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The Best Conditions for Parallel Stenting During EVAR: An *In Vitro* Study

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WHAT THIS PAPER ADDS?

- Juxtarenal abdominal aortic aneurysms can be treated with conventional endografts in combination with parallel stents. This is the first study describing which is the best endograft oversizing during an *in vitro* parallel-stent technique to obtain minimal gutters and stent compression, and low risk of endograft infolding: 30% oversizing.
- It is also the first study describing different endograft/parallel-stent *in vitro* combinations, detailing the characteristics of commonly used devices (Excluder and Endurant endografts, Viabahn and V12 stents) and illustrating the importance of avoiding the combination of self-expanding stents (Viabahn) and Endurant endografts because of the risk of stent compression.

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ABSTRACT

Objectives: The aim of this study is to identify which endograft, and to what degree of oversizing, in combination with what type of parallel stent, may result in the most adequate fit in a juxtarenal abdominal aneurysmal neck when using a parallel-stent technique.

Materials/Methods: *In-vitro* silicon aneurysmal neck models of different diameters, with one side-branch, were constructed. Two different endografts (Medtronic-Endurant Abdominal Stent Graft and Gore-Excluder abdominal aortic aneurysm Endoprosthesis; three diameters each), and two stents (self-expanding Gore Viabahn Endoprosthesis and balloon-expandable Atrium Advanta V12; 6-mm diameter) were tested, applying three endograft-oversizing degrees (15%, 30% and 40%). After remodelling using the kissing-balloon technique at 37 °C, the 36 endograft-stent-oversizing combinations were scanned by computed tomography (CT). The size of the results in gutters, parallel-stent compression and main stent-graft infolding were recorded.

Results: Increasing oversizing (15%, 30% and 40%) significantly decreased gutter areas (11.5, 6.2, 4.3 mm^2, $P < 0.001$); nevertheless, main endograft infolding of most 40%-oversized stent grafts was detected, particularly with Excluder devices. Lower stent compression, but wider gutters, were observed with the Excluder when compared to Endurant stent grafts, and with V12 when compared to Viabahn parallel stents. The Endurant–Viabahn combination resulted in maximum stent compression (35%).

Conclusions: Better endograft–stent apposition was achieved when using 30% endograft oversizing. Lower stent compression, but wider gutters, were observed with the Excluder stent-graft and V12 parallel stent, achieving maximum stent compression with the Endurant–Viabahn combination.

Endovascular repair of abdominal aortic aneurysms (EVAR) is widely spread. However, its main limitation is the requirement of a minimum length of the aneurysmal neck of 15 mm.[1,2] When this is not fulfilled, the alternative endovascular options include fenestrated or branched endografts.[3,4] The latter, however, are not readily available and in addition are expensive.

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Ever since the first case described by Greenberg,[5] using adjunctive branch vessel stenting during intentional endograft coverage, this new technique of parallel stenting, also known as the chimney, periscope or snorkel technique, has gained increasing popularity.[4–9] This is particularly valuable in emergency cases, or in bail-out cases when unintentional coverage of the visceral vessels occurs during EVAR. Despite the constantly increased use of parallel stent grafting, there is very little factual knowledge about which endografts and parallel stents provide the most optimal combination.[4–10]

The objective of this *in vitro* study is to report on the effect of the oversizing of two different endografts and their combination with two different parallel stents on the degree of gutters created between the parallel stents and the endografts, parallel-stent area compression and the infolding of endografts.

Materials/Methods

For this *in vitro* study, silicon models of juxtarenal aortic aneurysm necks were constructed. Ten straight silicon tubes of five different diameters (inner diameter (ID): 18, 20, 22, 25 and 27 mm), 50 mm long, were built as an aortic model. Intended aortic proximal and distal margins were marked. At 10 mm proximal to the distal edge (simulating a juxtarenal aneurysm with 10-mm neck to the renal arteries), a lateral elliptic perforation was created to which a 6-mm ID silicon tube, 20 mm long, was attached at a 30° inferior orientation. The downwards pointing orientation was intended to simulate the path of the renal artery, thus favouring parallel stent deployment.[9,11] Three zones in the silicon model were marked: the distal neck of 10-mm length; the 7-mm zone including the ostium of the 6-mm side-branched tube; and the 10-mm further proximal zone simulating the suprarenal landing zone (Fig. 1(A)).

