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A New Technical Solution in Custom-Made Aortic Stent Graft for Complex Aortic Aneurysms

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Abstract

Background: The endovascular treatment of aortic aneurysm with complex anatomy, requires adjunctive procedures for anchoring, sealing and visceral arteries perfusion, with increase of morbidity and mortality. A new custom-made Aortic Stent Graft (ASG) platform, the Dominus (Braile Biomedica®, São José do Rio Preto, Brasil) modified on the design of Endovsmarts.r.l.™ (Bergamo, Italy), based on the principle of the radial force modulation, is available in the market, simplifying the procedure. The study focuses on device design, technical features and results.

Methods: We treated 4 patients: 2 with abdominal aortic aneurysm and 2 with thoraco-abdominal aortic aneurysm, previously rejected by the others manufacturers, due to at least one of the following anatomical complexities: 78° aortic arch angle, 30° descending thoracic aorta angle, 40 mm aortic diameter at the level of renal arteries, 90° alfa angle, 60° abdominal aortic angle, and 6 mm iliac access diameter.

The primary endpoints were 30-day clinical and technical success. The follow-up was made by physical examination and computed tomography angiography at 1,3,6 months and then yearly.

Results: The thirty-day clinical and technical success was 100%. There was not any neurologic event. The mean fluoroscopy time, contrast medium volume and, time of procedure, were respectively 17.2 min, 300 ml, and 228 min.

In 1 case occurred the postoperative laceration of the external iliac artery, treated by a covered stent. The mean time of hospitalization was 4.4 days. During the 16 months median follow-up the patients were well and the computed tomography angiography confirmed the exclusion of the aneurysms and supraortic and abdominal visceral arteries patency.

Conclusions: In this preliminary experience, the new Dominus ASG platform allowed the effective endovascular exclusion of complex aortic aneurysms, otherwise un-treatable with the current available devices. More cases and longer follow-up are required for validating these encouraging outcomes.

Keywords: Pararenal aortic aneurysm; Thoraco-abdominal aortic aneurysm; Stent-graft; Fenestrated graft; Branched graft; Endovascular procedures

Abbreviations: ASG: Aortic Stent Graft; ETAA: Endovascular Treatment of Aortic Aneurysm; LZ: Landing Zone; CTA: Computed Tomography Angiography; EIA: External Iliac Artery; VA:Visceral Arteries; AAA:Abdominal Aortic Aneurysms; TAAA: Thoraco-Abdominal Aortic Aneurysm; CM: Contrast Medium; ICU: Intensive Care Unit;s-ICU: Sub-Intensive Care Unit; PL: Proximal Landing; CT: Coeliac Trunk); SMA: Superior Mesenteric Artery; RRA: Right Renal Artery; LRA: Left Renal Artery; BB: Bird-Beak; ET: Elephant Trunk; PRAA: Para-Renal Aortic Aneurysm; RRAA: Renal Arteries; JRAA: Juxta-Renal Aortic Aneurysm; F-EVAR: Fenestrated Endovascular Aneurysm Repair; B-EVAR: Branched Endovascular Aneurysm Repair; PG: Parallel Graft; PLZ: Proximal Landing Zone; LSA: Left Subclavian Artery

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Introduction

The Endovascular Treatment of Aortic Aneurysm (ETAA) has increased dramatically in the last decades because the lower morbidity and mortality. The ASG, must be delivered at the level of an healthy Landing Zone (LZ). If the LZs are un-suitable [1-3], several demanding procedures such as Fenestrated or Branched stent-grafts or Parallel Grafts have been designed to extend in healty aorta [4-6]. A new custom-made ASG platform, the Dominus™ (Braile Biomedica®, São José do Rio Preto, Brasil on the design of Endovsmarts.r.l.™, Bergamo, Italy), is available on the market for simplifying the procedure. This ASG relies on the principle of modulating the radial force. We report our preliminary experience, focusing on the device design, the technical features and the early results.

Methods

The study was conducted in our tertiary vascular referral hospital between January 2018 and December 2019. The use of the Dominus ASG platform was approved by the hospital Ethic Committee. All patients were classified as high risk for open surgery (**Table 1**) and gave their written informed consent for the procedure and personal details publishing.

Anatomic criteria: All the patients underwent to preoperative Computed Tomography Angiography (CTA), (Phillips Brilliance Extended Workspace CT 16-slice, Eindhoven, The Netherlands) of the thoraco-abdominal aorta. The CTA images were processed by 3-dimensional reconstruction software (OsiriX; Pixmeo SARL, Bernex, Switzerland). The Dominus ASG was indicated on patients, previously rejected by other current commercially available

Table 1. Clinical characteristics and procedural details of 4 patients treated in the preliminary Dominus Biomedica® ASG study.

Clinical characteristics					
	Case 1	Case 2		Case 3	Case 4
Demographics					
Age, years	61	73		82	82
Sex	female	female		female	male
Associated disease					
Cigarettes smoking	N	Y		Y	Y
Porphirya	Y	N		N	N
Sclerodermia	Y	N		N	N
Arterial hypertension	Y	Y		Y	Y
Chronic renal disease stage 2	Y	N		N	N
Ascending aorta substitution	Y	Y		N	N
Chronic obstructive pulmonary disease	Y	Y		N	Y
Hypercolesterolemia	Y	N		N	N
Heart failure	N	N		Y	N
Type 1 diabete	N	N		N	Y
AAA open repair	N	N		N	Y
American Society of Anestesiology class					
3	N	Y		Y	Y
4	Y	N		N	N
Serum cretinine concentration, mg/dl	1,39	Fs 0,87 Ss 0,57		1	0,59
Procedural details					
	Case 1	Case 2		Case 3	Case 4
General approach		Fs	Ss		
General endotracheal anestesia	Y	Y	Y	Y	Y
Cerebrospinal fluid drainage	Y	N	N	N	N
Estimated blood loss, mL	1450	900	600	100	1000
Red blood cells units transfusion	3	2	0	1	2
Percutaneous right femoral artery access	Y	Y	Y	Y	Y
Percutaneous left femoral artery access	Y	N	N	Y	Y
Rigth brachial artery access	Y	Y	Y	N	Y
8 Fr sheat	Y	Y	Y	N	Y

*AAA: Abdominal Aorta Aneurysm; Y: Yes; N: No; FS: First Stage; SS: Second Stage devices [7-11], because of the proximal LZ, aortic angulation, External Iliac Artery (EIA) diameter and aneurysmal involvement of Visceral Arteries (VA), scored as severe or difficult[1-3,12].

Device constructive design: The Dominus™ platform carries an ASG up to 50 mm in diameter with, at the occurrence, 4 external or internal pre-wired branches. The minimum required proximal and distal LZ starts from 10 mm in length with an aortic neck inner diameters up to 46 mm. The different stents configuration, amplitude of the fenestrations and the presence of bared stents interconnected by Dacron collars and patches, modulate the radial force, allowing the adaption of the ASG with the complex anatomy and the patency of VA. The ASG is constrained within the radiopaque, polymeric, hydrophilic sheath that facilitates the progression of the device in the tortuous anatomy. The retraction of the sheath, by a trigger handle or by a pull-back manouvre, delivers the ASG.

ASG design:

- Stents orientation (peak to peak or peak to valley)
- The ASG is made by independent nitynol stents, sewn on a Dacron textile (**Figure 1a**), with different orientations. The peak to valley orientation of the stents (**Figure 1b**) increases the flexibility that fits the aortic curves better (**Video 1**).The peak to peak orientation of the stents (**Figure 1c**), gives an increase of the rigidity and columnar support, that fit in the straight sections of the aorta.
- Dacron collar interconnecting free-flow apexes
- The radial force of the free-flow and the first covered stent, ensure respectively anchoring and sealing. The interconnexion of the apexes of the free-flow with a thin Dacron collar (2 mm in width) (**Figure 1b**) displaces and increases the radial force at the level of the first covered stent with a consequent improvement of the sealing.
- Large fenestrations

Fenestrations up to 360° (**Figure 1a,1c,1d**) and large up to 15 mm , allow to extend, proximally or distally, the LZ without impairment of the targets vessels patency.

- Scallops

The scallops can have different measures (**Figure 1a**). According to the anatomy, the stents can be realized in an asymmetric configuration for keeping the area of the scallop free.

- Interconnecting patches

The bare stents at the level of the large fenestrations, can be a point of uncontrolled radial force and ineffective adaptation of the ASG. The inter-stents Dacron patches modulate the radial force at this level (**Figure 1c,1d**).

- Nosecone length

The nosecone is normally 5 cm long, It is available shorter up to 1,5 cm, for an easier device housing in short zone zero.

- Internal-external side branch

In suprarenal Abdominal Aortic Aneurysms (AAA) and Thoraco-Abdominal Aortic Aneurysms (TAAA) the gap between the fenestration and the VA has to be bridged [13]. When the aneurysmal sac has not sufficient room for the bridging stents, the side branches can be designed in totally internal or in internal-external pattern (**Figure 1e**).

- Anti kinking structure

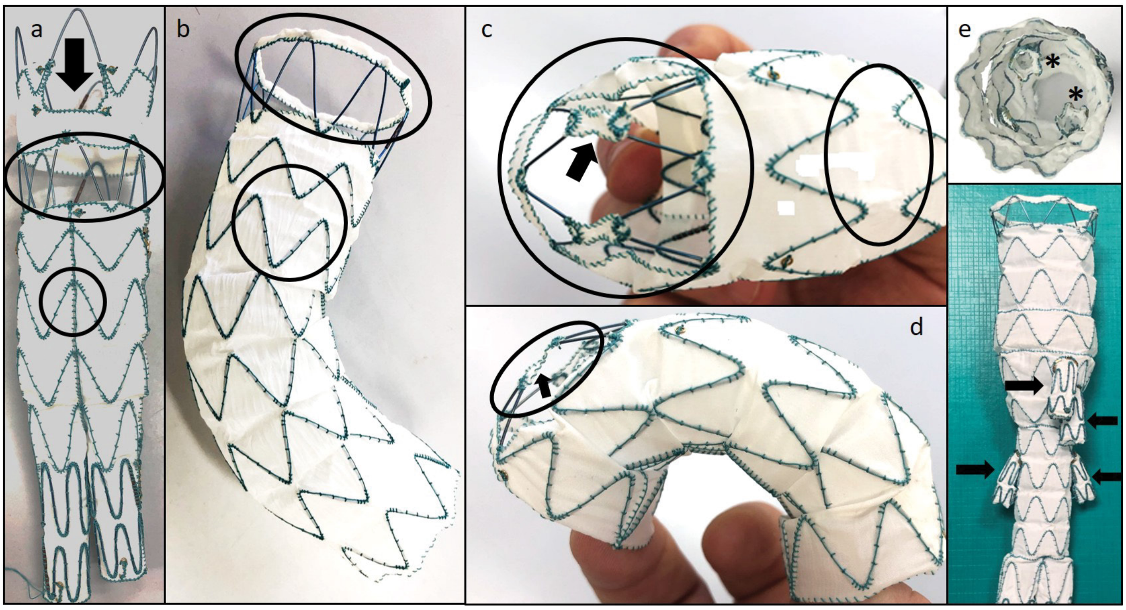

Figure 1 (a) Round ring: independent nitynol stents sewn on a Dacron textile; arrow: scallop at the level of the proximal edge of the ASG for the CT; oval ring: 360° fenestration for SMA and RRAA; (b) round ring: "peak-to-valley" stents orientation; oval ring: interconnexion of the apexes of the free-flow with a thin Dacron collar; (c) oval ring: "peak-to-peak" stents orientation; arrow: frontal view of the inter-stents connecting Dacron patch; round ring: frontal view of the 180° fenestration; (d) oval ring: lateral view of the 180° fenestration; arrow: lateral view of the inter-stents connecting Dacron patch; (e) asterisks: view from inside of 2 internal branchs; arrows: external branchs.

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The device is armed with 3 levels of rigidity making the structure anti-kinking.

- Free proximal segment of the ASG

After the ASG release, the absence of any proximal structural components related to the delivery mechanism of the ASG, enables the cannulation from the top.

Video 1 The ASG test bench shows the extreme mobility of the scaffold allowing the adaptation to the aortic tortuosities.

Patients and procedures

All the procedures were performed under general endotracheal anesthesia.

Three patients had a femoral access and 3 patients had a brachial access, through echo-guided percutaneous puncture, closed respectively by Perclose ProGlide (Abbott International, Diegem, Belgium) and by manual compression. One patient had a surgical cut down because the heavy calcifications.

The patients were systemically heparinized to achieve an activated clotting time >250 seconds. In TAAA, the spinal cord ischemia protection was obtained, in case 1 with the cerebrospinal fluid drainage and in case 2, by a 2-steps procedure. All the ASGs were engineered with 15% of oversizing. Once delivered, the adaptation of the ASG to the aortic wall was assured by compliant balloon inflation.

As primary endpoints we considered 30-day clinical and technical success, defined respectively as the absence of any major adverse event and the successful introduction, deployment of the device

Table 2: Anatomic measurements of 4 patients treated in the preliminary Dominus Biomedica® ASG study.

Anatomic measurements				
	Case 1	**Case 2**	**Case 3**	**Case 4**
Aneurysm classification	Type II	Type I	PRAA	IRAA
Aortic arch type	3	3	N	N
Radius of curvature, mm	28	18	N	N
Aortic arch angle	78°	68°	N	N
PLZ	2	ET	6	5
PLZ diameter, mm	30	35	26	28
PLZ length, mm	15	30	40	28
PLZ trombus thickness, mm	N	N	N	15
TA Angle	N	30°	N	N
TA Index of tortuosity	N	1,5	N	N
TAA length, mm	210	150	N	N
Alfa angle	N	N	90°	0
AAA angle	N	N	60°	0
AAA Index of tortuosity	N	N	1,2	1
Aneurysm max diameter, mm	65	60	50	52
CT aorta diameter, mm	54	34	27	26
SM aorta diameter, mm	40	N	23	31
RRAA aorta diameter, mm	30	N	22	40
CT diameter, mm	6	N	N	7
SM diameter, mm	6	N	N	7
RRA diameter, mm	5	N	N	7
LRA diamter, mm	5	N	N	6
Maximum CIA diameter, mm	11	13	13	10
DLZ	9	5	10	9
DLZ diameter, mm	20	34	14	25
DLZ length, mm	30	20	50	65
Maximum EIA diameter, mm	6	6	6	6

*PRAA: Para-renal Aortic Aneurysm; IRAA: Iuxta-renal Aortic Aneurysm; PLZ:Proximal Landing Zone; ET: Elephant Trunk; TA: Thoracic Aorta; TAA: Thoracic Aorta Aneurysm; CT: Coeliac Trunk; SM:Superior Mesenteric Artery; RRAA:Renal Arteries; RRA: Rigth Renal Artery; LRA: Left Renal Artery; CIA: Common Iliac Artery; DLZ:Distal Landing Zone; EIA: External Iliac Artery; N: No and patency of the bridging stents, without any type of surgical conversion or mortality, type I or III endoleaks or graft limb obstruction. As secondary endpoints we considered, neurologic events, any complication at the access site, the fluoroscopy time, the Contrast Medium (CM) volume , the time of procedure, acute kidney injury defined as an absolute rise in creatinine of ≥ 0,5 mg/dl at 24 or 48 hours [14], the number of days in Intensive Care Unit (ICU), in sub-Intensive Care Unit (s-ICU), and the hospital length of stay. The follow-up was made by clinical examination and by CTA at 1, 3, 6 months and then yearly.

Cases Series

The clinical and procedural details of the patients are listed in **Table 1**. The anatomic measurements are listed in **Table 2**.

Case 1: a 61 y/o female was admitted because of asymptomatic Crawford type 2 TAAA s/p surgical repair of ascending aorta aneurysm. The preoperative CTA showed a type III aortic arch, a 78° aortic arch angulation, a 15 mm length Proximal Landing (PL) in zone 2 (**Figure 2a**) and EIA measuring 6 mm diameter. The abrupt change of the diameter of the aneurysm at the level of the Coeliac Trunk (CT), and Superior Mesenteric Artery (SMA), respectively 54 mm and 40 mm (**Figure 2a** and **Table 2**), let little room.

