide of guide wires. After the stent graft was on position, it was deployed by pulling the control cables on the handle, first releasing the main stent and then two branches (**Supplementary Fig. 1A** and **Supplementary Video 1;** All supplementary files are available online.). After release, the distal end of the one-branched vascular prosthesis was anastomosed to the proximal Dacron tube of the stent and the air was carefully exhausted. Then CPB was restarted and rewarming was started. Innominate artery was anastomosed to the branched vascular prosthesis during rewarming (**Supplementary Fig. 1B**).

### Follow-up

Patients were contacted via outpatient review, telephone, or email after discharge. All patients were followed at 6 months and 1 year after discharge; then the follow-up was annually. Computed tomography angiogram (CTA) data were obtained at 6 months and 1 year after discharge. Loss to follow-up or death occurred at any time during the follow-up was recorded.

### Statistical analysis

For categorical variables, the chi-square test was used for statistical analysis. For continuous variables, the

**Table 2 Intraoperative details**

| | TP (N = 28) | TSG (N = 35) | P |
|---|---|---|---|
| SCP time (min) | 32.61 ± 8.93 | 21.56 ± 10.95 | ≤0.05 |
| CPB time (min) | 209.07 ± 58.84 | 191.00 ± 38.14 | 0.15 |
| Cross-clamp time (min) | 100.04 ± 31.07 | 88.66 ± 18.66 | 0.08 |
| Total operation time (min) | 418.78 ± 93.15 | 375.86 ± 76.76 | ≤0.05 |
| Total pRBCs (unit) | 6.64 ± 4.26 | 7.51 ± 3.29 | 0.36 |
| Concomitant procedures | | | |
| Bentall | 11 (39.29) | 13 (37.14) | 0.86 |
| Cabrol | 1 (3.57) | 0 (0.00) | 0.44 |
| CABG | 3 (10.71) | 1 (2.86) | 0.32 |
| AVR | 0 (0.00) | 2 (5.71) | 0.50 |

Data presented as mean ± standard deviation or n (%). TP: traditional procedure; TSG: two-branched stent graft; SCP: selective cerebral perfusion; CPB: cardiopulmonary bypass; pRBCs: packed red blood cells; CABG: coronary artery bypass grafting; AVR: aortic valve replacement

**Table 3 In-hospital details**

| | TP (N = 28) | TSG (N = 35) | P |
|---|---|---|---|
| ICU time (hours) | 149.63 ± 135.28 | 107.65 ± 66.38 | 0.12 |
| 24 hours chest drainage (ml) | 815.89 ± 517.22 | 590.74 ± 310.72 | ≤0.05 |
| Hospital time (days) | 26.38 ± 10.80 | 20.71 ± 6.12 | ≤0.05 |
| Ventilation time ≥72 hours | 6 (21.43) | 6 (17.14) | 0.67 |
| Pleural effusion | 0 (0.00) | 2 (5.71) | 0.50 |
| Reoperation for bleeding | 3 (10.71) | 0 (0.00) | 0.08 |
| Infection or sepsis | 2 (7.14) | 2 (5.71) | 1.00 |
| Heart arrest | 1 (3.57) | 0 (0.00) | 0.44 |
| Acute renal failure | 1 (3.57) | 0 (0.00) | 0.44 |
| Stroke | 1 (3.57) | 0 (0.00) | 0.44 |
| In hospital death | 2 (7.14) | 1 (2.86) | 0.58 |

Data presented as mean ± standard deviation or n (%). TP: traditional procedure; TSG: two-branched stent graft; ICU: intensive care unit

Student's t test and Mann–Whitney U test were used for statistical analysis when the data distributed normally and non-normally, respectively. Statistical analysis was completed in SPSS (Chicago, IL, USA). Data were presented as mean ± SD or n (%). P ≤0.05 was considered as statistically significant.

## Results

### Intraoperative results

All TSGs were well positioned, and the operation was successful in all patients. Details of the intraoperative results are shown in **Table 2**. The SCP time and total operation time in the TSG group were significantly less than those in TP group (P ≤0.05). CPB and cross-clamp time were also less in the TSG group compared with those in the TP group, although there were no statistical differences. No differences were found in blood transfusion and concomitant procedures between TSG and TP groups.

