Prospective Multicenter Study of the Low-Profile Relay Stent-Graft in Patients with Thoracic Aortic Disease: The Regeneration Study

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Background: To evaluate the early safety and clinical performance of the new low-profile RelayPro Thoracic Stent-Graft System in patients with thoracic aortic disease.

Methods: This was an international, prospective, single-arm study in patients diagnosed with thoracic aorta disease (aneurysm, pseudoaneurysm, dissection, penetrating atherosclerotic ulcer, or intramural hematoma) and treated with a RelayPro stent-graft (in bare stent and/or non-bare stent configurations). The primary endpoints were freedom from aneurysm or dissection-related mortality and stent-graft performance.

Results: A total of 31 patients were treated with the RelayPro thoracic stent-graft between 2014 and 2015 at 8 sites in Italy and Spain. Mean age was 72.1 (±10.2) years and 77% were male, 74% with hypertension, and 42% with a history of smoking. Twenty-four (77%) had aneurysms (fusiform in 46%, saccular in 42%, pseudoaneurysm in 12%); 5 (16%) had penetrating atherosclerotic ulcer; and 2 (6%) had chronic Type B dissection. Mean vascular access diameter was 9.1 mm (6−13 mm); 7 patients (23%) had vascular access of 7 mm or less. Technical success was 100% (primary, 90%; assisted primary, 10%). Freedom from aneurysm/dissection-related mortality through 30 days was 100%. Freedom from device-related major adverse events through 30 days was 94%. At 1 year, there was 1 (3%) type Ib and 1 (3%) type II endoleak, 1 (3%) nonaneurysm-related late death, and 1 (3%) secondary intervention (to correct type Ib endoleak).

Conclusions: The RelayPro has a 3−4 French profile reduction to allow endovascular repair of thoracic aortic disease in patients with smaller anatomies. This study shows good initial stent-graft performance and a favorable early safety profile.

INTRODUCTION

Thoracic aortic disease (TAD) is a group of pathologies that includes thoracic aortic aneurysms (TAAs), dissections, intramural hematomas (IMHs), penetrating atherosclerotic ulcers (PAUs), and aortic transections.[1] Open surgery reduces rupture risk

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compared with nonsurgical management over the long-term, but perioperative mortality rates are 12–44%.[2,3] Since its introduction, thoracic endovascular aneurysm repair (TEVAR) has been shown to be an effective and safe alternative to open surgical repair.[4–6] Improvements in devices, stent-graft diversity, and imaging now allow endovascular treatment options to patients who are considered physiologically unfit or unsuitable for open repair.[7–9] However, large-caliber delivery systems restrict TEVAR eligibility in patients with narrow or tortuous access vessels, with the need of an iliac conduit or predilation in 9–21% of cases.[10] As access vessels anatomy is also a predictor of perioperative complications, lowering the delivery profile of stent-grafts is an important development in this technology.[11,12]

More than 19,000 TAD patients worldwide have received a Relay stent-graft (Terumo Aortic, Sunrise, Fla) since 2005 when the first conformité européenne mark was granted. The second-generation RelayPlus device was approved by the FDA in 2012. Technical and clinical outcomes were evaluated in 2 prospective multicenter clinical registries. The Relay Endovascular Registry for Thoracic Disease studies (RESTORE and RESTORE II) reported results from first- and second-generation stent-graft devices (Relay, RelayPlus, Relay nonbare stent [NBS] Plus), respectively.[13–15] A pivotal U.S. Investigational Device Exemption (IDE) trial (NCT00435942) has also reported initial and midterm results on 133 patients treated with Relay (38 with RelayPlus) and 60 surgical control patients.[16] The 3–4 French profile reduction of the new RelayPro is expected to offer operative advantages in terms of stent-graft introduction and deployment, particularly in patients with narrow or tortuous access vessels.