A 22 Fr device carried a thoracic stent graft of 36x40x175 mm. The apexes of the free-flow, 12 mm in length, were interconnected among them with a 3 mm Dacron collar, to achieve a better radial force at the proximal LZ (**Figure 2b** and **Table 3**). A 22 Fr device, carried an abdominal stent graft, of 42x24x246 mm, with 6 mm internal branches for the CT, SMA and Right Renal Artery (RRA) and one internal-external 6 mm branch for Left Renal Artery (LRA) (**Figure 2c** and **Table 3**). Postoperative result is shown in **Figure 2d**. The patient was discharged on 6th postoperative day (**Table 4**). The 3 months postoperative CTA confirmed the effective results in terms of ASG conformation at zone 3, sealing, absence of any any Bird-Beack (BB) sign, alignment of the fre-flow with the subclavian artery and patency of supraortic and abdominal vessels (**Figure 2e**).

Case 2: a 73 y/o female was admitted because of asymptomatic Crawford type I TAAA s/p Elephant Trunk (ET) procedure. The preoperative CTA showed a type III aortic arch, a 68° aortic arch angulation, a 30° angulation at the level of the 9th vertebral body, resulting in a huge tortuousity of the distal segment of the elephant trunk (**Figure 3a** and **Table 2**) andEIA measuring 6 mm diameter. The spinal cord ischemia risk was prevented by a 2-steps procedure. During the first step we negotiated the kinked descending aorta by a 22 Fr device, carrying an ASG (40-38-250 mm), overlapping 60 mm inside the elephant trunk graft and ending 2 cm below the angle of the kinked aorta. The two first proximal stents were configured "peak-to-valley" for increasing the overlapping radial force while the distal stents were in "peak-to-valley" configuration for better adapting to the angulation (**Figure 3b**). During the second step (2 weeks later) a 22 Frdevice carried an ASG (42x38x180) with "peak-to-valley" configuration for better flexibility at the level of the kinked aorta (**Figure 3c** and **Table 3**). Postoperative results are shown in **Figure 3d**.

A delayed right retroperitoneal hematoma occurred on the 5th, postoperative day, at the level of the right EIA emploied as access, that was treated by a covered stent.

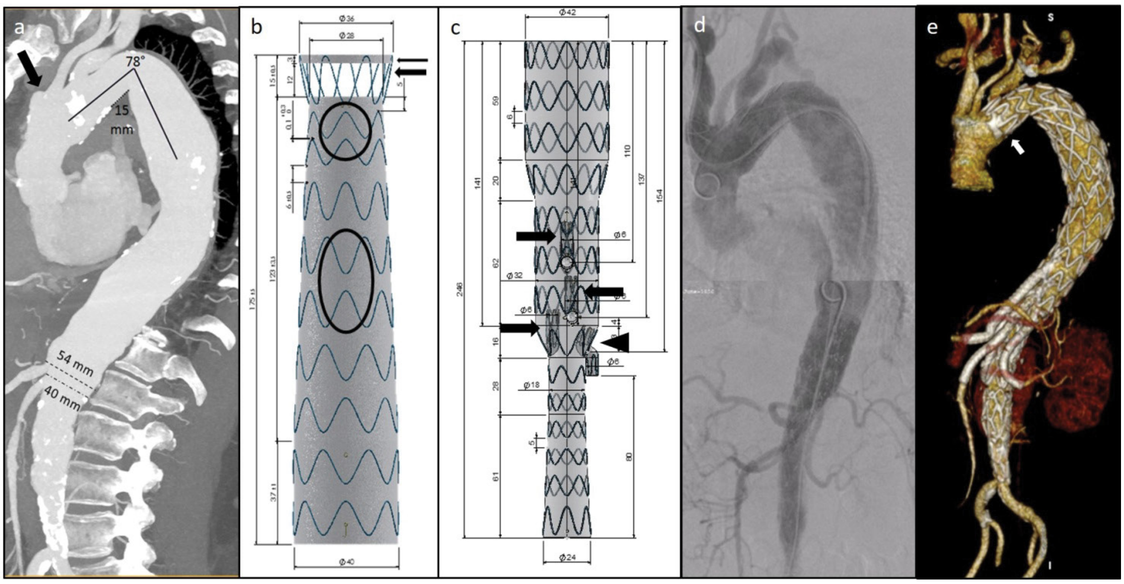

Figure 2 (a) Arrow: type III aortic arch with 78° aortic arch angulation; dotted line: 15 mm length PLZ; dashed lines: abrupt reduction of the diameter of the aorta at the level of CT and SMA, respectively 54 and 40 mm; (b) thoracic ASG technical drawing. Thin arrow: 3 mm Dacron collar interconnecting the apexes of the free-flow; thick arrow: free-flow at the level of the subclavian artery; round ring: first 2 stents in "peak-to-valley" configuration; oval ring: stents in "peak-to-peak" configuration; (c) abdominal ASG technical drawing. Arrows: 6 mm internal branches for the CT, SMA and RRA;arrowhead: internal-external 6 mm branch for LRA; (d) final arteriography: absence of any leak, good perfusion of the subclavian artery and splanchnic network; (e) 3 months postoperative 3D-view: effective conformation of the ASG at zone 3, absence of any BB, correct alignment of the free-flow and Dacron collar with the subclavian artery take-off (white arrow) and correct patency of supraortic and abdominal VA.

