EVAR 2014: Where Do We Stand?

Predicting outcomes after contemporary endovascular aneurysm repair.

BY NELSON OLIVEIRA, MD; FREDERICO BASTOS GONÇALVES, MD; SANDER TEN RAA, MD, PHD; ELLEN ROUWET, MD, PHD; JOHANNA HENDRIKS, MD, PHD; AND HENCE VERHAGEN, MD, PHD

Endovascular aneurysm repair (EVAR) has increasingly become preferred to open repair (OR) as the primary option for managing abdominal aortic aneurysms (AAAs) in morphologically suitable patients. Since the initial cornerstones of EVAR were set by Volodos et al[1] and Parodi et al,[2] an unrelenting quest for improvement followed, leading to the edification of a robust body of knowledge that serves as a foundation for this paradigm shift in AAA repair.

LONG-TERM OUTCOMES AFTER EVAR

The lower perioperative all-cause mortality conferred by EVAR has been consistently demonstrated in several trials when compared to OR.[3-6] However, an increased rate of reinterventions (Table 1) and a loss of the initial benefit have emerged from long-term data.[6-10]

An important point that can obscure this comparative analysis may be that reinterventions related to surgical access in the OR group, such as incisional hernias and adhesion-related bowel obstructions, have been underreported throughout most studies comparing both treatment modalities. Schermerhorn et al[11] found that in a population of 23,830 EVAR patients matched to a proportional OR group, 9% of the EVAR patients required an aneurysm-related secondary intervention in comparison to 1.7% of the OR group. Nevertheless, laparotomy-related complications occurred in 9.7% of the OR group and in 4.1% of the EVAR group, reducing the overall secondary intervention rate gap between both groups.

Additionally, the long-term results from randomized trials may no longer accurately represent contemporary EVAR. Through procedure centralization and accumulated experience, centers of excellence have now traversed a steep EVAR-related learning curve, currently allying improved technical execution to better patient selection, factors that may greatly influence long-term outcomes, thus reducing aneurysm-related adverse events.

Furthermore, during the randomized trials, AAA suitability was only 60% with ancestral devices,[12,13] and many of the implanted endografts have been significantly modified or even withdrawn from the market. Late-generation endografts have been designed to ensure active fixation and to increase conformability, allowing the treatment of patients with more complex proximal anatomy, thus broadening the eligible population. Moreover, despite treating more challenging anatomies, a lower incidence of endograft migration and loss of seal has been consistently reported, with consequent decreased rates of secondary interventions and aneurysm-related complications (Table 2).

Whether these results achieved in expert centers are reproducible worldwide can be debated. However, real-world registries have revealed encouraging results. The ENGAGE registry compiled data from 1,263 patients who have received the Endurant stent graft (Medtronic, Inc., Santa Rosa, CA) from 30 distinct countries.[14] Three-year results have been recently presented by Prof. Dittmar Böckler during the latest VEITHsymposium in New York. These results were notable for a 0% rate of endograft migration, a 1.5% rate of type I or III endoleak, and a 90.7% freedom from secondary intervention rate.

In addition to the decrease of device-related postimplantation complications, building an understanding of these complications has led to a more conservative approach in some selected patients, which has also contributed to a reduction in secondary intervention rates.

The management of type II endoleaks, which can occur in 10% to 30% of patients,[15] has changed in many high-volume centers despite the remaining controversy regarding the contribution of type II endoleaks to postimplantation rupture. In a systematic review, Sidloff et al concluded that aneurysm rupture after EVAR due to an isolated type II endoleak was a rare event but might occur in the absence of sac growth.[16] However, when analyzing the original reports of the 14 ruptures (0.9%) identified by those authors[17-20]

