

Poor past and look forward

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See **"Five-year outcomes of implantation of Absorb biodegradable stents using the bifurcation stenting technique: a case report"** Ioseliani D. G., Asadov D. A., Fomenko V. V., Azarov A. V., Semitko S. P. in **Original articles**, pp. 87-95

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Scaffold is a stent not made of metal, which was created to implement a fantastic idea: to use a device in coronary angioplasty that can fully dissolve over time. It consisted of a polymer coated with an antiproliferative agent (everolimus-eluting bioresorbable framework) in order to maintain functional properties of coronary arteries and avoid the long-term complications inherent in metal stents.

This idea was enthusiastically accepted in the early twenties of the twenty-first century by medical community. Based on the results of one-year randomized study Absorb III, the use of scaffolds has been approved by the Food and Drug Administration (FDA). Scaffolds were considered as part of a new era in surgery. A large-scale implementation and study of a new technology was started in percutaneous coronary interventions within multi-year randomized clinical trials with the same design: Absorb II, Absorb Japan, Absorb China, Prospect Absorb.

At the same time, already in the early studies, the fact of scaffold thrombosis and myocardial infarction were noted. Myocardial infarction in the area of placed scaffolds during the first year was observed significantly more often than with the use of high technology metal stents [1-4]. This led to the termination of scaffold production by Abbott in 2017. Further, in the clinical guidelines, the list of indications for scaffold use became shorter: not to use or to use only in clinical trials.

The cessation of scaffold production did not stop the initiated clinical observations planned for up to

7 years. The main idea was as follows: thrombosis in scaffolds occurred especially often in the first month of follow-up, but later the curve of complications was parallel to metal stents.

These observations gave hope for the implementation of the main idea of favorable coronary artery disease course after scaffold dissolvement.

The three-year follow-up was not optimistic, but there were no differences in the target complications with scaffolds or metal stents over a three to five year interval [5-8].

An example of a favorable five-year clinical observation with coronary angiography and optical coherence tomography was presented in the article by DG Ioseliani et al. *"Five-year outcomes of implantation of Absorb biodegradable stents using the bifurcation stenting technique: a case report"*.

The noted positive outcomes of scaffold use can be considered as incentives for further improvement of such stents with a new design, thinner structure or other material [Multiple presenters. BRS: Is there a future for the technology. