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ORIGINAL ARTICLE

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Endovascular repair of ascending aortic diseases with custom-made endografts

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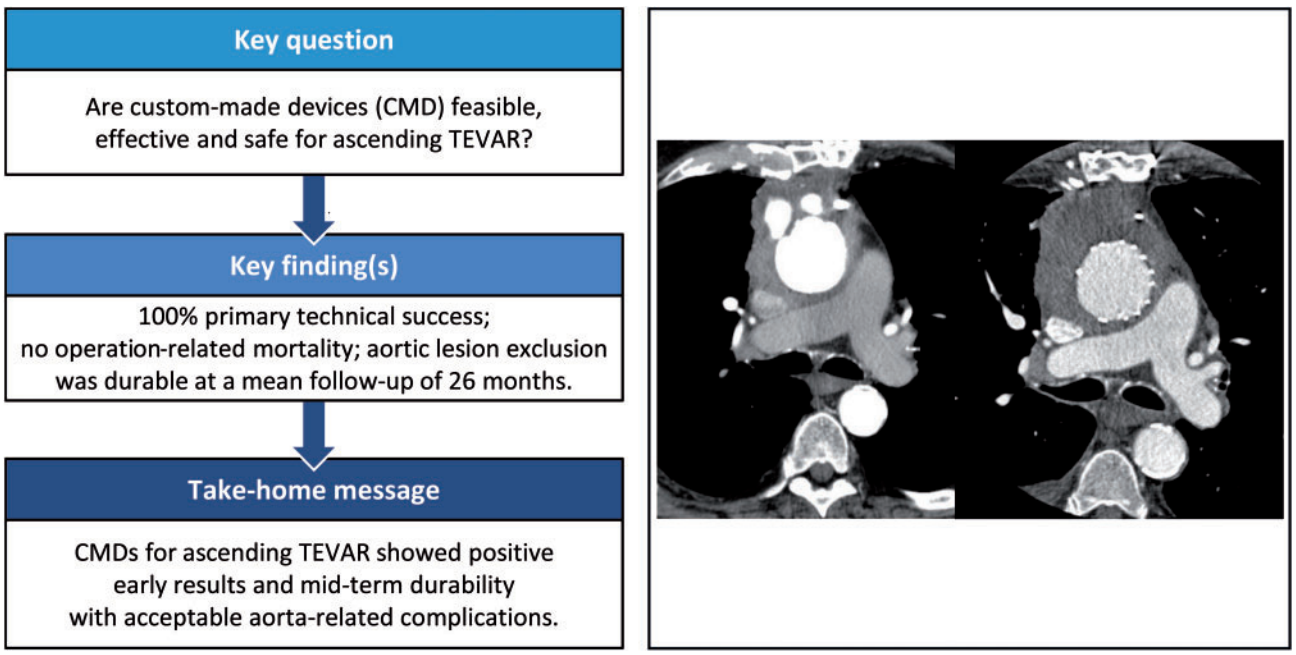

Abstract

OBJECTIVES: The aim of this article is to report the mid-term results of ascending thoracic endovascular aortic repair using a custom-made device (CMD).

METHODS: This was a retrospective study performed at tertiary centres. Nine patients considered unfit for open surgery received elective total endovascular repair of the ascending aorta with a Relay® (Terumo Aortic, Sunrise; FL, USA) CMD: pseudoaneurysn (n = 5), localized dissection (n =3) and contained rupture (n = 1).

RESULTS: Primary clinical success was achieved in all patients with no major complications and no early conversion to open surgery. All patients were discharged home and independent: median length of stay was 7 days (interquartile range, 6–18). No patient was lost to follow-up at a median 26 months (interquartile range, 12–36). Three patients died 2, 6 and 24 months after intervention; 1 was aorta related (late aorto-atrial fistula due to infection that required open surgery). At the last follow-up available, no endoleaks, migrations, fractures or ruptures were observed in the remaining 6 patients.

CONCLUSIONS: Ascending thoracic endovascular aortic repair with Terumo Aortic CMDs was technically feasible, effective and safe in very selected lesions. CMDs showed good ascending aorta conformability with different configurations and diameters, and satisfactory mid-term durability as shown by both structural integrity and aortic lesion exclusion.

Keywords: Ascending TEVAR Ascending pseudoaneurysm Custom-made endograft

ABBREVIATIONS

aTEVARs	Ascending thoracic endovascular aortic repairs
CMDs	Custom-made devices
CT-A	Computed tomography angiography
EGs	Endografts
IQR	Interquartile ranges

INTRODUCTION

In the last decade, several reports showed encouraging results of ascending thoracic endovascular aortic repair (aTEVAR) in different types of aortic diseases [1–5]. These reports included very selected cases of patients who were considered unfit candidates for open surgery, and nearly 90% were treated 'off-label' with standard endografts (EGs) [6]. Currently, the development of standard aTEVAR is limited by anatomic landmarks, aneurysm size and dissection location, but custom-made devices (CMDs) have shown satisfactory results in similarly challenging aortic lesions and potentially may be better suited to match the challenging ascending aorta anatomy in selected cases [7, 8]. A small number of CMDs have been used for aTEVAR. This report describes mid-term results of aTEVAR with Relay® (Terumo Aortic, Sunrise, FL, USA) CMDs for different ascending aorta lesions in high-risk patients for open surgery.