Endografts and parallel stents were deployed into the aortic silicon models as follows: in a 37 °C saline bath, parallel stents were first placed in the 6-mm silicon side branch leaving 2–3 cm into the intended visceral vessel (6-mm tube), and 2–3 cm in the silicon aortic lumen. Thereafter, the endografts were introduced and deployed in such a way so that the covered portion of the endograft reached 10 mm proximal to the side-branch ostium into the suprarenal landing zone. When bare stents were present in the endograft, it was deployed further proximally. Both the endograft and the parallel stent were simultaneously dilated (kissing ballooned) with an endograft remodelling balloon (Reliant™ stent-graft balloon catheter, Medtronic AVE, Santa Rosa, CA, USA) and a 6-mm balloon (Atrium Medical Corporation, Hudson, NH, USA) respectively, using 10 atm ballooning pressure.

A CT scan (Toshiba Aquilion One multidetector CT, 80 detectors protocol, 0.8 pitch, 0.5 mm slice thickness, 0.3 mm reconstruction interval, fc07 and adaptive iterative dose reduction three-dimensional (AIDR 3D) filters, 120 kv, 150 ma, 0.5 s turn, 30 × 30 cm fov, 512 × 512 matrix) was performed of the 37 °C saline bath with the aortic silicon models (six different models in every CT exam) fixated in such a way as to avoid inadvertent movement in a craniocaudal fashion (Fig. 1(B) and (C)). Axial slices from all models were recorded in blind codification of every model, and later exported to an external measurement programme. After each CT scan, endografts and stents were carefully removed and meticulously examined, and when no structural damage after repeated use was detected (stent or fabric fracture, perforation, folding, twisting or any other injury, not seen during the present study in any device), used for further testing; every stent, endograft and aortic silicon model was used in a maximum of six experiments. Finally, a separate CT scan of all deployed and ballooned parallel stents without endografts was performed in order to measure the maximum parallel stent inner area without endograft compression.

For this particular study, we used two different currently available endografts: Excluder™ (Gore Excluder abdominal aortic aneurysm (AAA) Endoprosthesis, W.L. Gore & Associates, Flagstaff, AZ, USA), an expanded polytetrafluoroethylene (ePTFE)-fabric endograft with infrarenal fixation, and Endurant™ (Medtronic Endurant Abdominal Stent Graft, Medtronic AVE, Santa Rosa, CA, USA), a polyester-fabric endograft with proximal suprarenal bare-metal stent fixation. Three samples of each endograft were used: 26, 28.5 and 31 mm, and 25, 28 and 32 mm proximal diameter, respectively.

Two different parallel stents were also selected: Viabahn™ (Gore Viabahn Endoprosthesis, W.L. Gore & Associates, Flagstaff, AZ, USA), a self-expanding nitinol and ePTFE covered stent graft, and Atrium Advanta V12™ (Atrium Medical Corporation, Hudson, NH, USA), a balloon-expandable stainless steel and ePTFE-covered stent graft. Both were 6 mm inner diameter (the most used diameter for renal parallel stents)[6,8] and 50 mm and 59 mm long respectively. The inner diameter of the parallel stents was not adjusted for the visceral branch as this was not an objective of the study; the 6-mm parallel stents rather made it easier to re-use them for several experiments.