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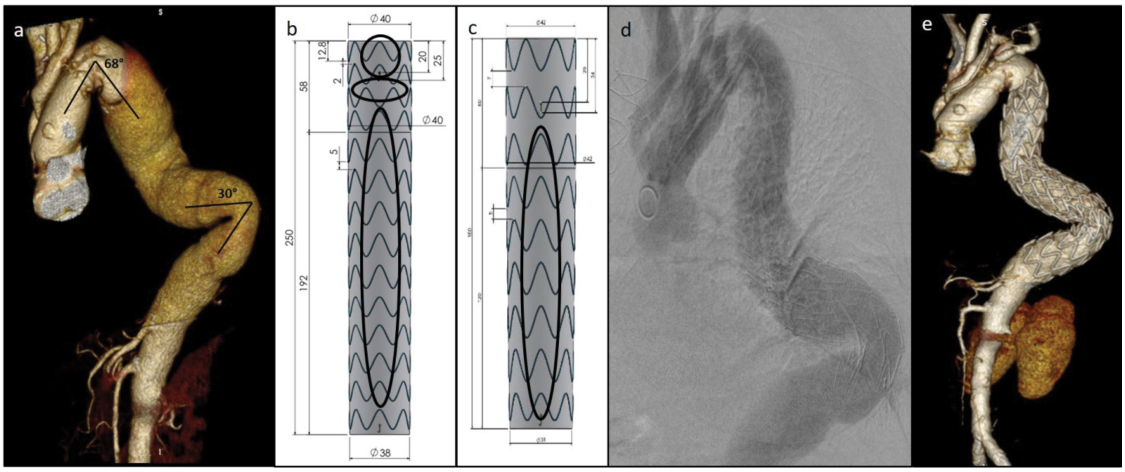

Figure 3 (a) Preoperative angio-CT: type III aortic arch , 68° aortic arch angulation and 30° descending thoracic aorta angulation; (b) proximal ASG technical drawing. Round ring: two proximal stents in “peak-to-valley” configuration; horizontal oval ring: two stents in “peak-to-peak” configuration; vertical oval ring: stents in “peak-to-valley” configuration;(c) distal ASG technical drawing. Vertical oval ring: stents in “peak-to-valley” configuration; (d) final arteriography: effective exclusion of the TAA; (e) 6 months postoperative 3-D view: correct patency of the ASG and aneurysm exclusion.

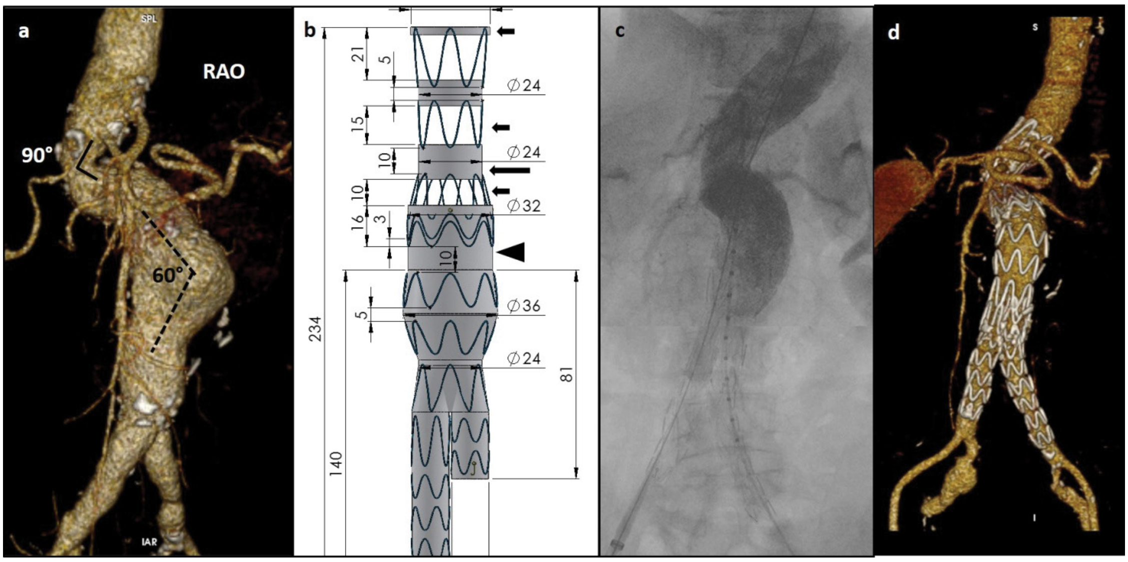

Figure 4 (a) Preoperative angio-CT:alfa angle of 90° and aortic angle of 60°; (b) ASG technical drawing: from top to bottom. 1st short arrow: Dacron collar interconnecting the free-flow apexes at the level of the CT; 2nd and 3rd short arrows: 360° fenestration for respectively SMA and RRAA; long arrow: 10 mm Dacron interspace between the SMA and RRAA fenestrations for adapting the ASG to the 90° alfa angle; arrowhead: 10 mm Dacron interspace for adapting the ASG to the curvature of the aortic angle; (c) final arteriography: correct perfusion of the VA with absence of any leak; (d) 3 months postoperative 3-D view: absence of any leak and correct perfusion of the VA and distal vascularization.

The patient was discharged on 7th and 4th postoperative days respectively after the 1st step and the 2nd step (**Table 4**). The 6 months postoperative CTA confirmed the correct patency of the stent grafts and aneurysm exclusion (**Figure 3e**).