METHODS

Study cohort

This was a multicentre, observational, retrospective cohort study involving tertiary referral university hospitals [9]. The local Ethic Committee waived the need for approval for the registration and use of anonymized data, according to the Italian National Policy in the matter of Privacy Act on retrospective analysis. Informed consent for intervention, data recording and analysis was signed by each patient. In all cases, aTEVARs was performed for diseases originating from the ascending aorta; in all cases, the EG was deployed and confined within the ascending aorta. All patients were considered at high risk for open surgery at the time of presentation, according to the individual medical history independently of age, and following a multidisciplinary team evaluation [10]. Informed consent to proceed with TEVAR was obtained from all of them.

Device description

Each device used was a specific customization of the Relay® NBS (non-bare stent) Plus (Terumo Aortic, Sunrise, FL, USA). It is a single-component tubular, fully covered custom-made EG with diameters ranging from 28 to 48 mm (Fig. 1); the shortest standard Relay® NBS is 100 mm (99–114 mm nominal length depending on the graft diameter). Customization can reduce total covered length to 65 mm while maintaining the benefit of the delivery system's 'support wires'. Two fixation points on the upper side of the delivery catheter allow the bottom of the most proximal spring to expand first towards the anatomic inner curvature, while preserving the ability to reposition. The atraumatic support wires hold the inferior portion of the graft to avoid retroflex.

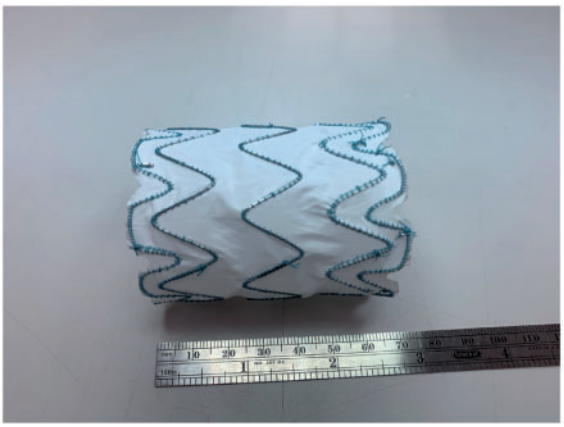

Figure 1: Customization of the Relay® NBS (non-bare stent) Plus (Terumo Aortic, Sunrise, FL, USA). This endograft is made by a single-component tubular, fully covered custom-made endograft.

The distal end of the graft can be replaced with a bare spring and so reduces the covered length to ~50 mm, but the overall stent graft length would still be 65 mm. Further customizable features include tapering of proximal and distal diameters (with the possibility of reverse tapering) and spring positioning along the length of the graft to increase sealing and conformability. According to manufacturer and considering those cases screened for customization to date, the refusal rate is <50% mainly due to acute type A aortic dissection, true ascending aneurysm involving the entire ascending aorta or post-surgical cases with proximal reconstruction characterized by an acute prosthetic angle.

Operative management

Complete cerebral and thoraco-abdominal computed tomography angiography (CT-A) was performed in all cases to evaluate the anatomy of the ascending aorta, the supra-aortic trunk, the brain vessels, the patency of the circle of Willis, dominance of the respective vertebral arteries and/or eventual access vessel sizing. As for all TEVAR procedures, a 3D centreline reconstruction was used to plan and size the EG; for these specific cases, a diameter equal to the intima-to-intima diameter was used [11]. Surgical interventions were performed in an operating theatre equipped to perform either open surgery or endovascular procedures, with the cardiac perfusion team on stand-by.

Common techniques employed for aTEVAR were the following:

- general anaesthesia,
- transoesophageal echocardiography monitoring,
- intravenous weight-adjusted heparinization to keep an activated clotting time at least ≥250 s throughout the procedure,
- preliminary angiography to identify the origins of the coronary arteries and mark the brachiocephalic trunk,
- deployment under temporary rapid cardiac pacing (generally, 190 bpm) via a transvenous pacing catheter or pharmacologically induced controlled hypotension and
- transthoracic echocardiogram and CT-A before discharge.

Postoperative antithrombotic therapy was standardized with all patients started on aspirin, with pre-existing oral anticoagulants continued postoperatively. Follow-up was performed according to the standard practice at each centre: generally, triple-phase CT-A surveillance was performed at 1 and 12 months, and annually thereafter.

Definitions and primary outcomes

Medical comorbidity grading, operative outcomes and follow-up were defined according to recommended reporting standards and best practice documents of the European Association for Cardio-Thoracic Surgery and the Society for Vascular Surgery [11–13]. Aortic lesion location was classified according to the different segments of the ascending aorta proposed by Roselli *et al.* [3] Shaggy aorta was defined as the presence of an irregular/ulcerated atheroma protruding ≥5 mm into the aortic lumen [14]. Porcelain aorta was defined as circumferential calcification of the entire ascending aorta preventing safe aortic cross clamping [15]. Primary outcomes were operative technical success, early (<30 days) and late survival, freedom from aortic reintervention. For this specific study, operative technical success was defined on an intent-to-treat basis starting with the implantation procedure and requiring the successful introduction and deployment of the EG in the absence of surgical conversion to open surgery, death ≤24 h or type I endoleaks.

Outcomes and statistical analysis

Statistical analysis was performed with SPSS, release 25.0 for Windows (IBM SPSS, Chicago, IL, USA). Categorical variables are expressed as number and percentage (%). Continuous variables were presented with mean ± standard deviation or median with interquartile ranges (IQR), based on data distribution. Data distribution was assessed by means of visual plotting and by means of the Shapiro–Wilk test for normality. All collected data were reviewed and if missing or inconsistent data were detected, relevant queries were posed to the investigators for resolution [16].