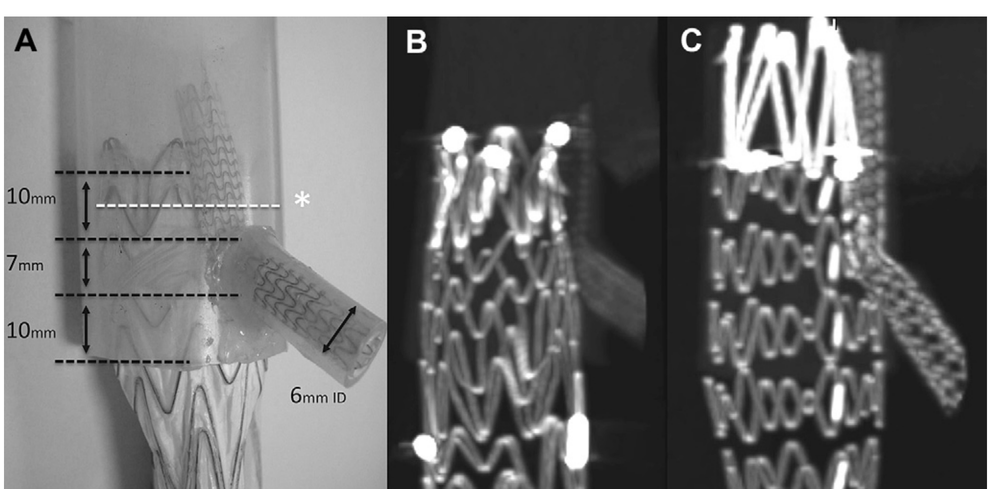

Figure 1. A) Endograft and parallel stent inside the silicon juxtarenal aortic model (Excluder–Viabahn combination), with 3 marked zones, visceral branch diameter (6 mm ID: inner diameter) and the site of axial measurements on CT scan (*). B) 3D reconstruction after CT scan of Excluder–Viabahn combination, and C) Endurant–V12 combination.

All endografts were tested in silicon aortic models following three oversizing conditions:

1) *Normal oversizing*: recommended oversizing for infrarenal aortic aneurysms following the instructions for use of each endograft manufacturer (usually around 15%).
2) *Excessive oversizing*: off-label conditions, one endograft size over recommended oversizing (around 30%).
3) *Over-excessive oversizing*: two endograft sizes over recommended oversizing (around 40%).

All six endografts (three from each manufacturer) were tested in the three oversizing conditions (Table 1), and with one single parallel stent (testing both parallel stents consecutively: Viabahn and V12). CT scans of the 36 combinations were obtained with blind codification.

Measures

Two independent investigators performed a blind analysis of all CT scans with an external imaging program (OsiriX Imaging Software v3.8.1, 32 bit); one of them measured it twice independently (in order to obtain intra- and inter-observer agreement). In axial slices, for every aortic model, the following data were manually measured (Fig. 1(A) and Fig. 2):

- *Gutters or gaps (mm^2)*: Inner area of the silicon aortic model (in mm^2) not covered by endograft nor parallel stent,[12] measured in axial slices 5 mm proximal to intended visceral ostium and 5 mm distal to the origin of the covered endograft (middle length of parallel stent–endograft overlapping). This point was chosen to standardise the measurement method, avoiding interference with proximal endograft radiopaque markers or distal inclination of the parallel stent in the renal ostium. In every model, the area in the left and right gutters was calculated together, using OsiriX's close polygon function.
- *Parallel-stent area compression (%)*: Internal area of the parallel stent, at the same level of the above-mentioned measure (compressed area, in mm^2), divided by mean internal area of the same parallel stent type in separate CT scan without endograft compression (maximum stent area, in mm^2).
- *Endograft infolding*: presence of folding of the endograft inside the aortic model (lack of apposition of the endograft to the aortic wall in areas other than parallel stent location, creating new gutters or gaps).

Table 1
Silicon aortic models inner diameters and endograft outer diameters used in the present study, and all their combinations in three different oversizings.

	Silicon aortic model	Endograft			
		Excluder		Endurant	
	Inner diameter (mm)	Diameter (mm)	OS	Diameter (mm)	OS
Normal oversizing (15%)	22	26	18%	25	14%
	25	28.5	14%	28	12%
	27	31	15%	32	19%
Excessive oversizing (30%)	20	26	30%	25	25%
	22	28.5	30%	28	27%
	25	31	24%	32	28%
Over-excessive oversizing (40%)	18	26	44%	25	39%
	20	28.5	43%	28	40%
	22	31	41%	32	45%

OS: Oversizing.

Statistical analysis

Descriptive parameters (described as median and range, and interquartile range (IQR) defined as 75th percentile − 25th percentile for each variable) and frequencies from all data were obtained using Statistical Package for Social Sciences (SPSS), Version 15.0 statistical package. Intra- and inter-observer agreement (measures between same and different observers) were calculated using the interclass correlation coefficient for absolute agreement. Mean measures of both observers were used for further analysis. Comparisons between different groups (oversizing group, endograft and parallel stent type) were made using the non-parametrical Kruskal–Wallis test and the Mann–Whitney test. P value <0.05 was considered to be statistically significant.

Results

Intra-observer and inter-observer agreements were very good (0.981 (95%CI 0.973–0.987) and 0.910 (95%CI 0.870–0.938), $P < 0.001$); therefore, mean measures between both observers were used.