Case 3: A 82 y/o female was admitted because of an asymptomatic Para-Renal Aortic Aneurysm (PRAA). The preoperative abdominal CTA showed a 90° alfa angle, the absence of the aortic neck, a 60° aortic angle (**Figure 4a** and **Table 2**), and EIAs measuring 6 mm in diameter. The PL was extended to zone 6. A 22 Fr device carried a bifurcated, bi-modular, ASG (30x14x234 mm). One Dacron collar interconnected the free-flow apexes, at the level of the CT, and two 360° fenestrations served respectively the SMA and Renal Arteries (RRAA) (**Figure 4b** and **Table 3**). A 10 mm Dacron interspace between the SMA and RRAA fenestrations accommodated the ASG to the 90° alfa angle (**Figure 4b**). A 16x14x100 BraileBiomedica® left limb stent graft completed the procedure. The patient was discharged on 6th postoperative day (**Table 4**). Postoperative result are shown in (**Figure 4c**). The 3 months follow-up CTA confirmed the effective relining and exclusion of the angulated aortic aneurysm (**Figure 4d).**

Table 3: ASG details of 4 patients treated in the preliminary Dominus Biomedica® ASG study.

ASG technical details				
	Case 1	Case 2	Case 3	Case 4
Stents orientation Peak-to-peak	Y	Y	Y	Y
Stents orientation Peak-to-valley	Y	Y	Y	Y
Dacron collar at free-flow apexes	Y	N	Y	N
360° fenestrations	N	N	2	1
Interconnecting patches	N	N	N	N
Normal nosecone length	Y	Y	Y	Y
Internal Side branchs	2	N	N	2
External Side branchs	N	N	N	N
Internal-external Side branchs	1	N	N	N
Standard coaxial fenestrations	N	N	N	1
Bridging stent-graft components				
CT stent graft diameter, mm	8x2	N	N	N
CT stent graft length, mm	57x2	N	N	N
SM stent graft diameter, mm	7	N	N	8
SM stent graft length, mm	58	N	N	37
RRA stent graft diameter, mm	7x2	N	N	8
RRA stent graft length, mm	57x2	N	N	37
LRA stent graft diameter, mm	6x2	N	N	8
LRA stent graft length, mm	58x2	N	N	37
Technical assessment				
ASG delivery/patency	Y	Y	Y	Y
CT delivery/patency	Y	Y	Y	Y
SM delivery/patency	Y	Y	Y	Y
RRA delivery/patency	Y	Y	Y	Y
LRA delivery/patency	Y	Y	Y	Y
Absence of type I endoleak	Y	Y	Y	Y

*ASG:Aortic Stent Graft; CT: Coeliac Trunk; SM: Superior Mesenteric Artery; RRA: Rigth Renal Artery; LRA: Left Renal Artery; Y: Yes; N: No

Table 4: Postoperative results of 4 patients treated in the preliminary dominusbiomedica® ASG study.

Postoperative results					
	Case 1	**Case 2**		**Case 3**	**Case 4**
Primary endpoints		Fs	Ss		
Any major adverse event	N	N	N	N	N
Surgical conversion	N	N	N	N	N
Mortality	N	N	N	N	N
Type I endoleak	N	N	N	N	N
Type III endoleak	N	N	N	N	N
Bridging stents patency	Y	Y	Y	Y	Y
Graft limbs patency	Y	Y	Y	Y	Y
Secondary endpoints					
Neurologic events	N	N	N	N	N
Access site complications	N	Y	N	N	N
Fluoroscopy time, minutes	35	12	5	10	24
Contrast medium volume, mL	500	250	200	200	350
Time of procedure, minutes	360	240	90	210	240
Postoperative creatinine mg/dl	1.17	0.88	0.96	0.98	0.99
ICU stay, days	3	2	2	N	N
s-ICU stay, days	1	1	1	2	2
Hospital length of stay, days	6	7	4	6	5

Fs: First stage"; Ss: Second stage; *ICU: Intensive Care Unit; s-ICU: sub-Intensive Care Unit; Y: Yes; N: No

Case 4: A 82 y/o male was admitted because of an asymptomatic Juxta-Renal Aortic Aneurysm (JRAA) s/p AAA open repair, developed at the level of the residual aortic neck of the previous aneurismectomy. The preoperative CTA showed an abrupt

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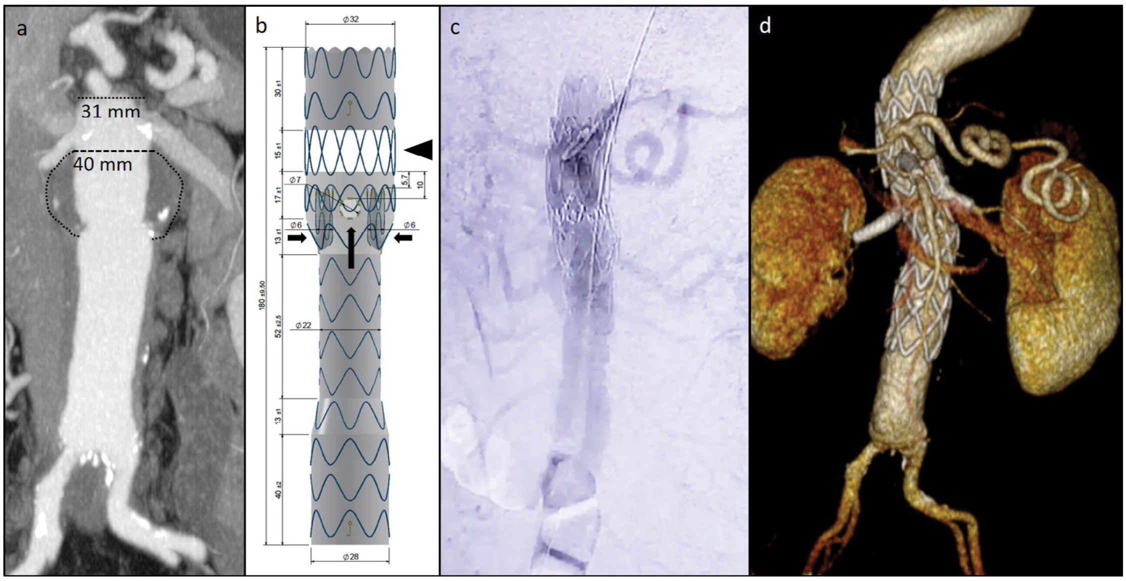