TABLE 1. LONG-TERM OUTCOMES AFTER EVAR

Study	Enrollment, Years	Main Devices	EVAR, N	Mean Follow-Up, Years (max)	Type I/III Endoleaks, N (%)	Secondary Interventions, N (%)	Conversion, N (%)	Migration, N (%)	Aneurysm Rupture, N (%)	Aneurysm-Related Mortality, N (%)
EUROSTAR[21]	1996–1999	Vanguard (Min-Tec, Freeport, Grand Bahama, The Bahamas), Stentor (Boston Scientific Corporation, Natick, MA)	1,190	3 (8)	258 (21.7)	319 (26.8)	84 (7.1)	153 (12.9)	29 (2.4)	36 (3)
EVAR-1[7]	1999–2003	Zenith, Talent (Medtronic, Inc.), Excluder (Medtronic, Inc.), AneuRx (Medtronic, Inc.), Quantum, (Boston Scientific Corporation	626	6 (10)	NS	146 (23.3)	25 (4)	NS	25 (4)	36 (5.8)
DREAM[8]	2000-2003	Zenith Talent Excluder, AneuRx, Quantum	173	6.4 (8.2)	12 (6.9)	48 (27.7)	3 (1.7)	7 (4.1)	1 (0.6)	2 (1.2)
Medicare[11]	2001–2004	NS	22,830	NS (> 5)	NS	NS (9)	NS (0.4)	NS	NS (1.8)	NS
OVER[9]	2002–2007	Zenith Excluder AneuRx	444	5.2 (9)	NS	98 (22.1)	NS	NS	6 (1.4)	10 (2.3)
ACE[6]	2003–2008		150	3 (4.8)	NS	24 (16)	NS	NS	3 (2)	6 (4)

Abbreviations: NS, not stated.

among 1,515 patients (10.2%) with type II endoleaks (N = 14,794), an undisputable relation between both events cannot be established in most cases, casting doubt upon their conclusions.

Hypothetically, type II endoleaks may be the only demonstrable evidence of otherwise undetectable, posture-dependent type I and III endoleaks,[22] suture-line holes,[23] or late fabric failure,[24] which lead to outflow blood streams from the sac to its main collaterals. Currently, a conservative approach to patients with type II endoleaks without sac growth seems to be preferred,[25] reserving intervention for patients with persistent sac growth.[18,26] And even for those, type II endoleak interventions have proved ineffective in preventing sac growth, as reported by Cieri et al,[27] and so focus should be directed toward detecting other causes for sac growth.

Type IA endoleaks are associated with late rupture after EVAR, and therefore, an aggressive approach has been warranted. However, additional directed endovascular procedures may be challenging, and conversion to open

repair has been associated with increased mortality.[13] Our group assessed a population of 383 EVAR patients treated at our center between August 2004 and December 2008. Fifteen patients presented with a primary uncorrected type IA endoleak. All patients were morphologically suitable for EVAR, stent graft oversizing was 10% to 20%, and the endograft had been accurately deployed. One aneurysm rupture (6.7%) occurred 2 days after EVAR. On the first postoperative CT angiography performed within the first week, eight patients (53%) no longer showed a type IA endoleak. On the second postoperative CT angiography, performed at a median of 5 months (range, 1–12 months) after EVAR, all of the remaining type IA endoleaks had also sealed. During a median follow-up of 27 months (range, 7–66 months), two patients underwent secondary interventions, one for aortic neck dilatation and one for stent graft migration at 12 months, but no type IA endoleak recurrences were observed. Although the risk for rupture persists until endoleak seal occurs, and therefore intraoperative correction should be attempted if technically possible, a conservative approach to type IA endoleaks may produce acceptable results in the midterm in patients with EVAR-suitable proximal neck anatomy, adequate device oversizing, and in whom the stent graft has been accurately deployed.

