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CASE REPORT

Stent Graft Migration Due to Structural Failure Nine Months After Thoracic Endovascular Aortic Repair Using Valiant Navion

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Objective: This report presents a case of stent graft migration that was suspected to have occurred due to failure of the Valiant Navion device (Medtronic Inc., Santa Rosa, CA, USA). This case was rare because the broken device was removed from the living patient and examined directly.

Case report: A 69 year old man who had previously undergone thoracic endovascular aortic repair (TEVAR) with arch vessel debranching (axillo—axillary bypass with left common carotid artery bypass) for distal arch aneurysm experienced stent graft (SG) migration 9 months after the primary surgery. Total arch replacement was performed, and the migrated SG was removed. The broken stent ring and suture seams were then found. The patient was discharged on post-operative day 41 and followed up in the outpatient department.

Discussion: Stent graft migration is a relatively rare complication after TEVAR and associated with type I or III endoleak, which can result in serious outcomes. In this case, it was suspected that migration had occurred after TEVAR due to structural failure of the Valiant Navion device; similar cases have been reported previously, suggesting a structural problem with the device. Therefore, other patients treated with the Navion device in the future will require careful follow up.

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INTRODUCTION

Structural failure of the Valiant Navion device (Medtronic Inc., Santa Rosa, CA, USA) has been reported after thoracic endovascular aortic repair (TEVAR),[1] and a warning was released by the Japanese Committee for Stent Graft Management. Stent graft (SG) fracture can lead to fatal complications, including type IIIb endoleak, but its detection with computed tomography (CT) is often difficult.[2,3] This case reports SG migration due to structural failure of the Navion device after TEVAR. This case was rare because the damaged SG was removed, and the broken stent ring and suture seams were examined directly during open surgery. Consent for publication and images was obtained from the patient.

REPORT

A 69 year old man with hypertension and mild to moderate aortic valve stenosis (AS) was referred for the management of a 73 mm distal arch aortic aneurysm (Fig. 1A). Total arch replacement (TAR) was carefully avoided at the time, as aortic valve replacement (AVR) might have been required in the future due to AS progression. Thoracic endovascular aortic repair with arch vessel debranching (axillo—axillary bypass with left common carotid artery bypass) was performed using the Valiant Navion device (Fig. 1B). The proximal neck diameter was 39 mm, the proximal device size was 46 mm, and sufficient oversizing was obtained. After TEVAR, the aneurysm shrank, but post-operative follow up CT at 9 months revealed SG migration (Fig. 1C and D). There was no endoleak, but the aneurysm had become enlarged. Echocardiography showed that the AS had progressed to moderate. Based on these findings, TAR and AVR were chosen as the secondary surgery.

The surgery was performed under general anaesthesia with a median sternotomy approach. After starting cardiopulmonary bypass (CPB) and systematic cooling, AVR was performed first using a 23 mm Inspiris Resilia (Edwards Lifesciences, Irvine, CA, USA) in the supra-annular position. The previous axillo—axillary bypass graft was dissected and cut at the right side and guided into the mediastinum via the third intercostal space. After circulatory arrest at 25 oC, antegrade cerebral perfusion was started for the brachiocephalic artery (BCA) and the previous debranched graft. The inside of the aorta was examined, and SG migration and flexion were detected. The proximal SG was removed from