MATERIAL AND METHODS

Device Description

The RelayPro Thoracic Stent-Graft System comprises self-expanding electropolished nitinol, sinusoidal stents that are sutured to tight woven polyester graft fabric for profile reduction. The wire diameter and design are identical to the Relay and RelayPlus thoracic stent-grafts, where no stent fractures were observed at 5 years of follow-up.[16] The RelayPro also has a shorter longitudinal curved nitinol wire compared with the previous generation that provides longitudinal support throughout the length of the device and enhances stent-graft conformability to the aortic arch and double-curved aortic anatomies.

RelayPro is available in 2 proximal end configurations; the bare stent (proximally uncovered stent, Fig. 1) and the NBS (proximally covered stent, Fig. 2); the bare stent has an uncovered, sinusoidal nitinol wire, and the NBS has a sinusoidal nitinol stent plus a crown-shaped nitinol stent that are both covered with fabric. All stent-grafts have platinum/iridium radiopaque marker bands, indicating the fabric edge and the spiral support strut. The new markers have been evaluated under micro–computed tomography (CT) scan studies to optimize positioning and contribute to profile reduction.

RelayPro incorporates a 3–4 F reduction of the delivery system profile: 19–22 F (23 F in the NBS configuration) compared with 22–26 F of the previous platform. The delivery system (Fig. 3) consists of a series of coaxially arranged sheaths and catheters, along with a tubular handle control system. The tip and the new thin-wall coiled primary introducer sheath have hydrophilic coating and a total working length of 90 cm.

Deployment comprises 2 stages: the first involves advancing the new, hydrophilic, thin-wall, coiled outer sheath; the second involves advancing a flexible inner sheath containing the compressed stent-graft. The dual-sheath system and the flexibility of the inner sheath allow fluid movement through tortuous and curved portions of the thoracic aorta.

In the NBS configuration, there are 2 heart-shaped nitinol wires (support wires) attached to the delivery system catheter. The distal end of the support wires present atraumatic tips that are tethered to the inferior proximal portion of the graft. The support wires are designed to control the expansion of the inferior portion of the graft and ensure proper apposition against the aortic inner curvature at the level of the arch, avoiding the so-called ''bird beak'' effect.

Study Design

The Regeneration study (NCT03207568) was a prospective, multicenter, single-arm study in patients with TAD who were eligible for TEVAR using the RelayPro thoracic stent-graft. Between 2014 and 2015, 8 sites (4 each in Italy and Spain) prospectively enrolled patients with TAD based on routine clinical assessment performed as part of the patients' standard care. All patients gave written informed consent before inclusion. Procedures were performed in accordance with Instructions for Use and local routine practice. Patients were discharged and followed up per standard clinical practice. Ethical approval was given by the institutional review board at each participating center, and the study was conducted in accordance with the Declaration of Helsinki (Fortaleza, Brazil 2013).