PREDICTING OUTCOMES AFTER EVAR: ADEQUATE SEAL

Aneurysm sac retraction has been associated with durable aneurysm exclusion,[28] for which an adequate proximal seal is a key factor.[29] Schanzer et al found that risk factors for inadequate proximal seal, such as a conical aortic neck (hazard ratio [HR], 1.17; 95% confidence interval [CI], 0.97–1.42), aortic neck diameter 28–32 mm (HR, 1.8; 95% CI, 1.44–2.23) or ≥ 32 mm (HR, 2.07; 95% CI, 1.46–2.92), aortic neck angle ≥ 60° (HR, 1.96; 95% CI, 1.63–2.37), were associated with sac enlargement.[30] The need to ensure an adequate proximal seal has driven most late-generation device designs to incorporate active fixation mechanisms and to become gradually more conformable to accommodate complex neck anatomy.

Proximal Seal in Angulated Proximal Necks

The Aorfix endograft (Lombard Medical Technologies PLC, Oxfordshire, UK) received US Food and Drug Administration approval in 2013 for the treatment of angulated necks (up to 90°). Weale et al reported[31] on the outcomes of 30 patients with more challenging proximal neck anatomies (mean infrarenal angle, 81.2°; range, 63°–110°). After a follow-up of 6 months, two

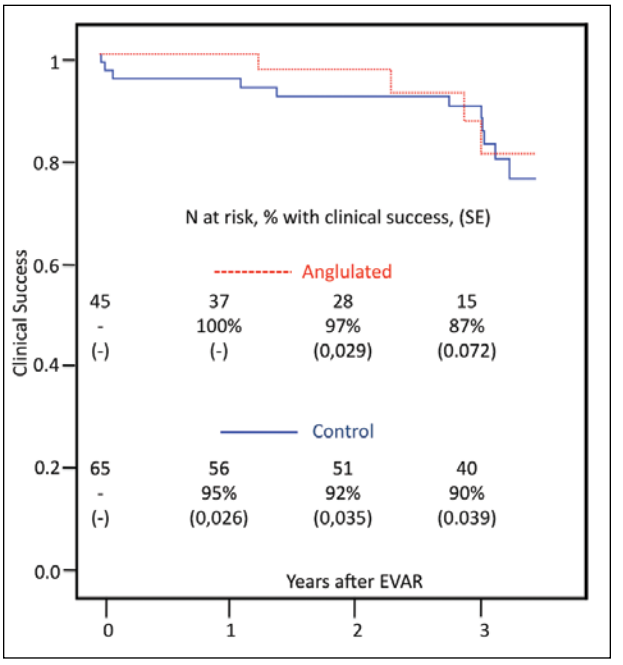

Figure 1. Midterm outcomes after EVAR in patients with severe proximal aneurysm neck angulation.

cases (6.7%) of primary proximal type I endoleaks were found to persist despite intraoperative ballooning of the proximal stent. The PYTHAGORAS trial 1-year data have been presented at the 2012 Society for Vascular Surgery meeting and revealed a 2.4% (n = 143) rate of type I or III endoleaks and a 2.1% rate of graft migration (> 10 mm). Long-term outcomes of this device in challenging proximal aneurysm necks remain to be reported.

Another highly conformable endograft that has also claimed a position in the treatment of AAA patients with angulated proximal anatomy is the Anaconda AAA stent graft system (Vascutek Ltd., Inchinnan, UK). In a group of 213 patients treated with this endograft with only 19 of these (8.9%) presenting proximal neck angulation ≥ 60°, Stella et al reported a single proximal type I endoleak during a mean follow-up of 23.2 (± 1.8) months.[32] Long-term results are still awaited, but these may be further postponed, as a voluntary recall has been issued by Vascutek in late October, regarding all Anaconda One-Lok and Anaconda bifurcated bodies. This recall was based on the report of three incidents of stent graft release wire fractures, which resulted in two open conversions.