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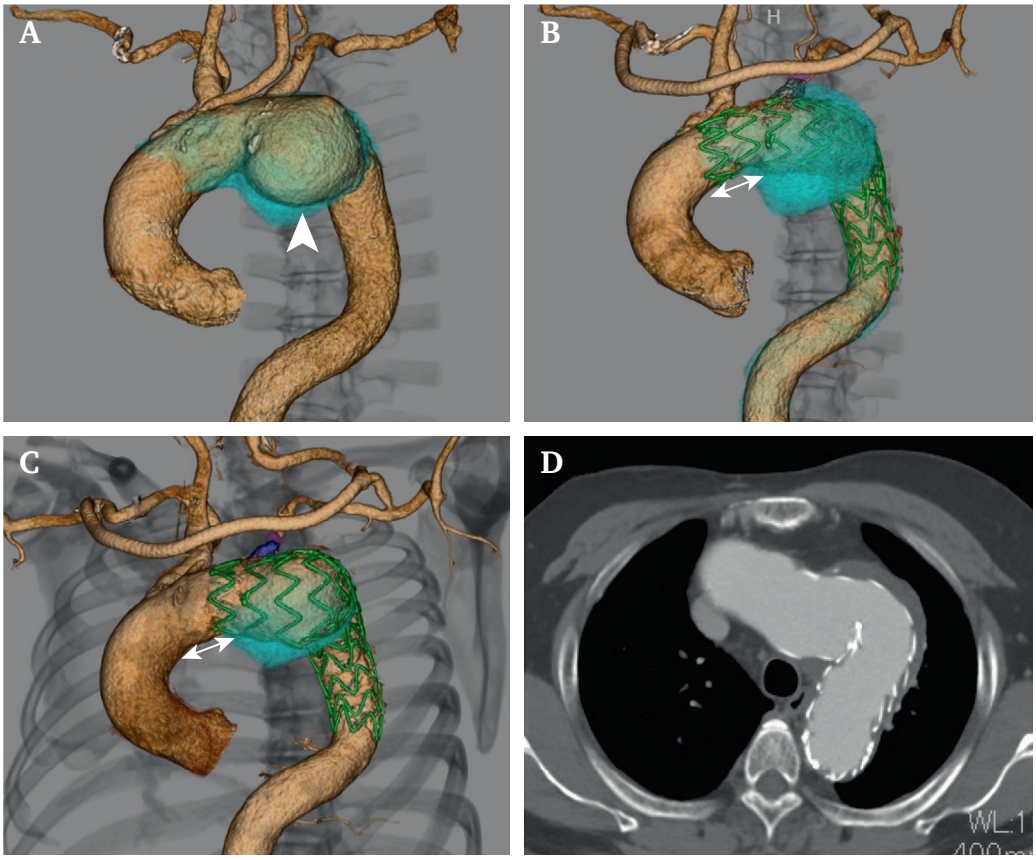

Figure 1. Pre-operative computed tomography images. A) The 73 mm distal arch aortic aneurysm at the initial visit (arrowhead). (B) Thoracic endovascular aortic repair with arch vessel debranching (axillo-axillary bypass with left common carotid artery bypass) was performed one year before presentation, and there was a sufficient proximal landing zone (arrow). (C, D) Stent graft migration occurred nine months after the primary surgery (arrow).

the aorta (Fig. 2A), and then the broken stent ring and suture seams securing the stent ring were found (Fig. 2BC). The aorta was resected at zone 1, and a 39—150 mm Frozenix (Japan Lifeline Co., Ltd., Tokyo, Japan) was placed into the distal aorta. After plasty of the proximal aortic stump was performed using an 8 mm polyester felt band, the distal aortic anastomosis was performed using a 30 mm four branched J graft (Japan Lifeline Co., Ltd., Tokyo, Japan). Cardiopulmonary bypass was re-started, then the BCA and previous debranched graft were reconstructed using the J graft branch, and a remnant of the branch was ligated. Finally, proximal anastomosis was achieved. A stent ring fracture was detected, retrospectively confirming the pre-operative CT (Fig. 2D). After surgery, the removed device was sent to Medtronic for investigation of the cause of device failure.

The patient was extubated on post-operative day (POD) 2, and the post-operative CT showed good graft formation and no other complications (Fig. 3). After rehabilitation, the patient was discharged on POD 41.

DISCUSSION

This case reports SG migration that was believed to have occurred due to structural failure of the Valiant Navion nine months after TEVAR. This case was rare because the broken device was removed from the living patient, and the broken stent ring and suture seams were examined directly.