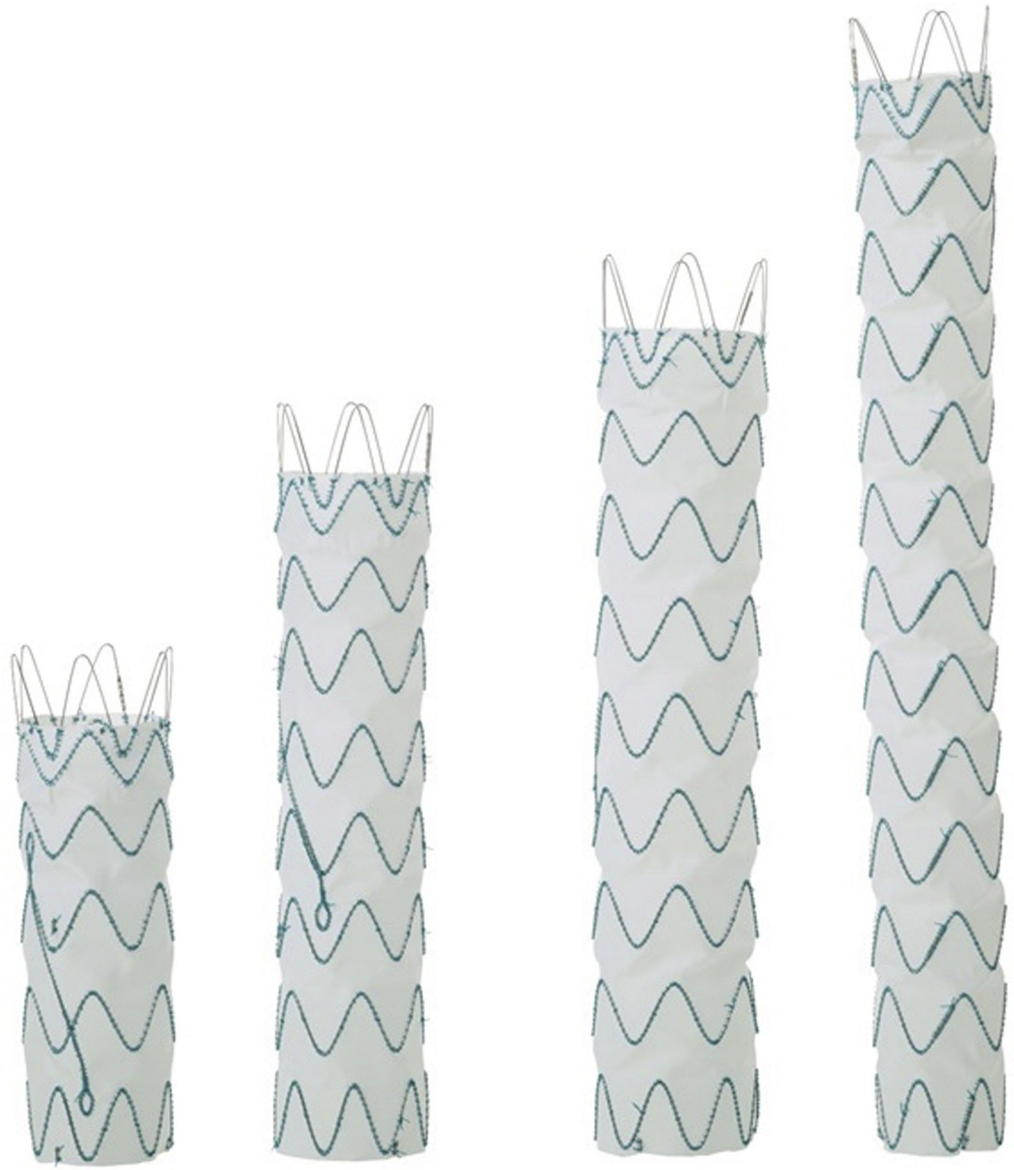

Fig. 1. The proximal bare stent RelayPro stent-graft, with the longitudinal curved nitinol wire visible on the 2 devices on the left that provides support and conformability.

Criteria for inclusion were consenting adult men and women with TAD (aneurysm, pseudoaneurysm, dissection, PAU or IMH); diagnosis confirmed within 3 months of the procedure (via contrast enhanced CT or magnetic resonance imaging); suitability for TEVAR; proximal and distal aortic neck diameters 18−42 mm; adequate proximal and distal landing zones; and adequate vascular access for insertion of the delivery system (19−23 F outer diameter). Excluded were patients with lesions requiring a delivery system with usable length >90 cm; aortic inner diameters unable to accommodate expanded inner secondary sheath outer diameter (approximately 10 mm); current or prior allergic or hypersensitive reactions to radiographic contrast medium, anticoagulants, polyester, nitinol, or any Relay stent-graft component; prior repair (endovascular or surgical) in the target aortic segment; and participation in chemical or medical stent-graft investigational clinical studies within 3 months or 1 year, respectively.

Outcomes

The primary endpoints were freedom from aneurysm/dissection-related mortality and stent-graft performance. Aneurysm/dissection-related mortality was defined as any death within 30 days of the procedure

Fig. 2. The RelayPro nonbare stent (NBS) proximal configuration consists of a sinusoidal nitinol stent plus a crown-shaped nitinol stent that are both covered with fabric. The longitudinal curved nitinol wire is visible on all the 4 devices.