The Endurant endograft is also a highly conformable device that is equipped with an enhanced fixation mechanism, which has been found to be advantageous in the treatment of severely angulated proximal

TABLE 2. OUTCOMES AFTER EVAR WITH THE LATEST-GENERATION ENDOGRAFTS

Author	Year	Device	N	Follow-Up, Months	Type I/III Endoleaks, N (%)	Secondary Interventions, N (%)
Bastos Gonçalves et al[33]	2012	Excluder	144	60	11 (7.7)	32 (22.5)
Makaroun et al[34]	2011	Endurant	150	12	1 (0.7)	11 (7)
Hogg et al[35]	2011	Excluder	216	31	8 (3.7)	NS
Rouwet et al[36]	2011	Endurant	80	12	0	3 (3.8)
Van Keulen et al[37]	2011	Endurant	100	12	1 (1)	5 (5)
Hiramoto et al[38]	2007	Zenith	325	28	3 (0.9)	28 (8.6)
Haider et al[39]	2006	Excluder/Zenith	181	12	4 (2.2)	5 (2.7)
Greenberg et al[40]	2004	Zenith	200	24	7 (3.5)	22 (11)
Cho et al[41]	2004	Excluder	50	32	0	3 (6)
Alric et al[42]	2002	Zenith	88	21	4 (4.5)	6 (6.8)

Abbreviations: NS, not stated.

anatomy.[37,43] Our group has reported on a series of 110 EVAR patients treated in three tertiary centers in the Netherlands with this stent graft.[44] Patients were included in the study group if one of the following two combinations occurred: a neck length > 15 mm with an infrarenal angle (β) > 75° and/or suprarenal angle (α) > 60°, or neck length > 10 mm with β > 60° and/or α > 45°. Forty-five patients were included in the angulated group. The mean preoperative suprarenal angle was 51° ± 21°, and the mean infrarenal angle was 81° ± 16°. The estimated clinical success at 1 and 3 years was 100% and 87% for the angulated group, respectively, and 95% and 90% in the control group, respectively, (*P* = .79) (Figure 1). Two postimplantation ruptures occurred, one in each group. In our population, neck angulation had no influence on clinical outcomes. The long-term results are to be reported in the near future.

Endoanchors

In an experimental model, Melas et al[45] demonstrated that endostaples increased endograft fixation to levels similar or greater than hand-sewn anastomosis. Endoanchors have been used preventively during EVAR in patients with challenging neck features (angulated or short proximal neck, diameter > 29 mm, or conical-shaped proximal neck)[46] and also to treat EVAR-related complications (migration and secondary type IA endoleaks).[47] Perdikides et al[46] preventively treated 13 consecutive patients with a median number of four endoanchors each (HeliFX Aortic Securement System, Aptus Endosystems, Inc., Sunnyvale, CA). Two patients presented with intraoperative type IA endoleaks (primary technical success, 85%). One required an additional proximal cuff, and the other had a limited type IA endoleak, which resolved spontaneously within 30 days. Over a median follow-up of 7 months (range, 2–17 months), no further neck-related adverse events occurred. In a report from Avci et al,[47] endoanchors were used to address endograft migration (with or without type IA endoleak). A median of six endoanchors were implanted per patient, and there was only one case of endoanchor dislodgement. During a median follow-up of 10 months (range, 3–18 months), migration had not recurred, and no endoanchor-related complications were identified. However, most patients had additional proximal cuffs with suprarenal fixation, which may have also contributed to their findings. Deaton et al[48] have reported on the midterm outcomes of 176 patients treated with endostaples. In all patients, EVAR was performed with Fortevo, an Aptus endovascular repair system. After 3 years (N = 155) and 5 years (N = 21) of follow-up, four patients (2.3%) presented with endograft migration. Three of these were attributed to proximal neck elongation (without loss of aortic apposition of the endograft), but the other patient had a proximal seal site with significant thrombus, which may have led to inadequate endoanchor fixation in the aortic wall. Despite high technical success and encouraging results, long-term clinical experience is still quite limited.