Stent graft migration is a relatively uncommon complication after endovascular aortic aneurysm repair and is associated with type I or III endoleak, which can lead to aneurysmal expansion, rupture, and re-intervention. A previous study showed that the incidence of thoracic SG migration was 7.3—19.3%.[4,5] Stent graft migration is likely to occur at the proximal landing zone and also the overlapping and distal landing zones.[4] Previous studies have reported that the risk factors or predictors of SG migration after TEVAR include aortic elongation, the proximal fixation length, and thoracic aortic aneurysm (TAA).[4,5] In terms of abdominal endovascular aortic repair, proximal neck angulation $>60^{\circ}$ increases the risk of device migration and endoleak.[6] In this case, the proximal neck length was sufficient at approximately 30 mm (Fig. 1B), and proximal neck angulation of the aortic arch was not steep. The only risk factor for migration in this patient was TAA; therefore, it was considered that the risk of migration was not inherently high. However, in terms of the results, migration occurred relatively early at nine months after TEVAR. It was unclear exactly whether the stent ring fracture was the cause or result of the migration but as mentioned above, stent graft breakage was suspected to be the cause of migration.

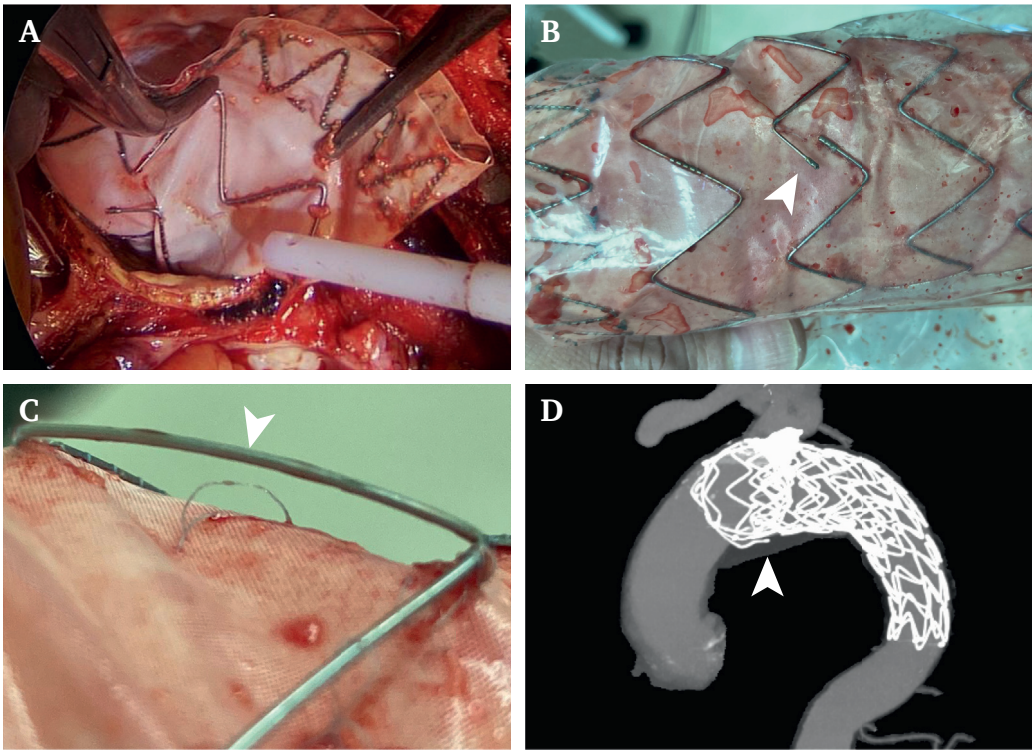

Figure 2. Intra-operative images. (A) The proximal stent graft was removed from the aorta. (B) The third stent ring from the proximal edge was broken (arrowhead). (C) Fracture of suture seams securing the stent ring was also detected (arrowhead). (D) A stent ring fracture was detected (arrowhead) by retrospective confirmation of pre-operative computed tomography.