RESULTS

Study cohort

Seven males and 2 females were treated: all patients were white/Caucasian. The mean age was 71 years ± 10 years (range, 62–81). Comorbidities and risk factors are shown in Table 1. Indication for aTEVAR was pseudoaneurysm ($n = 5$, Fig. 2), localized uncomplicated type A dissection ($n = 3$) and contained rupture ($n = 1$). Pseudoaneurysm aetiology was suture-line disruption of previous cardiac surgery ($n = 4$) and mycotic ($n = 1$). Aortic measurements are reported in Table 2. Ascending proximal landing zones were: 7 in 'zone 0B' and 2 in 'zone 0 C'. Distal landing zone was 'zone 0 C' in all cases. All interventions were performed on an elective basis. Access was by surgical cut-down in 6 cases through the apex of the left ventricle ($n = 3$), transfemoral ($n = 2$) and right subclavian artery ($n = 1$). Three percutaneous approaches were performed through the right femoral artery ($n = 2$) and the right subclavian artery ($n = 1$). There were 2 adjunctive procedures: a planned transcatheter aortic valve implantation ($n = 1$), and femoral endarterectomy with patch angioplasty ($n = 1$). There were no branch vessel procedures. A single EG was used in all cases: 6 EGs were straight tubes (Fig. 3), in 3 patients we implanted a single-tapered ($n = 2$) or reverse-tapered ($n = 1$, Fig. 4) EG. The mean oversizing was 15% ± 4 (range, 10–20). Table 3 summarizes individual patient/procedure characteristics.

Early outcomes

Primary clinical success was 100%. There was no operative mortality, endoleak or conversion to open surgery. Femoral patch reconstruction was required in 1 patient because of the poor quality of the access vessel. The mean operation time was 93 ± 33 min (range, 45–142). No patient required blood transfusion. All patients were transferred to intensive care unit; 6 patients were extubated 12 h after intervention and were ambulatory on postoperative day 1; and 3 patients remained for 4 days or more. One patient developed pulmonary oedema and spinal cord ischaemia: complete EG lesion sealing determined complete thrombosis of the false lumen into the dissected descending thoracic aorta and resulted in paraplegia, which persisted despite

cerebrospinal fluid drainage and haemodynamic optimization (Fig. 5). There were no other major complications such as cerebrovascular events, valve impairment, myocardial infarction, retrograde aortic dissection, incidental occlusion of arch or visceral vessels and aortic rupture. All patients were discharged home and resumed an independent life: the median hospital stay was 7 days (IQR, 6–18). No patient was lost to follow-up during a median 21 months (IQR, 12–36). Seven (78%) patients were followed up at 12, 3 ≥ 36, and 1 > 60 months. During follow-up, 3 patients died, 1 of pneumonia, 1 from multiple organ failure and 1 due to postoperative sequelae of open surgery after conversion for an infected aorto-atrial fistula. Ongoing primary clinical success was maintained in 6 (67%) patients, who did not develop endoleaks, EG migrations, nitinol fractures or associated adverse aortic events. Pseudoaneurysm diameter shrunk or completed reabsorbed in all cases. In dissection-related cases, no proximal or distal EG-related new entry was observed.

Table 1: Demographic data, baseline comorbidities and risk factors in patients treated with ascending thoracic endovascular aortic repair (*n* = 9)

Variables	Ascending TEVAR (*n* = 9)
Demographics	
M:F, *n*	7:2
Age, mean± SD	71 ± 10
Comorbidities, *n* (%)	
Hypertension	8 (89)
Valve disease	7 (78)
Coronary artery disease	6 (67)
Previous cerebrovascular accident	2 (25)
Diabetes	3 (33)
Atrial fibrillation	2 (22)
Left heart insufficiency	1 (11)
Chronic kidney disease (eGFR < 30 ml/min)	1 (11)
Risk factors	
Previous cardiovascular surgery (patients), *n* (%)	8 (89)
Bentall, *n*	3
Biological valve, *n*	2
Mechanical valve, *n*	1
CABG, *n*	3
AVR (biological), *n*	2
MVR, *n*	1
Descending TEVAR, *n* (%)	1
Shaggy aorta, *n* (%)	1 (11)
Porcelain aorta, *n* (%)	1 (11)
Rupture, *n* (%)	1 (11)
EuroSCORE-II, mean ± SD[a]	15 ± 13

AVR: aortic valve repair; CABG: coronary artery bypass graft; eGFR: estimated glomerular filtration rate; F: female; M: male; MVR: mitral valve repair; *n*: number; SD: standard deviation; TEVAR: thoracic endovascular aortic repair.
[a]http://www.euroscore.org/calc.html.

DISCUSSION

Clinical series on aTEVAR are becoming more frequent in the literature and, although usually small in numbers, show encouraging technical and clinical outcomes, thereby highlighting the importance of very careful patient selection [1–5, 7]. The ascending aorta poses multiple geometric and haemodynamic challenges to endovascular repair and anatomical feasibility is by far the most crucial aspect for technical and clinical success: access vessel size, mode of EG deployment and adjunctive intraoperative manoeuvres are no longer so determinant [6, 17]. In an investigational device evaluation, Khoynezhad *et al.* [18] screened 39 patients and treated 6 with aTEVAR; poor access vessels accounted for 18% of screening failure. Muetterties *et al.* [6] did not report vascular access complications as a main cause of primary technical failure. In our series, different access vessels were used with no major access-related complication and correct advancement and deployment, even when larger EGs were used.