	Conversions, N (%)	Sac Growth, N (%)	Migration, N (%)	Ruptures, N (%)	Aneurysm-Related Mortality, N (%)
	5 (3.5)	37 (24)	5 (3.5)	1 (0.7)	2 (1.4)
	0	0	0	0	0
	4 (1.3)	17 (7)	4 (1.3)	2 (0.7)	2 (0.7)
	0	2 (2.7)	0	0	0
	0	5 (5)	1 (1)	0	3 (3)
	0	NS	0	1 (0.3)	3 (0.9)
	1 (0.6)	2 (1.1)	0	0	0
	5 (2.5)	5 (2.5)	6 (3)	1 (0.5)	1 (0.5)
	1 (2)	16 (32)	0	0	0
	4 (4.5)	21 (24)	6 (7)	2 (2.2)	6 (6.8)

Furthermore, the fixation force of endoanchors is greatly reduced if deployed into calcified plaque or thrombus, which may limit their applicability.

Endovascular Aneurysm Sealing: The Nellix System

Endovascular aneurysm sealing is a novel concept based on the endovascular repair of AAA through the complete seal of the aneurysm sac with polymer-filled endobags. Anterograde perfusion is ensured through dual-balloon-expandable endoframes that are anchored in position by the filled endobags, fixing the device within the aneurysm and simultaneously eliminating the potential space for the development of endoleaks.

In an initial report, Donayre et al treated 22 patients with the Nellix system (Endologix, Inc., Irvine, CA), with one case of early postoperative mortality. This patient was the first case treated and died from multiorgan failure after the intervention, which was not found to be device- or aneurysm-related.[49] However, this event would lead to a change in the procedure protocol, reducing the duration of aortic occlusion. In the remaining 21 patients, recovery was uneventful, and during a mean follow-up of 7.3 months (± 10.2 months), a single type IA endoleak was detected (4.8%), which spontaneously resolved. Krievins et al reported on an extended group of patients, including the previously reported population treated with the Nellix system, as well as patients outside the devices' original instructions for use (IFU).[50] During a mean follow-up of 15 ± 6 months, one additional endoleak was reported (a type IB endoleak) and was resolved with a secondary endovascular intervention.

Despite being promising, some limitations remain to be solved with this technology. Although Nellix was designed to broaden the range of patients who are anatomically suitable for EVAR, neck-related IFUs are similar to "common" devices.[51] Additionally, endobag filling may produce hazardous effects on the aneurysm wall, as the transmitted pressure may potentially cause intraoperative aneurysm rupture or thrombus dislodgement, with a risk of renal embolization. Furthermore, treatment of ruptured AAAs, when an integrate wall is absent, can lead to endobag prolapse throughout the rupture site with inadequate aneurysm seal and compression of the neighboring structures. As for the remaining stent grafts, accurate device positioning still remains of paramount importance, particularly in challenging proximal neck anatomy to avoid unintended endobag prolapse into the lumen. Proximal type I endoleaks in patients treated with the Nellix system cannot be addressed the same way as patients treated with other endografts. Finally, the effect on long-term sac dynamics is uncertain as thrombus reabsorption may leave the patient at risk of developing late endoleaks. In conclusion, long-term outcomes are still somewhat unpredictable.

Addressing Short Proximal Necks

Short proximal aneurysm neck lengths remain the most important morphological restraint to EVAR.[52] Sweet et al

found that AAAs in up to 47% of men and 63% of women have a proximal neck length of < 15 mm (N = 1,063).[53] In a EUROSTAR registry report (N = 3,499), Leurs et al found that patients with neck lengths ≤ 10 mm were at increased risk of presenting with a proximal type I endoleak during a median follow-up of 12 months (HR, 2.13; 95% CI, 1.17–4.6).[54] A report from AbuRahma et al is also in accordance with these findings.[55] At 3 years, rates of freedom from proximal type I endoleak were 80% for patients with proximal neck lengths > 15 mm (N = 195) and 53% for patients with proximal necks shorter than 10 mm (N = 17) (*P* = .03).