Fig. 3. The RelayPro delivery system provides for a 3–4 F size reduction compared with previous generation.

and thereafter all deaths due to the treated pathology, including fatality caused by aneurysm rupture, a primary or secondary procedure, surgical conversion, or complications of TEVAR leading to new aortic pathology (e.g., retrograde dissection leading to fatal cardiac tamponade).[17] Stent-graft performance was evaluated by the technical success rate. Technical

success was defined as complete exclusion of aneurysm, absence of endoleak, complete covering of traumatic rupture, and complete covering of entry tear with increase of true aortic lumen in dissection cases. Complications were classified and graded as described in the reporting standards.[18] The secondary endpoint was freedom from device-related major adverse events (MAEs) through 30 days, which included types I, III, or IV endoleaks, stent migration (>10 mm), lumen occlusion, aorta rupture, and conversion to surgical repair.

Data Analysis

Continuous data were reported as mean and standard deviation (SD) or median and range, depending on normality assumptions. Categorical data were reported as counts and percentages. All data were managed and analyzed with SAS 9.4 (2010 by SAS Institute Inc., Cary, NC).

RESULTS

Patient Flow and Characteristics

A total of 32 patients were enrolled between 2014 and 2015. One patient was excluded before the procedure due to heavy calcification at the planned access site, so 31 patients finally underwent TEVAR with a RelayPro stent-graft. Median (SD) follow-up was 404.5 (±211.5) days for 30 patients (one patient was lost to follow-up).

Key patient characteristics included mean age of 72.1 years, 77% male, 74% with hypertension, and 42% with history of smoking (Table I). Twenty-four patients (77%) presented with TAA (Table II). The morphology was fusiform in 46% of cases and saccular in 42%; 3 patients (12%) presented with a pseudoaneurysm. The median time (range) from TAA diagnosis to treatment was 37 (2−354) days. Seven patients (23%) were treated for nonaneurysm etiology: 5 (16%) with PAU and 2 (6%) with chronic Type B dissection. In this subgroup, the median time from diagnosis to treatment was 16.5 (2−64) days.

Procedural Results

The choice of stent-graft configuration was an investigator decision: 16 (52%) patients received the bare stent device, 14 (45%) received the NBS, and 1 (3%) patient received both configurations. A total of 26 (84%) patients underwent the surgical procedure under general anesthesia, and 1 patient had cerebrospinal fluid drainage (Table III). Mean vascular access diameter at the level of the iliofemoral vessels was 9.1 mm (6−13 mm) with 7 patients (23%) with vascular access of 7 mm or less. Twenty-one patients (67%) were treated with a percutaneous femoral approach. Zones 0−3 in the aortic arch (Z0−Z3) were targeted for proximal landing in 48% of cases according to the Ishimaru classification.[19] One patient had surgical debranching of the innominate artery (IA) and the left common carotid artery (CCA) from the ascending aorta, 1 patient had IA to left CCA to left subclavian artery (LSA) bypass (Fig. 4), 2 had right CCA to left CCA to LSA bypasses (Fig. 5), and 6 patients had left CCA to LSA bypasses. Seven patients (22%) required stent-graft ballooning, 5 in the bare stent cohort (1 to fix an endoleak, 4 to achieve a better stent-graft expansion and apposition) and 2 in the NBS cohort (performed as part of standard practice at institution). Primary technical success was achieved in 28 cases (90%). Three patients required a proximal extension due to intraoperative type Ia endoleak; all 3 procedures (10%) qualified as assisted primary technical successes after the adjunctive maneuvers. All patients completed the intervention with aneurysm exclusion or coverage of the entry tear (Table IV).

Safety

Two patients (6%) with access vessel diameters of 10 mm and 8 mm, respectively, had vascular access complications. One patient had access site hematoma and a second had ruptured access site false aneurysm; both events were grade 1 (mild) (Table IV). Other grade 1 (mild) complications were fever ($n = 2$, 6%); operative bleeding ($n = 2$, 6%); and 1 cardiac event (3%).

