Commentary: polymerization and its similarity with building solid evidence

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Polymerization and Its Similarity With Building Solid Evidence

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When endovascular aneurysm sealing (EVAS) was first commercially launched in 2013, it seemed like an earthquake on endovascular aneurysm repair (EVAR) grounds, as it introduced the use of polymer combined with stent-grafts for the treatment of abdominal aortic aneurysms. But it was not the addition of polymer per se to the conventional procedure that was so different from EVAR, but rather the fact that this meant the abandonment of a well-established EVAR principle: fixation of the stent-graft through radial force in a supposedly healthy proximal aortic neck. Contrarily, in EVAS, the fixation of the stent-grafts is achieved through polymer-filled endobags that anchor themselves within the aneurysm sac and, if present, in its associated thrombus.[1] This model seems to kill two birds with one stone: The polymer not only provides the fixation of the stent-grafts but also fills the entire aneurysm sac, hence minimizing the likelihood of type II endoleaks. So much for the theory.

However, clinical evidence has taught us differently. While many would agree that the proximal aortic neck necessary for EVAR fixation is not always as healthy as we want it to be, most would say the same about the thrombus present within many aneurysms. Thrombus tends to be a rather heterogeneous mass, with some softer and some stiffer components, some parts containing less liquid, some parts more fluid. Interestingly, this is part of the foundation on which the "EVAS house" was built. Looking at it from that perspective, it does not come as a surprise that migration turned out to be an issue in heavily thrombus-laden aneurysms. Accordingly, the calculations performed on data derived from the EVAS FORWARD IDE trial cohort revealed an association between thrombus load and migration,[2] leading to the updated instructions for use (IFU) in 2016. Consequently, aneurysms with a defined amount of thrombus are now considered to be outside the IFU, a both necessary and important step. The efficacy of the updated IFU was made evident in a presentation to the 2017 Society of Vascular Surgery Annual Scientific meeting: Retrospectively applying the new criteria from the updated IFU to the patients treated within the EVAS FORWARD IDE trial would lead to significantly reduced endoleak and migration rates.[2]

One endpoint, however, was not influenced by the updated IFU: the rate of type II endoleaks. All large EVAS studies[3–5] revealed a very low incidence of type II endoleaks compared with standard EVAR devices.[6] This in turn seems to prove that one of the primary goals of the EVAS concept, namely, the reduction of type II endoleaks, was broadly achieved. Even though the clinical relevance of type II endoleaks is subject to debate, there is no doubt that a low occurrence is still desirable.

This brings out another interesting aspect. While the device has now been commercially available for 5 years, there is still only 2-year follow-up data available.[2,5] Hence, the conclusions drawn in the review by Reijnen and Holden[7] in the April 2018 issue of the *JEVT* must be taken with great caution. As we learned from the very long-term follow-up data from the EVAR-2 trial,[8] it is not so much the early phase that separates the wheat from the chaff but rather the long-term performance of a treatment modality. As such, EVAS has yet to prove whether it can meet the requirement of lasting durability combined with the reduction of secondary interventions. Metaphorically speaking, compared with the process of polymerization, we are still in the phase of waiting until the polymer solidifies. Time will tell whether the concept of EVAS will rewrite the history of EVAR.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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References

1. Donayre CE, Zarins CK, Krievins DK, et al. Initial clinical experience with a sac-anchoring endoprosthesis for aortic aneurysm repair. *J Vasc Surg*. 2011;53:574–582.
2. Carpenter JP. Nellix System for endovascular aneurysm sealing: effect of IFU refinements from the EVAS FORWARD IDE. Paper presented at: The 2017 Vascular Annual Meeting of the Society for Vascular Surgery; May 31–June 3, 2017; San Diego, CA, USA.
3. Böckler D, Holden A, Thompson M, et al. Multicenter Nellix EndoVascular Aneurysm Sealing system experience in aneurysm sac sealing. *J Vasc Surg*. 2015;62:290–298.
4. Carpenter JP, Cuff R, Buckley C, et al; Nellix Investigators. One-year pivotal trial outcomes of the Nellix system for endovascular aneurysm sealing. *J Vasc Surg*. 2017;65:330–336.e4.
5. Thompson MM, Heyligers JM, Hayes PD, et al, for the EVAS FORWARD Global Registry Investigators. Endovascular aneurysm sealing: early and midterm results from the EVAS FORWARD Global Registry. *J Endovasc Ther*. 2016;23: 685–692.
6. Guo Q, Du X, Zhao J, et al. Prevalence and risk factors of type II endoleaks after endovascular aneurysm repair: a meta-analysis. *PLoS One*. 2017;12:e0170600.
7. Reijnen MM, Holden A. Status of endovascular aneurysm sealing after 5 years of commercial use. *J Endovasc Ther*. 2018;25:201–206.
8. Sweeting MJ, Patel R, Powell JT, et al.; EVAR Trial Investigators. Endovascular repair of abdominal aortic aneurysm in patients physically ineligible for open repair: very long-term follow-up in the EVAR-2 randomized controlled trial. *Ann Surg*. 2017;266:713–719.