Endograft oversizing

A progressive increase of stent-graft oversizing from 15% to 30% and further to 40% resulted in a significant decrease in median gutter area (11.5, 6.2 and 4.3 mm^2 respectively, in response to better endograft–parallel stent apposition in higher oversized endografts), with non-significant changes in parallel-stent area compression despite excessive oversizing (11%, 20% and 14%; Table 2 and Fig. 3).

However, endograft infolding was noticed with increase of stent-graft oversizings: none in the 15%-oversized group; 17% Excluder and 0% Endurant in the 30%-oversized group; and 100% Excluder and 17% Endurant in the 40%-oversized group (Fig. 4(A)).

Endografts and parallel stents

Analysing all oversizings together, and the behaviour of each endograft and parallel stent independently, the V12 parallel stent showed higher resistance to stent compression between the endograft and the aortic wall than the Viabahn (9% and 23% median area compression, $P < 0.001$), but a non-significant tendency towards wider gutters (Table 3, Fig. 4(B) and (C)). No other significant differences were observed, but similarly the Excluder endograft showed a tendency towards lower stent compression but wider gutters than Endurant devices.

When all possible combinations between endografts and parallel stents were analysed, some tendencies were also observed: the Viabahn stent showed the highest stent compression and the smallest gutters in combination with the Endurant endograft (35% and 3.9 mm^2). Gradually, lower stent compression but wider gutters were seen when the Viabahn stent was used with the Excluder endograft (17% and 4.8 mm^2) or when the V12 stent was used with any endograft (0–11% and 6.7–9.7 mm^2).

Analysing separately the three oversizing groups, the same tendencies in gutter area and parallel stent compression depending on endograft and stent device were seen in all groups; these trends did not significantly change depending on degree of endograft oversizing.

Discussion

Some case reports and short series have described the use of the parallel stent technique to preserve visceral branch perfusion

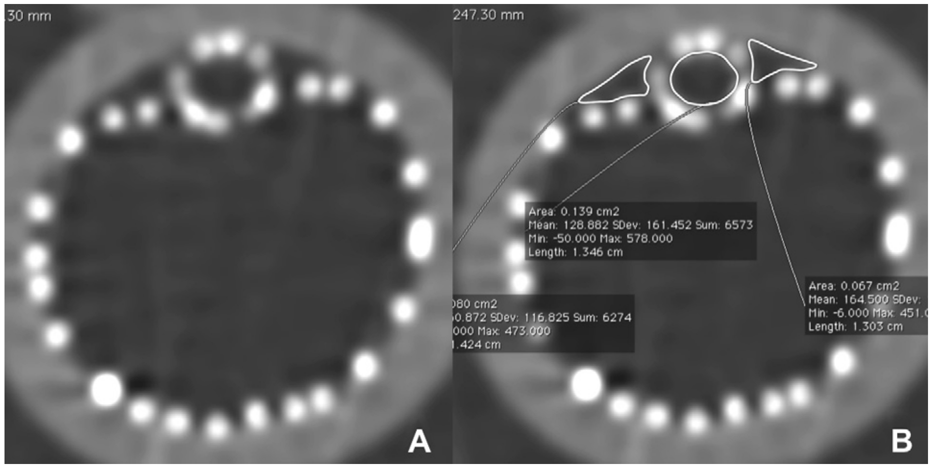

Figure 2. A) CT scan axial exam of an endograft–parallel stent model (Endurant–V12 combination), and B) measure of internal and external gutters area, and parallel-stent area.

during EVAR,[4–10] showing good initial results: 94–100% technical success, 84–100% 1-year parallel stent patency and 0–12% early type I endoleak.[4–9] However, a variety of technical details, materials and procedures have been used, usually based on empirical suggestions, making it hard to standardise this method. In this study, we tried to objectively demonstrate which are the best conditions when applying this technique, using a bench model.