The introduction of dedicated EGs with specific characteristics that would better accommodate the ascending aorta could help to improve the results of aTEVAR. However, there are currently no devices approved for use in the ascending aorta and available options are to use a short proximal extension standard graft or an abdominal cuff outside instructions for use, an investigational

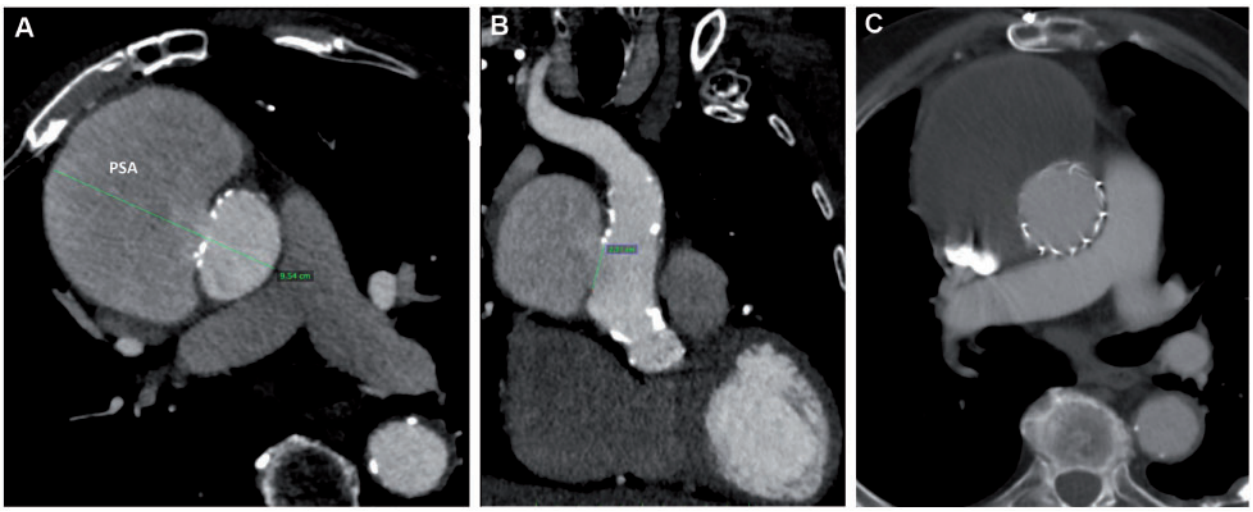

Figure 2: Preoperative computed tomography angiography (**A**) with multiplanar (**B**) reconstruction of a 66-year-old male with a huge pseudoaneurysm originating from the cannulation site of a previous coronary artery bypass graft. Follow-up computed tomography angiography (**C**) at 38 months shows complete thrombosis of the pseudoaneurysm.

device (as part of a clinical investigation) or a CMD [5–7, 18]. Two different series on investigational devices reported an overall primary technical success as high as 97%, while the use of CMD has been published mostly anecdotally in the literature [5–7, 18, 19].

The recent review performed by Muetterties *et al.* [6] of 118 total patients treated by aTEVAR revealed that nearly 90% of the ascending lesions were treated 'off-label' with standard abdominal or thoracic EGs. These data underline both the possibility of adaptation of available EG technology and the lack of a dedicated device for the endovascular treatment in this aortic area. In such a context, another potential concept would be the refinement of a single endovascular valve-carrying conduit that might increase the number of patients, especially those currently not amenable to aTEVAR because of an aortic lesion too close proximally to the aortic root [20]. Nonetheless, aTEVAR outcomes have been shown to be more dependent on the underlying aortic disease. In their updated experience of type A dissection, Lu *et al.* [21] warned that 48% of patients developed a major complication; a focal aortic lesion may be a better indication for aTEVAR. In the largest experience so far, Roselli *et al.* [3] reported significantly better aTEVAR outcomes in pseudoaneurysms in comparison with other types of lesions. In a previous series treating focal lesions such as pseudoaneurysms or penetrating ulcers, we had similarly good results with no early mortality and no aorta-related reintervention during follow-up [22]. In the present experience, CMDs were deployed with no technical complication and successfully sealed the aortic lesion in all cases. Though the presence of a mechanical valve or patent coronary artery bypass grafts may be contraindications for aTEVAR, the customization process may be very helpful in this circumstance, as was the case with 3 patients in this experience. The nose cone in 1 patient with a mechanical valve was further customized to be ultrashort, and an axillary access was necessary to optimize the navigation of such an ultrashort device. Customization of the device length also helped to preserve the patency of a coronary artery bypass graft. Another encouraging aspect is that CMDs had durable results at 31 months of follow-up, which compares favourably to the mean follow-up period of 17 months of the published aTEVAR series [6].

However, the number of suitable cases for this kind of approach remains low, mainly due to the nature of the disease, particularly type A aortic dissection; nearly all aortic dissections have a retrograde component and this translates into a lack of a proximal landing zone in the ascending aorta. Furthermore, the primary entry tear is very often close to the sinotubular junction

Table 2: Aortic sizing and measurements

Variable	
Size, mean ± SD (range)	
Aortic lesion diameter	55 ± 25 (26–97)
Aortic lesion length	30 ± 16 (5–55)
Aorta diameter	
Proximal neck	34 ± 5 (26–42)
Distal neck	34 ± 7 (20–44)
CA-BCT distance	85 ± 19 (65–115)
Inner curve angle (°)	107 ± 27 (60–143)

BCT: brachiocephalic trunk; CA: coronary artery; *n*: number; SD: standard deviation.