### In-hospital outcomes

In-hospital details are shown in **Table 3**. Chest drainage within 24 hours after the operation was significantly less in the TSG group compared with that in the TP group (P ≤0.05). Hospital time in the TSG group was less than that in the TP group (P ≤0.05). Intensive care unit time in the TSG group was also less than that in the TP group, but there was no statistical difference. No statistical difference was found in hospital mortality between TSG and TP groups. One (2.86%) patient died in the TSG group; this patient got serious catheter-derived infection after operation and died of septic shock at postoperative day 6. Two (7.14%) patients died in the TP group, and one patient experienced reoperation for bleeding and acute renal failure; this patient finally died of multiple organ dysfunction syndrome at postoperative day 3; another patient died of heart arrest at postoperative day 3. No statistical differences were found in postoperative complications including ventilation time ≥72 hours, pleural effusion, reoperation

**Table 4 Aortic diameters at diaphragmatic level during follow-up**

| | TP (N = 23) | TSG (N = 27) | P |
|---|---|---|---|
| Before operation | | | |
| Aortic diameter (cm) | 3.15 ± 0.54 | 3.13 ± 0.37 | 0.86 |
| FL diameter (cm) | 1.98 ± 0.75 | 1.73 ± 0.71 | 0.23 |
| TL diameter (cm) | 1.16 ± 0.46 | 1.36 ± 0.65 | 0.24 |
| Before discharge | | | |
| Aortic diameter (cm) | 3.22 ± 0.36 | 3.20 ± 0.37 | 0.78 |
| FL diameter (cm) | 1.83 ± 0.68 | 1.72 ± 0.77 | 0.60 |
| TL diameter (cm) | 1.41 ± 0.50 | 1.48 ± 0.65 | 0.71 |
| 1 year after discharge | | | |
| Aortic diameter (cm) | 3.35 ± 0.55 | 3.35 ± 0.48 | 0.97 |
| FL diameter (cm) | 1.54 ± 0.93 | 1.66 ± 0.96 | 0.68 |
| TL diameter (cm) | 1.86 ± 0.57 | 1.70 ± 0.73 | 0.40 |

Data presented as mean ± standard deviation. TP: traditional procedure; TSG: two-branched stent graft; FL: false lumen; TL: true lumen

for bleeding, infection or sepsis, heart arrest, acute renal failure, and stroke. No leakage fracture, shifting, or kink was detected in postoperative CTA.

### Follow-up data

Two and two patients required to drop out after discharge in TP and TSG groups, respectively. Finally, 24 patients in the TP group and 32 patients in the TSG group entered the follow-up cohort. The mean follow-up time was 11.17 ± 1.74 months (ranged from 6 to 12 months) in the TP group and 11.94 ± 4.29 months (ranged from 6 to 30 months) in the TSG group (P = 0.41). No late deaths occurred during this period.

CTA data at 1 year after discharge showed the patency in the main graft and two branches in all patients in both groups (P = 1.00). One patient (4.17%) and one patient (3.13%) showed slightly leakage in TP and TSG groups, respectively (P = 1.00). One patient (3.13%) in the TSG group showed graft kink; intervention was not performed since the hemodynamics was not influenced.

At the diaphragmatic level, false lumen complete thrombus formation was observed in nine (37.50%) patients in the TP group and 12 (37.50%) patients in the TSG group 1 year after discharge (P = 1.00). As shown in **Table 4**, no statistical differences were found in aortic diameter, false lumen diameter, and true lumen diameter at this level during follow-up. Representation of follow-up CTA image is shown in **Supplementary Fig. 2**.

## Discussion

Some studies reported that extensive aortic repair had a better prognosis compared with hemiarch replacement in the treatment of ATAAD,[2,12] but surgical management of aortic arch in extensive aortic repair was still a high-invasive and risky procedure for patients with ATAAD. Extensive aortic repair was very complicated since it required extensive manipulation in aortic arch, brachiocephalic vessels, and proximal descending aorta. For extensive aortic repair, the elaborate anastomoses between the graft and brachiocephalic vessels were usually extremely difficult and time-consuming because of their deep surgical field, which made patients under a high risk of cerebral injury. Besides, anastomoses in extensive aortic repair always resulted in intraoperative or postoperative bleeding, which would lengthen operation time and increase the rate of reoperation for bleeding.