Parallel stents (usually described as chimney when a parallel stent is placed in the proximal part of the endograft, as snorkel or periscope when it is placed in the distal part and as sandwich when it is placed in-between endografts)[6,7,11,13] is an off-label use of aortic endografts and stents, employed in selected patients considered unfit for other endografting techniques. The most reported endografts used with this technique are Endurant,[7] Zenith (Cook Inc., Bloomington, IN, USA)[9] and Excluder.[7,10] The first two devices are polyester-fabric grafts, with different skeletons (nitinol and stainless steel stents, respectively), but both with proximal bare stent for suprarenal fixation and high radial expansile forces.[14]

Table 2
Differences in gutters, parallel stent compression (median measures and interquartil ranges [25th–75th range]) and main endograft infolding (% and number), among different main body endograft oversizings.

	Oversizing			P
	15% Normal	30% Excessive	40% Over-excessive	
Gutters (mm^2)	11.5 (10.1–16.6)	6.2 (4.6–9.4)	4.3 (2.6–4.6)	<0.001
Endograft				
Excluder	14.8 (10.5–23.2)	6.1 (4.6–10.7)	4.3 (3.4–4.6)	0.002
Endurant	10.9 (8.9–11.9)	6.2 (3.9–10.4)	3.7 (2.4–4.7)	0.010
Parallel stent				
Viabahn	10.6 (7.2–17.1)	4.6 (3.9–8.3)	2.7 (1.9–4.4)	0.005
V12	11.7 (11.1–18.6)	8.9 (6.1–10.6)	4.5 (4.2–4.7)	0.002
Stent compression (%)	11% (0–29)	20% (11–26)	14% (9–25)	0.684
Endograft				
Excluder	7% (0–25%)	17% (8–24%)	13% (3–18%)	0.715
Endurant	11% (6–40%)	22.7% (8.0–32%)	17% (10–36%)	0.918
Parallel stent				
Viabahn	27% (12–40%)	23% (15–31%)	23% (12–36%)	0.796
V12	3% (0–10%)	17% (0–23%)	13% (0–15%)	0.225
Infolding of the main endograft (% and number)	0% (0/12)	8% (1/12)	58% (7/12)	0.001
Excluder	0% (0/6)	17% (1/6)	100% (6/6)	0.001
Endurant	0% (0/6)	0% (0/6)	17% (1/6)	0.368

On the other hand, the Excluder is an ePTFE endograft with an infrarenal fixation and lower radial expansile forces.[14] We therefore selected these two stent grafts, the Endurant and the Excluder.

Regarding parallel stent, most groups use Viabahn self-expanding or Advanta-V12 (iCAST in the USA) balloon-expandable stents.[4,6,7,9] The higher flexibility in the first (nitinol frame), and higher radial force in the second (stainless steel frame), also make these parallel stents the main focus in our *in vitro* model testing.

The presence of a parallel stent increases aortic neck perimeter, and probably determining proximal endograft oversizing only by aortic circumference diameter (supposing a perfect circle and ignoring parallel stent) leads to underestimation. In the present study, increasing oversizing showed better endograft apposition to aortic and parallel stent surface, with decreasing gutter area (11.5, 6.2 and 4.3 mm^2, $P < 0.001$) without increasing parallel stent compression (11%, 20%, 14%, $P = 0.684$) with both types of stent grafts included in the study.

However, 40% oversizing was related to endograft infolding (100% Excluder and 17% Endurant endografts). It supports previous reports of collapsed thoracic and abdominal endografts, mainly Excluder and TAG devices, where excessive oversizing (and proximal lack of apposition in thoracic endografts) were supposed to be related.[15–17] This infolding can be related to type I endoleaks, collapse, lesser proximal fixation and migration. Thereby, although 40% oversizing is related to the smallest gutters and not increasing stent compression, it cannot be recommended and should be avoided in the chimney technique.

According to our findings, 30% oversizing is the most optimal when using a single parallel stent. It results in a decreased gutter area without increase of stent compression and contributes to a minimal risk of stent-graft infolding. Indeed, this is the same stent-graft oversizing reported by some groups (25–35%).[9] However, the majority of reports on the parallel stent technique either use the most commonly recommended stent-graft oversizing without parallel stents (10–15%)[4] or simply do not report the stent-graft oversizing.[6,7]

In our model, self-expanding stents showed significant higher compression rate than balloon-expandable stents (23% and 9%), probably due to the lower radial force in self-expanding stents. A higher stent-compression tendency was noticed in these stents when used with Endurant stent grafts, (35% Viabahn stent compression when compared to Endurant, but only 17% when compared to Excluder devices), possibly due to Excluder's higher