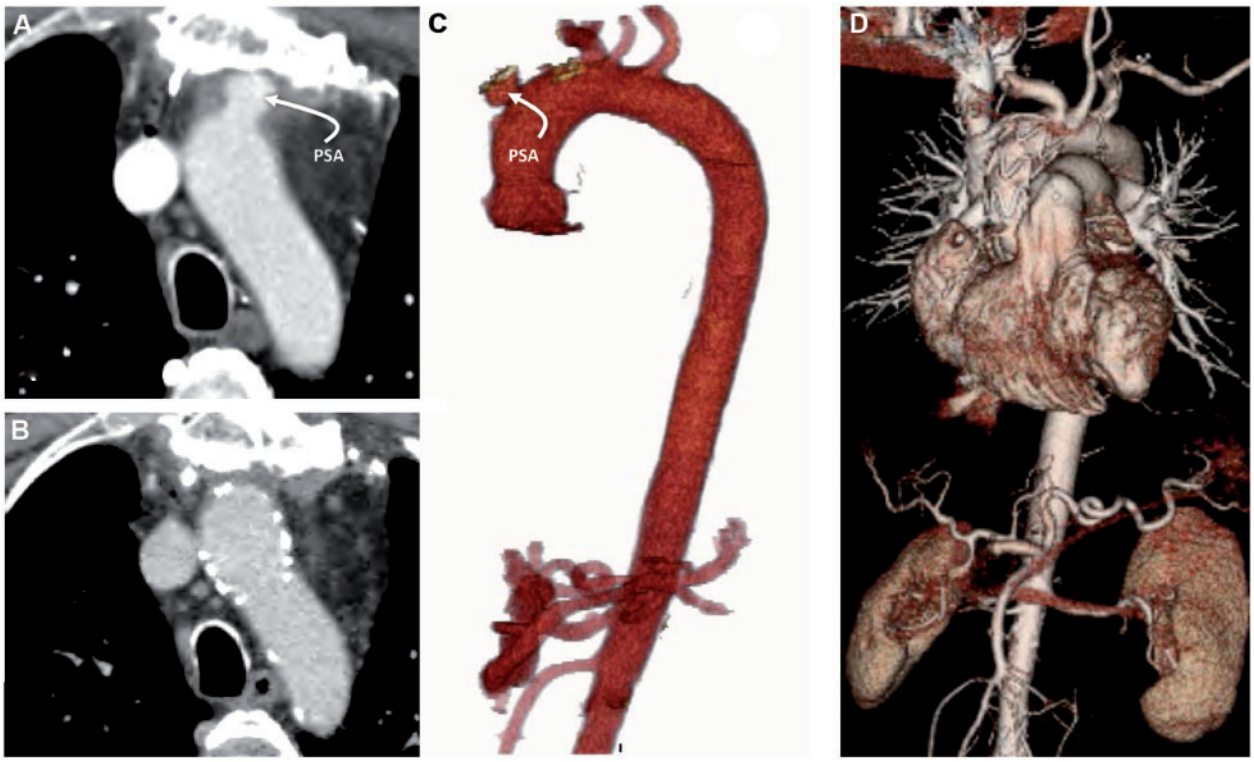

Figure 3: A 57-year-old male with cannulation site pseudoaneurysm (white arrows) following coronary artery bypass graft surgery. Axial image (**A**) shows the pseudoaneurysm was very close to the sternum originating from the anterior aspect of the outer curve of the ascending aorta (**C**). Follow-up computed tomography angiography (**B**, **D**) at 84 months shows the complete reabsorption of the pseudoaneurysm, as well as the intact structure and anatomic adaptation of the endograft to the ascending curvatures. PSA: pseudoaneurysm.

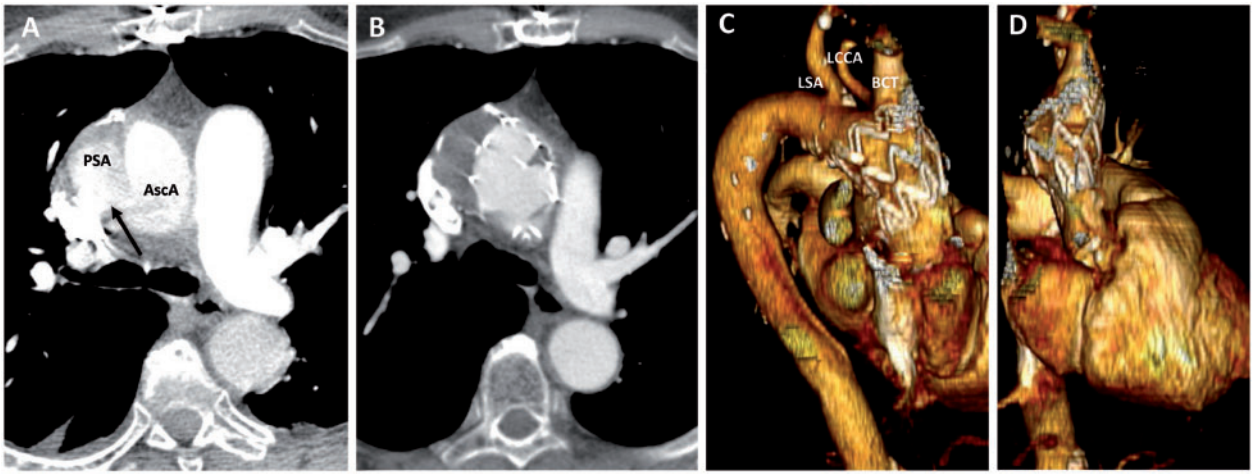

Figure 4: Preoperative computed tomography angiography (**A**) with multiplanar (**B**) reconstruction of a 75-year-old female with a suture-line disruption pseudoaneurysm (black arrow) after previous Bentall operation for an ascending aortic aneurysm. Follow-up computed tomography angiography (**B**) with volume rendering 3D reconstructions (**C** and **D**) at 36 months shows the good adaptation of the reversed tapered endograft as well as the complete exclusion of the pseudoaneurysm with the distal landing zone just before the origin of the brachiocephalic trunk. AscA: ascending aortic aneurysm; BCT: brachiocephalic trunk; LCCA: left common carotid artery; LSA: left subclavian artery; PSA: pseudoaneurysm.