No patient died through 30 days of follow-up. There were 2 type I endoleaks (one each type Ia and Ib), and no reinterventions were performed within 30 days of follow-up. Freedom from MAEs at 30 days was 94%. There was one grade 2 (moderate) systemic complication that delayed recovery due to cerebrovascular accident (stroke, 3%): this was the patient treated with both a RelayPro and an NBS stent-graft (220 mm lesion length). The patient had a previous debranching with rerouting of the IA and left CCA into the ascending aorta to accommodate the proximal landing zone (Z0). After successful device implantation, the patient developed near occlusion of the left CCA believed to be the cause of speech impairment with right arm and leg loss of strength. The patient was followed until partial recovery (confirmed 10 weeks after the endovascular procedure). No paraplegia or paraparesis was reported.

Table I. Baseline demographic and clinical data

	$n = 31$
Age, years	
Mean (SD)	72.1 (±10.2)
Median (range)	75.0 (39–85)
Male, *n* (%)	24 (77%)
ASA class ≥3, *n* (%)	7 (23%)
Risk factors[a], *n* (%)	
Hypertension	23 (74%)
History of smoking	13 (42%)
Prior AAA	12 (39%)
Hypercholesterolemia	9 (29%)
Hyperlipidemia	8 (26%)
COPD	7 (23%)
Diabetes	5 (15%)
Coronary artery disease	4 (12%)

AAA, abdominal aortic aneurysm; ASA, American Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease.
[a]Occurring in at least 10% of patients.

Table II. Disease characteristics

	$n = 31$
Aneurysm, *n* (%)	24 (77%)
Aneurysm morphology, *n* (%)	
Fusiform	11 (46%)
Saccular	10 (42%)
Pseudoaneurysm	3 (13%)
Days since diagnosis, median (range)	37 (2–354)
Aneurysm measurements (mm), mean (SD)	
Lesion length	109.7 (±67.8)
Proximal neck length	28.5 (±14.5)
Distal neck length	37.8 (±18.5)
Maximum lesion diameter	58.6 (±16.1)
Aortic diameter proximal to lesion	32.1 (±4.8)
Aortic diameter distal to lesion	30.0 (±4.5)
Nonaneurysm etiology, *n* (%)	7 (23%)
PAU	5 (16%)
Dissection (degenerative, type B)	2 (6%)
Days since diagnosis, median (range)	16.5 (2–64)
Nonaneurysm etiology measurements (mm), mean (SD)	
Lesion length	68.0 (±44.5)
Proximal neck length	35.0 (±29.3)
Distal neck length	33.6 (±9.5)
Maximum lesion diameter (PAUs only)	38.0 (±4.2)
Aortic diameter proximal to lesion	27.9 (±3.6)
Aortic diameter distal to lesion	25.3 (±4.1)

Table III. Intraoperative data

	$n = 31$
Anesthesia	
General	26 (84%)
Regional/local	5 (16%)
Intended landing zone, *n* (%)	
Z0	1 (3%)
Z1	3 (10%)
Z2	6 (19%)
Z3	5 (15%)
Z4	16 (52%)
Access site diameter (mm)	
Mean	9.1
Range	6–13
Stent-graft used	
RelayPro	16 (52%)
Relay NBS Pro	14 (45%)
Both	1 (3%)
Mean number of units per procedure	1.39
Number of stent-grafts used, *n* (%)	
1	21 (68%)
2	8 (26%)
3	2 (7%)
Planned additional device	7 (23%)
Unplanned additional device	3 (10%)
Percutaneous access, *n* (%)	21 (68%)
Additional procedures, *n* (%)	10 (31%)
Ballooning maneuver, *n* (%)	7 (22%)

Other adverse events (not qualifying as complications according to Chaikof et al.) included back pain (3 events in 3 patients); pain in extremity (2 events in 2 patients); and pyrexia (2 events in 2 patients).[18] One patient had adverse events which combined qualified as serious (tracheobronchitis, urinary tract infection, and inadequately controlled diabetes mellitus); the patient died because of medical complications 6 weeks after implant.