In an effort to address these problems, Shimamura et al. developed an open stent grafting technique, in which branches of the main graft could be adjusted from 1 to 3.[13] However, their stent graft was not self-expandable and its release needed the guide of guide wires from the femoral artery and left brachial artery, which made the operation complicated and did not reduce the operation time, especially the SCP time. Chen et al. developed a series of open stent grafting technique to simplify the arch replacement procedure,[7,8,14–16] but their stent implantation was under direct vision without the guide of guide wires. It was difficult to manipulate and might mislead the graft into false lumen, which was catastrophic for patients.[17] Besides, there was totally no cerebral protection when performing anastomosis between vascular prosthesis and the stent graft. Shrestha et al. adopted the Thoraflex Hybrid graft (Vascutek, Inchinnan, UK), which consisted of a four-branched graft with a stent graft at the distal end in the arch replacement procedure.[9] However, their device only reduced one anastomosis between the vascular

prosthesis and the stent graft; anastomoses between the graft and brachiocephalic vessels were not changed a lot. Zhu et al. simplified the traditional extensive aortic repair procedure by preserving the autologous brachiocephalic vessels.[10] Their technique simplified hemostasis and anastomosis, but its indications were strictly and only patients with undamaged brachiocephalic vessels could adopt this technique. The most important thing was all these techniques did not decrease the circulatory arrest time compared with the TP.

In order to solve these problems and simplify the extensive aortic repair procedure, we developed a novel TSG and delivery system. Our results showed that the SCP time was significantly decreased by using this device. Our device has several advantages in extensive aortic repair. 1) The two-branched design made the stent graft easy to adapt to the left common carotid artery and left subclavian artery and the stent implantation avoided the extensive dissection around these two arteries. 2) The use of our device reduced two anastomoses compared with the conventional extensive aortic repair, which made hemostasis more easy. 3) This design provided a better cerebral protection by reducing SCP time and reserving innominate artery for SCP during stent release. 4) The integral stent support design in our device was very firm, and it was not easy to shift and kink after implantation. 5) The use of guide wires in our delivery system avoided the stent graft implanted in false lumen. 6) Guide wires were inserted from the arch incision antegrade; it was convenient compared with retrograde insertion from the femoral artery and left brachial artery.

In-hospital results showed that our technique simplify the arch replacement procedures with good outcomes. The SCP time and postoperative chest drainage in the TSG group were significantly decreased compared with the TP group, which showed our technique provided a better hemostasis. One patient died in TSG group, it was not stent related and the mortality was lower than the TP group, although there was no statistical difference. Stent shifting and kink were factors affecting the effectiveness of arch repair with stent graft. No graft shift occurred in our study; the incidence was lower than that in the previous report.[17] This might be because our stent graft was deployed by the delivery system and that avoided the effect of repeatedly cooling for the self-expandable nitinol stent.[18]

Our follow-up data showed a similar 1 year performance between TSG and TP groups. CTA data showed that the main graft and branches were patency in all patients without shifting. During the follow-up, only one patient showed graft kink and one patient showed slightly leakage in the TSG group, which had no hemodynamic effects. Reintervention for leakage is rare in stent implanted during open surgery since the proximal stent was sewn in the distal end of the vascular prothesis.[8] Besides, postoperative thrombosis and remodeling of the aortic false lumen have no differences between TSG and TP groups. These results showed our device was reliable.

Our study has two limitations. First, the sample size was limited, and this made it hard to get statistical differences between two groups in some parameters, like CPB time and in-hospital mortality. In addition, our study did not investigate the long-term performance of this TSG because of the limited follow-up time.

## Conclusions

Our technique with a novel TSG and delivery system was effective with satisfactory early and mid-term outcomes in the treatment of ATAAD. It simplified the total arch replacement procedures. However, investigation on its long-term results is still needed.

## Acknowledgment

This work was supported by the National Natural Science Foundation of China (No. 81900421 to Dr. An).