Figure 5 (a) Preoperative angio-CT, coronal view:abrupt change of the aortic diameter from 31 mm just below the SMA (dotted line) to 40 mm at the level of RRA (dashed line); mural thrombus 1,5 cm in thickness involving the origin of the RRAA (curved dotted lines); (b) technical drawing. Arrowhead: 360° fenestration for CT; short arrows: 6 mm diameter internal branchs for both RRAA; long arrow: 7 mm diameter coaxial fenestration for SMA; (c) final arteriography: correct perfusion of the VA with absence of any leak; (d) 1-year postoperative 3-D view: correct patency of the VA with exclusion of the aneurysm.

change of the visceral aorta diameter, in 13 mm of length, from 31 mm just below the SMA up to 40 mm at the level of RRA; a mural thrombus, 15 mm in thickness, involved the origin of the RRAA (**Figure 5a**) (**Table 2**). The diameter of EIA was 6 mm. The zone 5 was indicated as proximal LZ. A 22 Fr device carried the ASG (32x28x180 mm), with one 360° fenestration for CT, one standard coaxial fenestration of 7 mm in diameter for SMA, and 6 mm internal side branchs for both RRAA. Two stents in "peak-to-valley" configuration assured the ASG flexibility at the level of infrarenal aorta (**Figure 5b**) (**Table 3**). Postoperative results are shown in **Figure 5c**.

The patient was discharged on 5th day (**Table 4**). The 1 year postoperative CTA showed the patency of the VA with exclusion of the aneurysm (**Figure 5d**).

Results

The 30-day clinical and technical success were 100%. The technical details are listed in **Table 3** and the Post-operative course in **Table 4**. There was neither neurologic event nor renal function impairment. The mean fluoroscopy time, CM volume and the time of procedure were 17,2 minutes, 300 ml and 228 minutes respectively.

The mean time of hospitalization was 5,6 days. The cumulative period of observation was 64 months and the median follow up was 16 months (range: 8-24).

Discussion

Because the clear survival advantage in postoperative and mid-term run, ETAA has largely replaced open repair of more aortic aneurysms, but the severity of the anatomy affects the intraoperative and short-term results [3,15,16] and in challenging cases the complex anatomy makes the procedure unfeasible.

If the LZs are un-suitable, several skillness demanding procedures have been developed to allow the seal and the anchoring. Surgical arterial debranching during hybrid procedure have shown satisfactory results, anyway it cannot be considered a minimally invasive procedure and exposes the patient to a longer intervention in case of one-step procedure, or to a risk of rupture during the delay, in case of two-step procedure [6,17].

Fenestrated Endovascular Aneurysm Repair (F-EVAR) allows endovascular options for JRAA [18-20], but it is however a complex endovascular technique, requiring high level of expertise and, is burdened with a not negligible rate of complications during the follow up [21]. Branched Endovascular Aneurysm Repair (B-EVAR) is another level of technological complexity, but even in high turn-over centers, has a mortality rates of 10% and not insignificant risks of paraplegia [22,23].

The alternative Parallel Graft (PG), performed with "off the shelf" material, has several advantages but it cannot be considered easier than F-EVAR or B-EVAR and furthermore it is not standardized [24-26]. The off-the-shelf endograft with physician-modified ASG, allows a postoperative mortality comparable to current results of F-EVAR and PG in terms of type Ia endoleak, branch stent occlusion and procedure time [27], but it requires an adjunctive time for modification and a specific learning curve [28].

The new custom-made Dominus Biomedica® ASG, by the radial force modulation, is thought to simplify the ETAA. The aim of this first study is to evaluate the concept, technical aspects, clinical safety, and functionality.

In case 1, the type 3, the short length of the Proximal Landing Zone (PLZ) and the severe angulation of the aortic arch hampered the precise adaptation of the ASG with lack of sealing, so we moved the PL in zone 3 (**Figure 2a**), covering the origin of the Left Subclavian Artery (LSA) and potential need of a carotid-subclavian bypass. The peculiar technical solution of the Dominus stent graft, with 3 mm in width, Dacron collar, interconnecting the apexes of the free-flow and the proximal first two stents in "peak-to-valley" modality (**Figure 2b**), increased respectively, the radial force of the ASG at the level of the short PLZ and improved the adaptation of the ASG to the severe aortic arch angulation. The anti-kinking structure of the shaft, enabled the device to negotiate the narrowed iliac access and the angulated gothic aortic arch. The ASG was released with precise collimation of the free-flow and of the Dacron collar(**Figure 2e**) preserving mean-time the patency of the subclavian artery. In the abdominal segment of the TAAA, because of the little room of the aneurysmal sac, it was crucial to deliver the ASG with the best orientation of the internal branchs with the target arteries.