Table 3: Case series summary: patient data, anatomy, technical details and outcome

Patient	Gender, age (years)	Aortic disease	Aortic diameter (mm, proximal) (months)	EuroSCORE-II	Aortic diameter (mm, distal)	CA-BCT distance (mm)	Device design	EG oversizing (%)	Size (mm diameter × length)	Outcome	ARM	Follow-up
# 1	M, 66	PSA	40	5.7	40	113	Straight	15	46/46 × 65	Alive	No	38
# 2	M, 61	PSA	34	6.1	20	65	Tapered	18	40/36 × 65	Dead	Yes	24
# 3	M, 81	Rupture	35	25.8	37	115	Straight	10	40/40 × 75	Alive	No	21
# 4	M, 75	Dissection	30	2.8	30	78	Straight	20	36/26 × 65	Alive	No	12
# 5	M, 57	PSA	26	10	30	70	Straight	15	30/30 × 65	Alive	No	84
# 6	F, 75	PSA	37	4.9	44	74	Reverse tapered	18	38/48 × 65	Alive	No	36
# 7	M, 84	Dissection	32	23.8	34	69	Straight	10	38/38 × 65	Dead	No	2
# 8	F, 62	Dissection	33	10.9	31	87	Straight	15	38/38 × 65	Dead	No	6
# 9	M, 81	PSA	42	40.9	40	94	Tapered	10	48/44 × 90	Alive	No	14

ARM: aorta-related mortality; BCT: brachiocephalic trunk; CA: coronary artery; EG: endograft; F: female; M: male; PSA: pseudoaneurysm.

and the ostia of coronary arteries may be compromised. Finally, the ascending aorta diameter increases during an acute event by up to 33%, which is most pronounced in the mid-ascending aorta [23]. Any oversizing in this context would be detrimental as the objective is to return the adventitia back to the intimal–medial layer and not vice versa. Only the aortic annulus remains stable and unaffected by the dissective process, making the Endobentall concept (combining transcatheter aortic valve implantation and TEVAR in a single device), which uses this as proximal sealing zone (with secondary sealing zones at the sinotubular junction level and at the level of the BCT), so promising. Such a disruptive approach could pave the way for a more standard aTEVAR, specifically in acute dissection [20].

Both early and aorta-related mortalities are also the 2 major outcomes in endovascular interventions. What is surprisingly favourable in the literature on aTEVAR is that clinical outcomes are satisfactory, especially if we consider that all patients treated with aTEVAR were deemed to be at high risk for open surgery, even in high-volume aortic centres where, regardless of the aetiology, ascending/arch reoperations entail an in-hospital mortality rate of 9–14% [17, 24, 25]. Ascending TEVAR appears to be a good alternative option for patients who would otherwise be treated by conservative therapy or an unacceptably high-risk open surgery defined by a multidisciplinary team evaluation, which is suggested by thoracic aortic guidelines [3, 22]. In our series, operative mortality was 0% despite a predicted mean 15% operative risk score. This risk prediction may be distorted as long as no risk stratification score for thoracic aortic disease is currently validated for endovascular treatment; in fact, current risk scores do not describe the actual risk in the specific group of aortic patients. Nevertheless, these data are supported by the sensitivity analysis of Baikoussis *et al.* [17] who estimated a pooled mortality rate of 2.9%. Both these figures are acceptable for such high-risk patients. The only shortcoming of our experience was the late development of an aorto-atrial fistula because of EG infection. This is a rare but increasingly reported complication after cardiac surgery, caused by iatrogenic or infectious processes in as much as 64% of the cases [26]. Although our series is limited in number,