## Disclosure Statement

The authors declare that they have no competing interests.

## References

1) Nienaber CA, Clough RE. Management of acute aortic dissection. Lancet 2015; **385**: 800–11.
2) Zhang H, Lang X, Lu F, et al. Acute type A dissection without intimal tear in arch: proximal or extensive repair? J Thorac Cardiovasc Surg 2014; **147**: 1251–5.
3) Malvindi PG, van Putte BP, Sonker U, et al. Reoperation after acute type a aortic dissection repair: a series of 104 patients. Ann Thorac Surg 2013; **95**: 922–7.
4) Lio A, Nicolo F, Bovio E, et al. Total arch versus hemiarch replacement for type A acute aortic dissection: a single-center experience. Tex Heart Inst J 2016; **43**: 488–95.

5) Kim JB, Chung CH, Moon DH, et al. Total arch repair versus hemiarch repair in the management of acute DeBakey type I aortic dissection. Eur J Cardiothorac Surg 2011; **40**: 881–7.
6) Uchida N, Shibamura H, Katayama A, et al. Operative strategy for acute type a aortic dissection: ascending aortic or hemiarch versus total arch replacement with frozen elephant trunk. Ann Thorac Surg 2009; **87**: 773–7.
7) Chen LW, Dai XF, Lu L, et al. Extensive primary repair of the thoracic aorta in acute type a aortic dissection by means of ascending aorta replacement combined with open placement of triple-branched stent graft: early results. Circulation 2010; **122**: 1373–8.
8) Chen LW, Wu XJ, Dai XF, et al. A self-adaptive triple-branched stent graft for arch repair during open type A dissection surgery. J Thorac Cardiovasc Surg 2015; **149**: 1278–83.e1.
9) Shrestha M, Kaufeld T, Beckmann E, et al. Total aortic arch replacement with a novel 4-branched frozen elephant trunk prosthesis: single-center results of the first 100 patients. J Thorac Cardiovasc Surg 2016; **152**: 148–59.e1.
10) Zhu JM, Qi RD, Chen L, et al. Surgery for acute type A dissection using total arch replacement combined with stented elephant trunk implantation: preservation of autologous brachiocephalic vessels. J Thorac Cardiovasc Surg 2015; **150**: 101–5.
11) Yu B, Liu Z, Xue C, et al. Total arch repair with open placement of a novel double-branched stent graft for acute Type A aortic dissection: a single-centre experience with 21 consecutive patients. Interact Cardiovasc Thorac Surg 2019; **28**: 262–9.
12) Sun L, Qi R, Zhu J, et al. Total arch replacement combined with stented elephant trunk implantation: a new standard therapy for type A dissection involving repair of the aortic arch? Circulation 2011; **123**: 971–8.
13) Shimamura K, Kuratani T, Matsumiya G, et al. Hybrid endovascular aortic arch repair using branched endoprosthesis: the second-generation "branched" open stent-grafting technique. J Thorac Cardiovasc Surg 2009; **138**: 46–52; discussion 52-3.
14) Chen LW, Wu XJ, Lu L, et al. Total arch repair for acute type A aortic dissection with 2 modified techniques: open single-branched stent graft placement and reinforcement of the dissected arch vessel stump with stent graft. Circulation 2011; **123**: 2536–41.
15) Dai XF, Chen LW, Wu XJ, et al. Total aortic arch reconstruction with triple-branched stent graft or hemiarch replacement for acute Debakey type I aortic dissection: five-years experience with 93 patients. J Card Surg 2015; **30**: 749–55.
16) Chen LW, Dai XF, Wu XJ, et al. Ascending aorta and hemiarch replacement combined with modified triple-branched stent graft implantation for repair of acute DeBakey type I aortic dissection. Ann Thorac Surg 2017; **103**: 595–601.
17) Shen K, Tang H, Jing R, et al. Application of triple-branched stent graft for Stanford type A aortic dissection: potential risks. Eur J Cardiothorac Surg 2012; **41**: e12–7.
18) Henderson E, Nash DH, Dempster WM. On the experimental testing of fine Nitinol wires for medical devices. J Mech Behav Biomed Mater 2011; **4**: 261–8.