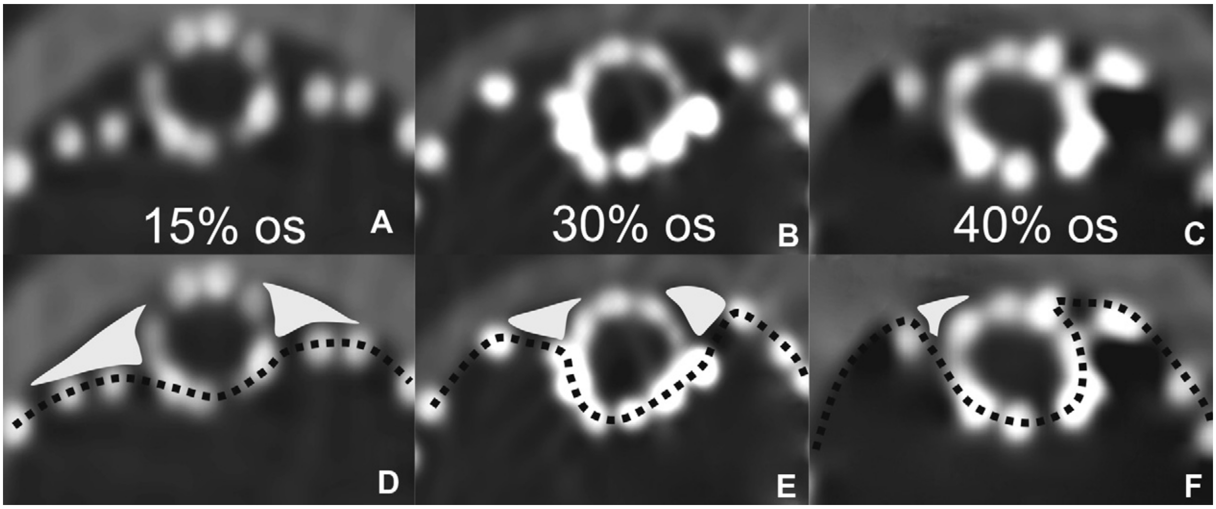

Figure 3. Progressive increase of main endograft oversizing (OS: 15% in A, 30% in B, 40% in C), resulted in significant decrease in gutter area (white area) and endograft path (dotted line) measured in the same images (D, E and F). In these examples, in Endurant–V12 combinations.

flexibility and lower expansile radial force. Furthermore, stent skeleton design is different: the Excluder has overlapping stent rings and the Endurant has successive stent rings, and that might influence the behaviour when exposed to a parallel stent.

The higher stent area compression in self-expanding stents resulted in higher stent deformity and endograft expansion, reaching a better filling of the free gaps between devices; hence, slightly smaller gutters were seen (4.7 mm^2 in Viabahn vs. 8.9 mm^2 in V12 stents). On the other hand, balloon-expandable stents showed similar results in terms of gutters or stent compression when used with any of the two stent grafts. It is probably due to its higher radial force compared to both endografts, leading to minimal stent deformity and endograft expansion, and consequently reaching minimal changes in gutter area.

No clinical data can assure which is the boundary of minimal safe stent compression. However, greater stent-area compression suggests higher risk of stent thrombosis, and 35% compression indeed suggests high risk of thrombosis. Therefore, self-expanding stents should preferably be used with Excluder but not with Endurant devices, whereas balloon-expandable stents could be safely used with both Excluder and Endurant devices. Referring to gutters, again, no clinical data advocate which is the minimal safe gutter area, but lowest area suggests lower risk of proximal endoleak.

In non-randomised clinical series, excellent short-term patency rates and low taxes of proximal endoleaks without differences between parallel stents have been described.[4–9] However, most groups are using Endurant and Zenith endografts in combination with balloon-expandable parallel stents (V12), or Excluder endografts with self-expanding parallel stents (Viabahn).[4,6,7,9] Whenever Viabahn is used in combination with Zenith stent grafts, there are reports of reinforcement of the parallel stent using additional bare-metal stents relining the Viabahn and avoiding stent compression.[9,18,19] This technique could also allow better conformability and kink resistance in angulated configurations or as periscopes. However, there is no clear evidence on whether such a modification results in clinically improved outcomes.