Most of the available devices require at least 10 mm of nondiseased infrarenal aorta to achieve an adequate proximal seal. Recently, the Ovation Prime system (TriVascular, Inc., Santa Rosa, CA) was approved to treat AAAs with proximal necks lengths ≥ 7 mm. In an initial report, Mehta et al did not identify any type I endoleaks among 152 patients treated with this device during the first year of follow-up.[56] However, the mean neck length in this population was 23 ± 13 mm, and in fact, only 25 patients had a proximal neck length < 10 mm. Long-term outcomes are awaited.

Although EVAR for patients with short (< 10 mm) proximal necks within the IFU of these recent devices remains controversial, endovascular exclusion of juxtarenal or suprarenal AAAs cannot be addressed by standard EVAR. Currently available treatment options for these patients include fenestrated EVAR (FEVAR) and chimney EVAR (Ch-EVAR), which achieve proximal seal in the infrarenal and suprarenal aorta, preserving visceral collateral patency.

FEVAR

Since FEVAR was first reported in 1999,[57] this method has gained acceptance due to encouraging results. In a group of 30 patients treated with the Zenith Fenestrated graft (Cook Medical, Bloomington, IN), Greenberg et al did not report any proximal type I endoleaks or aneurysm ruptures during a period of 24 months.[58] Two patients (6.7%) presented with renal artery occlusions, and five (16.7%) required secondary interventions, but none would need renal substitution therapy. Verhoeven et al also did not identify any secondary proximal type I endoleaks in a group of 100 patients with juxtarenal AAAs treated with this device during a median follow-up of 24 months.[59] Although two patients (2%) had presented intraoperatively with a primary proximal type I endoleak, they were successfully treated with ballooning. Target vessel patency was 96.7%, and renal substitution therapy was necessary in two patients (2%).

Recently, the British Society for Endovascular Therapy and the Global Collaborators on Advanced Stent-Graft Techniques for Aneurysm Repair (GLOBALSTAR) reported on 318 patients who underwent FEVAR.[60] During a median follow-up of 6 months, proximal type I endoleaks were reported in 14 patients (4.4%), and target vessel patency was 98.4%.

The Anaconda stent graft (Vascutek Ltd.) is another currently available fenestrated device. Although Bungay et al[61] reported the successful treatment of four patients with a 100% success rate of target vessel cannulation, the reported experience remains scarce.

Until recently, FEVAR required individually customized stent grafts for each patient's morphological features, which carried a significant delay due to device manufacturing, thus limiting FEVAR to the elective setting. However, in a report from Azzaoui et al, the anatomy of the infrarenal aorta and main visceral branches was found to be highly predictable.[62] These findings enabled the production of off-the-self fenestrated devices designed to fit a significant range of patients.

The Zenith p-Branch (Cook Medical) was the first device designed to accommodate a wide range of anatomies.[63] The original Zenith fenestrated stent graft was modified, incorporating dome-like fenestrations with an outer diam-

eter of 15 mm and an inner diameter of 6 mm reinforced with nitinol wires. These fenestrations allow the catheterization of renal arteries that fall within the outer diameter range. Sobocinski et al found that in a group of 100 patients, 70 were suitable for endovascular treatment with one of the two off-the-shelf fenestrated endograft designs studied.[64] However, these patients had previously been treated with customized fenestrated endografts, which may introduce a selection bias in these authors' findings, thus limiting their conclusions. Nevertheless, Kitagawa et al reported a technical success rate of 100% in a group of 16 patients treated with the Zenith p-Branch endograft, which also included two cases of ruptured aneurysms.[65]

Another available off-the-shelf fenestrated device is the Ventana fenestrated system (Endologix, Inc.). Holden et al reported their initial experience with the fenestrated Ventana device[66] in a group of 15 patients with pararenal and juxtarenal AAAs. Technical success was 100%, with no reported type I or III endoleaks at up to 1 year of follow-up. In another report with 31 patients, Quiñones-Baldrich et al reported[67] a technical success rate of 97% (N = 30), a 30-day clinical success rate of 94% (N = 29), and no confirmed type I endoleaks. However, last April, the Ventana clinical trial was suspended due to a higher-than-expected number of reinterventions.