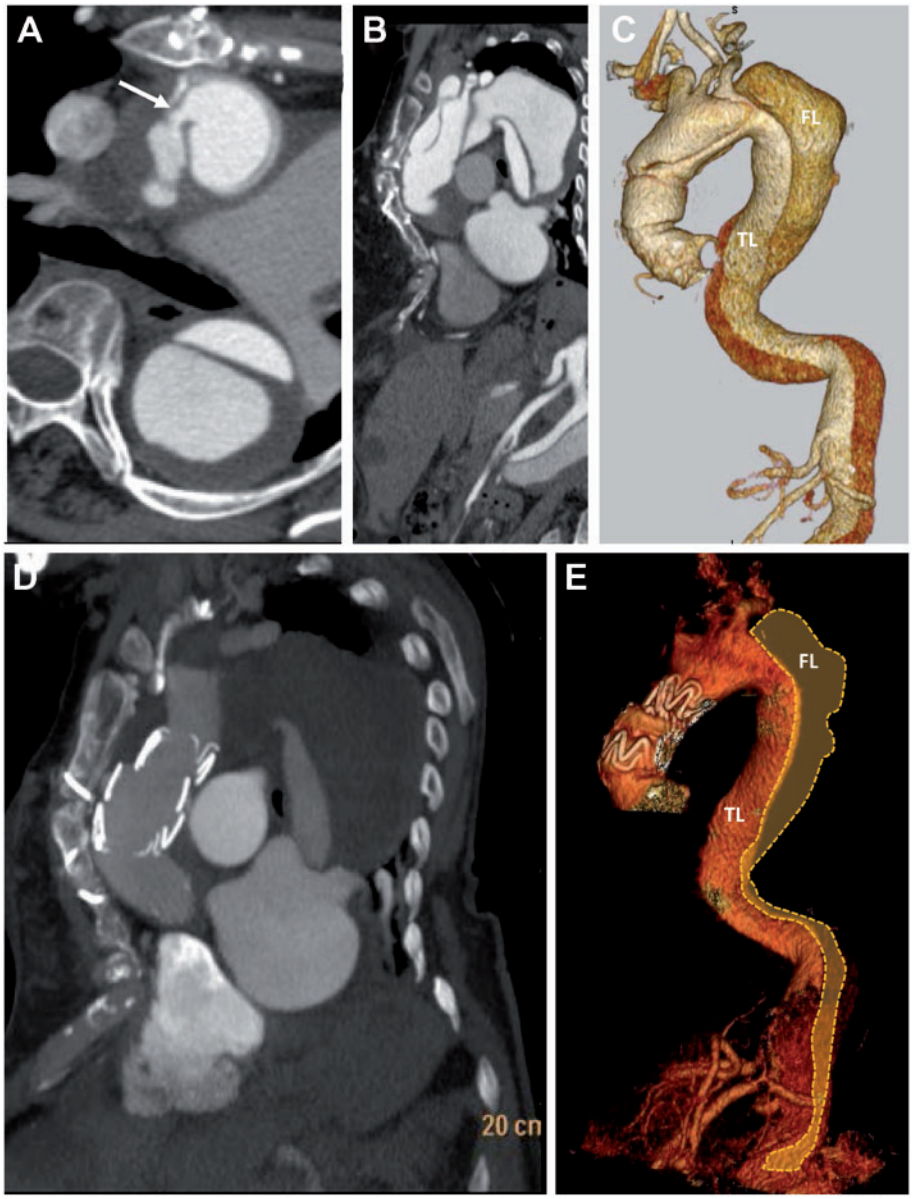

Figure 5: A 62-year-old female with a DeBakey type I dissection following an aortic valve repair plus ascending prosthetic graft replacement. Preoperative computed tomography angiography (**A**) with multiplanar (**B**) and volume rendering 3D (**C**) reconstructions shows the entry tear (**A**, white arrow) in the ascending aorta with a dilated false lumen and a non-collapsed true lumen. Postoperative computed tomography angiography with multiplanar (**D**) and volume rendering 3D (**E**) shows the complete remodeling in the ascending aorta with the complete thrombosis of the false lumen (orange area). FL: false lumen; TL: true lumen.

this means a 12.5% rate of late (≥6 months) major complication requiring reoperation/conversion to open surgery. Though potentially concerning, this result is in line with the 18% rate reported by Roselli *et al.* [3] in the largest single-centre experience published so far, and better than the 67% freedom from late aorta-related complications estimated on the current literature [6]. Secondly and most encouraging from a technical point of view, we observed that the CMDs maintained both structural integrity and lesion exclusion durability.

Finally, a word of caution should be made about the potential decrease of left ventricular ejection fraction overtime after very proximal TEVAR, which has been linked to increased arterial stiffness due to EG inability to comply with longitudinal movements during the cardiac cycle. These findings and their clinical relevance need to be confirmed or put into perspective [27, 28].

Limitations

There are several limitations of the current study. It is a retrospective analysis with individual cases from a large number of centres with heterogeneous indications for the procedure, as well as different device configurations and operative techniques. There is also sampling bias as patients undergoing total open repair were not included for comparison, but this reflects the careful selection process for these types of procedures.

CONCLUSION

In our experience, CMD for aTEVAR was feasible, safe, and effective with 100% technical success in deployment and lesion sealing

exclusion, and no operation-related mortality. Further studies are needed to reconfirm our results and to eventually enable a broader application. Despite 1 late reintervention, CMDs showed good ascending aorta adaptability with different EG configuration and diameters, and satisfactory mid-term durability as showed by both structural integrity and aortic lesion exclusion.

Conflict of interest: Martin Czerny, Vicente Riambau, Roman Gottardi and Michele Antonello are consultants for Terumo Aortic® and recipients of research grants to their institutions. The remaining authors declare no conflict of interests relevant for this study.

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Author contributions

Gabriele Piffaretti: Conceptualization; Data curation; Formal analysis; Methodology; Software; Supervision; Validation; Writing—original draft; Writing—review & editing. **Martin Czerny:** Data curation; Methodology; Supervision; Validation; Writing—original draft; Writing—review & editing. **Vicente Riambau:** Data curation; Validation. **Roman Gottardi:** Data curation; Supervision; Validation. **Thomas Wolfgruber:** Conceptualization; Validation. **Chris Probst:** Data curation; Validation. **Peter Matt:** Data curation; Validation. **Michele Antonello:** Data curation; Validation. **Gino Gerosa:** Validation. **Mohamad Hamady:** Data curation; Validation. **Federico Fontana:** Validation. **Sandro Ferrarese:** Validation. **Chiara Lomazzi:** Data curation; Supervision; Validation. **Viviana Grassi:** Data curation; Writing—review & editing. **Sebastian Fernandez-Alonso:** Data curation; Validation. **Santi Trimarchi:** Conceptualization; Data curation; Formal analysis; Methodology; Supervision; Validation; Writing—original draft; Writing—review & editing.