The causes of the structural failure of the SG were metallic stent ring fracture, suture seam rupture, and graft fabric distress, among others.[7,8] The intra-aortic pulsation environment may lead to stent ring metal fatigue. Ruptured suture seams cause stent detachment from the graft surface and may lead to stent ring fracture. Verzini et al.[1] reported two patterns of structural failure of the Navion device: stent enlargement, fracture, and disconnection from the graft; and integrity loss of the graft longitudinal seam.

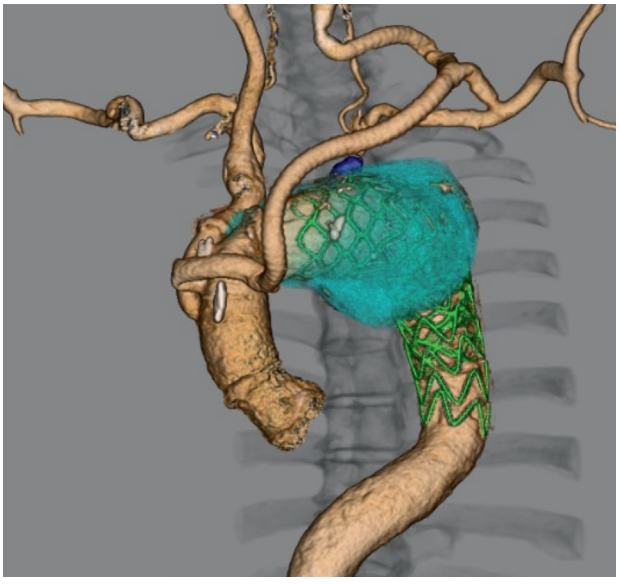

Figure 3. Post-operative computed tomography showed good graft formation and no other complications.

In the present case, stent enlargement was unclear, but the third lesser curvature side of the stent ring from the proximal edge was completely broken. The longitudinal seam of the graft was intact, but breakage and fraying of the suture securing the graft was observed in multiple parts of the stent ring (Fig. 2B). This stent was not originally located at the proximal landing zone, but the broken stent and suture might have caused migration by affecting the expansion force and SG balance. Type Ia endoleak was not observed, but surgical conversion was required due to the short proximal landing zone and sac expansion.

Structural SG failure is typically a long term complication, although it occurred in the early phase after TEVAR in this patient. Structural failure can cause type IIIb endoleak, as observed in five patients in a previous study.[1] The incidence of type III endoleak after TEVAR has been reported to be 2.1%,[9] which is considered a rare complication but can lead to fatal events, including aneurysmal rupture; therefore, prompt re-intervention is needed. Stent graft fracture and type IIIb endoleak cannot be detected by annual CT.[2,3] In this case, SG fracture was not detected before open surgery, and stent ring breakage was identified by reviewing the pre-operative CT post-operatively. Type Ia or IIIb endoleak were not detected pre-operatively, but a normal, delayed (approximately 30

seconds) enhanced CT was performed. The aneurysm sac was enlarged, and more delayed phase enhanced imaging might have detected the small endoleak.

In terms of re-intervention, without diagnosis of other failures, Medtronic recommended that the Navion device should be completely relined to avoid future potential complications.[10] In this case, the longest Frozenix device was used, which was 15 cm in length, but it was not long enough to completely cover the Navion graft (Fig. 3). Stent ring enlargement of the Navion device and the loss of the distal sealing zone of the Frozenix device may lead to new endoleak; therefore, careful follow up is needed and secondary endograft extension should be considered.

Conclusion

This was a rare case of a damaged Navion device that was examined directly during open surgery. Migration was suspected to be caused by the broken stent ring and suture seams of the excised SG. Therefore, other patients with Navion device implants require careful follow up.

DISCLOSURE STATEMENT

All authors have no conflicts of interest to declare.

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None.

AUTHOR CONTRIBUTIONS

Study conception: KK, MS; surgical procedure: KK, MS, KN, KI, AK; writing: KK, MS; critical review and revision: all authors; final approval of the article: all authors; accountability for all aspects of the work: all authors.

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