Although off-the-shelf FEVAR has demonstrated encouraging results, these have been limited to a few centers. Furthermore, whether this technically demanding treatment option should be extended to small-volume centers remains controversial, as data are still scarce.[68]

CHIMNEY EVAR

Initially reported as a bailout technique for inadvertent renal artery coverage during EVAR, the placement of a parallel conduit to the main endograft to allow perfusion of collateral vessels has been used to treat AAAs with short proximal necks to elongate the proximal seal zone.[69] In an early outcome study, Coscas et al noted two (12.5%) proximal type I endoleaks (N = 16). Twenty-five of a total 26 target vessels (96%) remained patent at a median follow-up of 10.5 months, although renal function had deteriorated in three patients (18.8%), two of whom required renal substitution therapy.[70] Bruen et al reported one (4.8%) proximal type I endoleak among 21 patients.[71] Primary target vessel patency was 84% at 1 year of follow-up, and two patients (9.5%) required renal substitution therapy. Similar results were published by Lee et al among 28 patients,[69] with two patients (7.1%) requiring permanent hemodialysis. During a mean follow-up of 10.7 months, two patients (7.1%) presented with proximal type I endoleaks, and primary target vessel patency was 98.2% (55 of 56 target vessels).

CONCLUSION

EVAR has allowed AAA patients who were, until recently, considered inoperable to benefit from endovascular intervention. The technological investment in this particular field allied with increasing experience progressively challenged morphological restrains, extending treatment to patients with complicated proximal neck anatomy. Although we can no longer rely on historical data to project the results of contemporary patients, adverse anatomy clearly affects outcomes, and so, judicious patient and device selection are key to achieving sustained clinical success. The development of off-the-shelf fenestrated endografts may overcome stent graft manufacturing-related delays, enabling FEVAR to be performed in the acute setting, but real-world experience will be required to allow generalization of this treatment option. ■

Nelson Oliveira, MD, is with the Department of Vascular Surgery, Erasmus University Medical Centre in Rotterdam, The Netherlands. He stated that he has no financial interests related to this article. Dr. Oliveira may be reached at +31 107031810; n.gomesoliveira@erasmusmc.nl.

Frederico Bastos Gonçalves, MD, is with the Department of Vascular Surgery, Erasmus University Medical Centre in Rotterdam, The Netherlands. He stated that he has no financial interests related to this article. Dr. Gonçalves may be reached at +31 107031810; f.bastosgoncalves@erasmusmc.nl.

Sander ten Raa, MD, PhD, is with the Department of Vascular Surgery, Erasmus University Medical Centre in Rotterdam, The Netherlands. He stated that he has no financial interests related to this article. Dr. ten Raa may be reached at +31 107031810; s.tenraa@erasmusmc.nl.

Ellen Rouwet, MD, PhD, is with the Department of Vascular Surgery, Erasmus University Medical Centre in Rotterdam, The Netherlands. She stated that she has no financial interests related to this article. Dr. Rouwet may be reached at +31 107031810; e.rouwet@erasmusmc.nl.

Johanna Hendriks, MD, PhD, is with the Department of Vascular Surgery, Erasmus University Medical Centre in Rotterdam, The Netherlands. She stated that she has no financial interests related to this article. Dr. Hendriks may be reached at +31 107031810; j.m.hendriks@erasmusmc.nl.

Hence Verhagen, MD, PhD, is with the Department of Vascular Surgery, Erasmus University Medical Centre in Rotterdam, The Netherlands. He has disclosed that he is a consultant to Medtronic, Inc. and Gore & Associates. Dr. Verhagen may be reached at +31 107031810; h.verhagen@erasmusmc.nl.

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