Device Performance

There was one type II endoleak at discharge that resolved spontaneously; another was recurrent at 1 year but did not require treatment. There was no migration, lumen occlusion, aorta rupture, kinking, or conversion to surgical repair during follow-up. At 30 days, one patient had a minimal type Ia endoleak: the patient previously underwent IA to left CCA to LSA bypass for a Z1 deployment, and the resulting aortic landing zone allowed contrast to be filtered via the left CCA and LSA stumps into the sac. The investigator was confident the problem would resolve spontaneously, did not treat, and subsequently confirmed that the endoleak was not present at the 6-month CT scan. One patient had a type Ib endoleak (treated after 15 months with an additional device and associated with <10 mm distal migration).

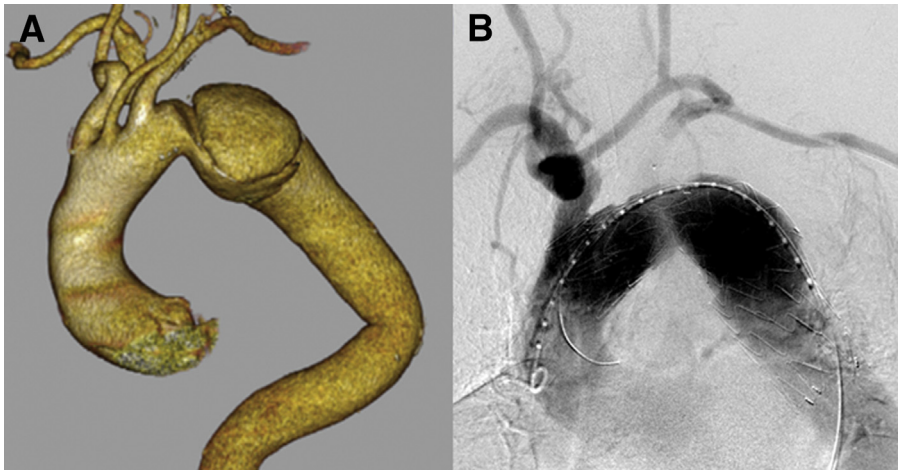

Fig. 4. Preoperative image **(A)** of 80-year-old man with 91 mm thoracic aortic aneurysm and **(B)** intraoperative angiogram after innominate artery to left carotid to left subclavian artery bypass and implant of RelayPro (courtesy of Dr Giudice, Rome, Italy).

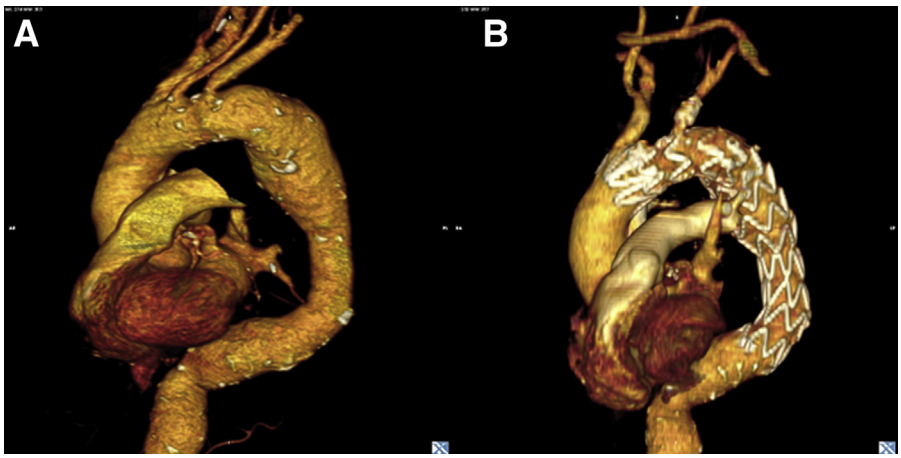

Fig. 5. Preoperative image **(A)** of 75-year-old man with 60 mm thoracic aortic aneurysm and **(B)** postoperative image after right carotid to left carotid to left subclavian artery bypass and implant of RelayPro (courtesy of Dr Giudice, Rome, Italy).