Reviewer information

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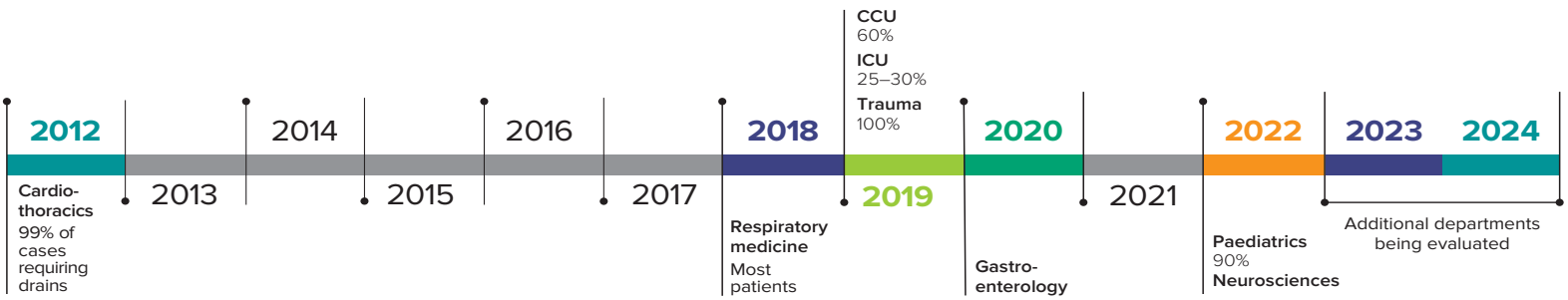
Real-world experience with Thopaz+

The Oxford University Hospitals NHS Foundation Trust experience

Thopaz+ is a portable digital chest drainage and monitoring system developed by Medela. It offers continuous objective monitoring of fluid loss and air leaks, which facilitates assessment of patients' progress, as well as standardisation of chest drainage management across different departments.[1] Clinical evidence has demonstrated that Thopaz+ is a useful tool in the management of patients that require chest drains and has clear clinical advantages compared with underwater seal drains.[1–3]

Thopaz+ and its predecessor, Thopaz, have been used within the Cardiothoracic Department at Oxford University Hospital NHS Trust since 2012. A report on this experience contributed to National Institute for Health and Care Excellence (NICE) Medical Technology Guidance 37.[1,4] Use of Thopaz+ in Oxford has since expanded to other departments within the trust. This document summarises the experience with Thopaz+ based on interviews with healthcare professionals (HCPs) at Oxford University Hospital NHS Trust in February/March 2024.

*Evolution of Thopaz+ use in Oxford: initial introduction by department and current usage**



*Percentage of cases using Thopaz+, where known from interviews.

CHEST DRAINAGE PROTOCOLS

Each department has a chest drain protocol based on their use of Thopaz+ or underwater seal drains, and whether active suction or physio mode is needed.

MOBILISATION

Improved and earlier mobilisation is a major advantage of Thopaz+ in relation to complications associated with immobility.

OBJECTIVE AND CONTINUOUS MONITORING LEADS TO IMPROVED DECISION-MAKING

Continuous monitoring improves chest drain decision-making by providing objective estimates/measurement of leakage. It helps determine when air leaks are resolving (allowing for earlier drain removal and discharge planning) or when further intervention is needed (such as referral to a surgeon).

LENGTH OF STAY

Digital drainage facilitates day-case procedures by giving HCPs confidence that their patients have no persistent air leaks or fluid loss.

RESPIRATORY

70% of patients following pleural intervention and 60% undergoing thoracoscopy return home the same day.

CORONARY CARE UNIT (CCU)

Length of stay of 7 days with Thopaz+ compared with 10 days with underwater seal drains.

THROUGHOUT THE PATIENT JOURNEY

Thopaz+ can be used throughout a patient's journey, which can reduce the possibility of issues and errors, because drains can become kinked or displaced whenever a device is changed. Suction can be added to a Thopaz+ device set up to provide straightforward drainage simply by pressing a button to initiate suction via the device itself.

COSTS AND EFFICIENCIES

The use of the device can lead to improved operational efficiencies and cost savings, which may justify the acquisition costs. From an evidence-based practice project in the USA, a digital air leak detection device after pulmonary lobectomy led to cost savings of $2,659 per hospital day.[5]

IMPROVED PATENT SAFETY

Thopaz+ is a closed system, reducing incidents, errors, mishaps, and infections. As a dry system, Thopaz+ prevents issues with water and device positioning. Non-medical staff can manage Thopaz+ if it is knocked over, with no patient impact. Thopaz+ has its own suction source, preventing complications with wall suction becoming displaced or unclipped.

STAFF EXPERIENCE

Precise fluid and air leak measurements including time trends, improve clinician confidence and decision-making and facilitate continuity of care. The user-friendly interface makes it easier to track air leaks and fluid output. Nursing time is saved with easy canister replacement, reduced manual monitoring, and visual and audible notifications alert HCPs of issues.

PATIENT EXPERIENCE

Patients can move around freely without nursing or healthcare assistant support. Earlier discharge reduces hospital stay. Patients can monitor their progress in terms of reducing volumes of fluid and air leaks on the display.

Summary of the real-world experience with Thopaz+

The experience of HCPs within Oxford University Hospitals NHS Foundation Trust over the past 12 years has shown that Thopaz+ has multiple benefits in the right circumstances and should be available for the vast majority of patients requiring a chest drain.

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> Overall, our experience at Oxford University Hospitals NHS Foundation trust has shown that Thopaz+ is an indispensable asset for HCPs, redefining standards of care and operational efficiency across multiple medical departments. We encourage all units using chest drains to consider making the move from underwater seal drains to Thopaz+ in the vast majority of patients requiring chest drainage.

Quotes from interviews with a number of healthcare professionals at Oxford University Hospital NHS Trust:

> From the NHS perspective, I think it probably allows us to make earlier decisions about withdrawing chest drains and getting peopleout of hospital earlier.

> There are a number of ways to recoup the costs: efficiencies in the system, less litigation because things don't go wrong, staff sickness due to back injuries, and length of stay if you can get patients home quicker.

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Read the full report:

The summary report has been written by HSJ Advisory on behalf of Medela AG, reflecting the views expressed in interviews with healthcare professionals. Medela AG funded the project and had input into the development of this report.

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