The abdominal ASG was deployed with 45 mm overlap inside the thoracic ASG. The antegrade portals cannulation of the 4 side endo-branches was expeditious and their location inside the ASG lumen allowed sufficient space, inside the anevrysmal sac, for the deployment of the bridging-stents.

In case 2 the descending thoracic aorta presented a 30° angulation located in zone 4-5 (**Figure 3a**). In this case the challenge was to cross the kinked descending aorta with the 22 Fr device and to deploy the device at the level of the ET. The antegrade through-and-trough wire technique and the anti-kinking structure of the shaft allowed sufficient support and trackability for the progression of the ASG. The different stents configuration guaranteed the flexibility of the ASG to follow the morphology of the aneurysm without any kinking or bending (**Figures 3b and 3c**).

In case 3, the PRAA presented an alfa angle of 90°, the absence of infra-renal aortic neck and an aortic angle of 60° that hampered the anchoring, the sealing and the collimation maneuvers of the ASG during the delivery (**Figure 4a**). In this case, the anchoring was obtained extending the PL in zone 6, covering the CT, SMA and RRAA which patency was assured by the respective circumferential fenestrations. The sealing was obtained by the Dacron interspaces, among the bare stents of the circumferential fenestrations. These fabric interspaces, acting as pivot point of the metallic scaffold (Video 1), adapted the ASG to the angulations of the aortic neck (**Figures 4b and 4c**). Furthermore, the stiffness of Dacron textile, in this point of morphologic transition, assured the columnar support for maintaining the ASG in correct place [29]. It was enough to deliver the ASG at the correct height without any need of collimation and catheterization of the target arteries (**Figures 4c and 4d**).

In Case 4, the JRAA had a diameter of 40 mm, at the level of the RRAA, with a large mural thrombus that limited the space of the aneurysmal room for the external branches (**Figure 5a**). The PL was moved to zone 5. The patency of the CT was assured by a circumferential fenestration (**Figure 5b**). At the level of the SMA the diameter of the aorta was 31 mm, preventing the possibility of a large fenestration including CT and SMA because of the risk of a type 2 leak.

This problem was fixed with a normal axial fenestration and a covered stent to the SMA. Due to the aortic diameter enlargement, at the level of the RRAA (40 mm), with a thick mural thrombus reducing the aneurysmal room, the ASG was engineered with two internal branchs that, once cannulated from the top, left sufficient space for the delivery of the bridging covered stent to RRAA (**Figure 5b**).

One more Braile endograft distinctive features is the absence of structural components at the proximal part of the ASG which prevent the cannulation from the top.This was useful in case 1 and 3, were the target arteries had a downward course. The proximal cannulation, following the oblique direction of the VA take-off, facilitated the engagement. Others ASG allow the proximal cannulation but their employment is limited to suprarenal aortic segment without any possibility to extend proximally with TEVAR.

Concerning the access, a diameter of EIA ≤ 7 mm is scored as difficult for progression and delivery of the device [12]. EVAR and TEVAR usually require a large access site, up to 24 French sheath, for accommodating all the graft components. Our 4 patients presented an EIA diameter of 6 mm, that is not suitable for housing a 24 Fr device, especially in tortuous courses. In case 2 the 22 FrBraile sheath advanced anyway but the postoperative course was complicated by the lesion of the right EIA, not with standing it was possible to deliver the ASG with correct collimation of the fenestrations and orientation of the branches.

To overcome the difficulties of the complex anatomies, the Dominus™ ASG has expandedthe horizon of customization. The entire ASG is designed strictly following the morphology of the aorta. This allows for precise adaptation of the ASG to the variable morphology of the aneurysm.The fenestrations and the branches may be engineered in different ways for bridging variable gaps between the ASG and the target arteries.

In our experience, the peculiar Dominus's ASG design allowed to exclude the aneurysm of patients not otherwise treatable, simplifying a complex procedure. The total mean fluoroscopy time, including the patient with 2 steps ETAA, was 17,2 min. This value of fluoroscopy time is less than 36, 79 and 56 min, for complex ETAA respectively treated by mobile C-arm, fixed C-arm or fixed C-arms with 3-dimensional image fusion, as reported by de Ruiter et al. in their metanalysis [30]. Regarding the CM, the mean volume of 300 ml employed in our experience is in the range of the volume reported in complex aortic aneurysm [31]. The mean time of procedure was 228 min. This values is less than 350 min reported in TAAA and is less than 250 min in JRAA treated by combined imaging protocol using low-frequency pulsed fluoroscopy, fusion imaging, and low-concentration iodine contrast for endovascular aneurysm repair of aortic aneurysms of varying complexity, as reported by Dias et al. [31].

The limits of this report are the number of the patients and the duration of the FU. We need to enroll more patients to follow the fate of this ASG as a function of the modification of the aortic wall and the patency of the sidebranchs.

Conclusions

Advances in endograft technology has broadened the applications of this technique to the complex TAAA and AAA. The

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Dominus Biomedica® ASG, relying on the innovative principle of modulation of the radial force, seems able to fit to the extreme aortic anatomies, allowing the patency of VA with an effective sealing. Our preliminary experience on 4 cases shows satisfactory results in complex TAAA and in AAA, considered unfit for endo-repair and refused by current manufacturers. More patients and longer follow-up are needed to validate these outcomes.

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Conflicts of Interest

The authors declare the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: the corresponding author Gaetano La Barbera is proctor for Endovsmarts.r.l.

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