DISCUSSION

In the last 2 decades, endovascular repair has progressively developed to be applied to more segments of the aorta, to simplify delivery, to improve accuracy in deployment, to ensure fixation and seal, and to reduce profile to accommodate smaller access vessels without compromising strength and durability.[18] Smaller access vessels are a predictor of perioperative complications and restrict eligibility for women, Asians, and young patients: populations who generally have smaller iliac diameters and who represent a greater share of thoracic aortic pathologies (in comparison with abdominal).[20,21] Masuda et al. reported an access-related complications rate of 12% that was statistically associated with Asian ethnicity (patients with a mean 8.2 mm external iliac artery diameter), age > 80 years, and external iliac diameters smaller than 7.5 mm.[22] A meta-analysis by Georgiadis et al. showed that smaller delivery sheaths in endovascular repair had better access vessel closure.[23]

The Cook Zenith Alpha study evaluating a 18–23 F device (outer diameter) in 110 patients hypothesized that a smaller insertion platform would lead to better TEVAR outcomes and demonstrated a 4% rate of MAEs at 30 days in a population with large percentages of patients with smaller anatomies (42% women; 38% Asian ethnicity).[24] Stroke rates were 1.8% and 5.0% (at 30 days and 12 months, respectively); secondary intervention rates were

Table IV. Technical and clinical results

	$n = 31$
Technical success	31 (100%)
Primary technical success	28 (90%)
Assisted primary technical success	3 (10%)
Complications (to 30 days)	
Freedom from device-related major adverse events	29 (94%)
Endoleak type Ia[a]	1 (3%)
Endoleak type Ib[b]	1 (3%)
Endoleak type II	2 (6%)
Endoleak types III, IV	0 (0%)
Vascular access (grade 1)	2 (6%)
Fever (grade 1)	2 (6%)
Operative bleeding (grade 1)	2 (6%)
Cardiac (grade 1)	1 (3%)
Cerebrovascular (grade 2)[c]	1 (3%)
Distal neuropathy	1 (3%)
Thoracic pain	1 (3%)
Migration	0 (0%)
Lumen occlusion	0 (0%)
Rupture	0 (0%)
Conversion to open surgery	0 (0%)
Complications (to 1 year)	
Endoleak type Ia	0 (0%)
Endoleak type Ib[b]	1 (3%)
Endoleak type II (recurrent)	1 (3%)
Endoleak types III, IV	0 (0%)
Migration[d]	0 (0%)
Lumen occlusion	0 (0%)
Rupture	0 (0%)
Conversion to open surgery	0 (0%)
All-cause mortality	
Operative deaths	0 (0%)
Late deaths (1 month to 1 year)	1 (3%)
Aneurysm-related mortality	
Operative deaths	0 (0%)
Late deaths (1 month to 1 year)	0 (0%)
Secondary interventions[b]	1 (3%)

[a]Minimal: after an IA to left CCA to LSA bypass and stent-graft deployment, the resulting aortic landing zone allowed contrast to be filtered via the left CCA and LSA stumps into the sac; resolved spontaneously at 6-month follow-up.
[b]An additional device was used after 15 months to correct a type Ib endoleak.
[c]Stroke with partial recovery 10 weeks after implant.
[d]One patient with a type Ib endoleak also had <10 mm distal migration at 1 year.

0.9% (30 days) and 1.8% (12 months); type I/III endoleaks were 3.0% (30 days) and 3.6% (12 months); a mean 1.85 devices were used per patient, and there was a single and asymptomatic wire form fracture at 1 year.[24]

Another study comparing 33 patients treated with the low-profile Cook Zenith Alpha stent-graft (group ZA) with 34 patients treated with the standard Zenith TX-2 (group TX) showed similar rates of technical success (93.9%, ZA; 91.2%, TX) and type I endoleaks (6%, ZA; 9%, TX); 30-day mortality was 9.1% in the ZA group and 0% in the TX group ($P = 0.07$); differences in mean minimum access vessel diameters (5.07 mm, ZA; 6.65 mm, TX $P = 0.002$) and iliac tortuosity indices (1.34, ZA; 1.25, TX $P = 0.02$) were significant.[25] The same institution subsequently reported a total of 70 patients who received the Zenith Alpha stent-graft with a follow-up of 22.3 (±15.9) months, showing ongoing clinical success of 87.1%, 4.3% type Ia endoleak, 2.9% type Ib, and 1.4% secondary intervention rate.[26]

The Medtronic Valiant Evo study evaluating the new Valiant Navion 18−22 F thoracic stent-graft started in April 2016 and is ongoing (no results published to date).