In this study, we attempted to mimic morphological conditions encountered during the use of parallel stent grafting, such as the most common aortic diameters and stent-graft oversizing, downwards pointing renal artery, with all models in a 37 °C saline bath and all devices remodelled with a kissing balloon technique. However, some limitations affect our study: silicon aortic models do not replicate native aortic elasticity (where performance of endografts and parallel stents, stent compression or bending in the junction with the visceral branch could be different), only two endograft and two parallel stent models were tested under ideal

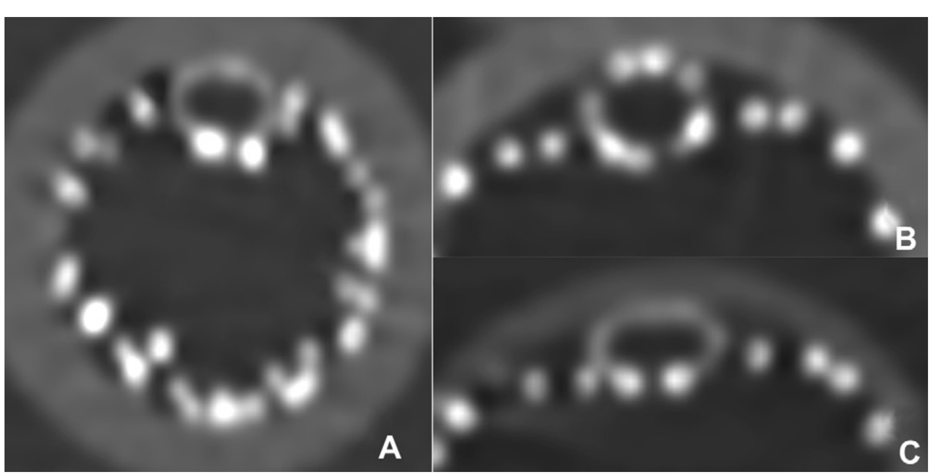

Figure 4. A) Over-excessive (40%) oversizing was related to endograft infolding (Excluder–Viabahn combination in this picture). B) V12 balloon-expandable stents showed higher compression resistance than C) Viabahn self-expanding stents (in these two examples, in combination with Endurant endografts).

Table 3
Differences in gutters and parallel stent compression (median measures and interquartil [25th–75th] ranges) among each endograft and parallel stent independently, and afterwards analysing all possible combinations of endografts and parallel stents.

Device	Type	Gutter		Stent compression	
		mm^2	*P*	%	*P*
Endograft	Excluder	6.1 (4.5–12.5)	0.448	15% (0–23)	0.181
	Endurant	5.7 (3.9–10.9)		20% (9–35)	
Parallel stent	Viabahn	4.7 (3.6–10.3)	0.129	23% (16–35)	<0.001
	V12	8.9 (4.5–11.7)		9% (0–15)	
Combinations	Viabahn – Excluder	4.8 (4.4–13.0)	0.270	17% (13–25)	0.047
	Viabahn – Endurant	3.9 (2.7–8.1)		35% (21–38)	
	V12 – Excluder	6.7 (4.5–14.8)	0.847	0% (0–16)	0.470
	V12 – Endurant	9.7 (4.7–11.6)		11% (3–14)	

conditions, and they could not respond with exactly the same behaviour in other device combinations or more compelling aortic morphologies (such as angulated or calcified necks). In addition, we only used one parallel stent of one unique size, strictly parallel to the main endograft and not in an oblique position, and the small number of samples may also influence the significance of our results. Hence, we are developing new *in vitro* studies in native cadaveric aortas, with larger series, more parallel stents and different device models.

Conclusions

This *in vitro* study of EVAR with parallel stents shows that there is a better endograft–parallel stent apposition and lower gutter area while using excessive endograft oversizing (30%). Wider gutters are seen when using 15% stent-graft oversizing, and stent-graft infolding occurs when 40% super-oversizing is used, and should be avoided. There is a lower stent compression and wider gutters when using Excluder compared to Endurant stent grafts, and Atrium-V12 compared to Viabahn parallel stents with a maximum stent compression in a combination of Endurant–Viabahn. Therefore, 30% endograft oversizing should be recommended, using any of both endografts or parallel stents, but the Endurant–Viabahn combination must be avoided.

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None.

Conflict of Interest

Dr. Riambau receives consultancy fees from Medtronic Inc. and W.L. Gore & Associates.

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