In our study, RelayPro demonstrated favorable short-term safety and performance results in a challenging patient population with expanded anatomical indications; the 31 study patients with aneurysm (77%) and nonaneurysm (23%) pathologies had a mean access site diameter of 9.1 mm (6−13 mm) with 7 of them (23%) with access vessels diameter ≤ 7 mm. Twenty-one patients (67%) were treated percutaneously. Comparisons between the 2 configurations of the RelayPro (bare stent and NBS) were planned and calculated using the Fisher's exact test or chi-squared test, but no significant differences were noted and so results are presented for the entire cohort. No aneurysm or dissection-related mortality occurred; overall technical success was 100% (primary 90%; assisted primary 10%), and the occurrence of device-related MAEs at 30 days was 6%.

Three patients (10%) required intraoperative proximal extension to fix a type Ia endoleak. We attribute the rate of unplanned adjunctive procedures to the learning curve associated with the delivery system. Operators can precisely position the proximal portion of the stent-graft at initial (partial) deployment and then fully release the prosthesis in an uninterrupted motion. Failure to deploy fully the device in a continuous motion can lead to migration when systolic blood pressure is high and the stent-graft offers resistance.

In comparison with the RelayPlus device in the RESTORE II registry, all-cause mortality was similar; 3% RelayPro versus 4% RelayPlus.[14] Systemic complications were lower for RelayPro, with 1 cardiac and 1 cerebrovascular (stroke) complication reported (3% in each case); the RelayPlus device reported 5 (2.9%) cardiac, 1 pulmonary (0.6%), 7 renal (4.0%), and 4 other (2.3%) complications.

The results also compare favorably with the data from 133 patients who received the RelayPlus stent-graft as part of the U.S. IDE trial: 5% aneurysm-related mortality; 20% 30-day MAE rate; and 1% type I endoleak.[16]

These RelayPro results are also in line with data reported for larger bore thoracic stent-graft systems, despite variability in aneurysm morphology, patient populations and anatomy, and study design. In the GORE CTAG European multicenter registry, for example, 100 patients (with comparable distribution of pathologies but with 33% emergency cases) showed 92% primary technical success and the following 30-day results: 90% survival; 34% major complications rate (1% primary type Ia endoleak; 4% paraplegia; 11% stroke).[27] In the GORE CTAG U.S. trial with 66 patients treated, stroke and reintervention rates were both 1.5% at 1 year, whereas the incidence of type I/III endoleak was 3.4%.[28] Medtronic Valiant Captivia registry reported 100 patients treated for aneurysm and aortic dissection with 100% technical success; 4% 30-day all-cause mortality (3 device related); retrograde type A dissection in 2 patients; conversion to open surgery in 1 patient; 4% stroke; 6% type I endoleak.[29] In the pivotal Medtronic Valiant U.S. trial (VALOR II) at 1 year, aneurysm-related mortality and type I/III endoleak rates were both 4%, stroke rate was 6.5%, and secondary intervention rate was 1.2% in 160 patients.[30]

Difficult access vessel anatomy represents a major limitation of TEVAR; newer stent-graft devices must therefore address those patients with smaller access vessels with lower profiles, but without compromising outcomes. The RelayPro profile was reduced without altering the wire diameter of the existing Relay stent-graft platform; the expectation is that the durability already demonstrated (no stent fractures reported at 5 years in the U.S. IDE trial) will be maintained.[16] The results of this study must be interpreted within its limitations that include a small sample size, a limited geographic area, and a limited follow-up period.

CONCLUSION

This prospective, multicenter study reports the operative and early results of the low-profile RelayPro stent-graft that allows endovascular repair of patients with smaller anatomies. The results show a high level of stent-graft performance and a favorable safety profile for the treatment of thoracic aorta disease. Ongoing follow-up will help to confirm the long-term safety, performance, and durability of the RelayPro.

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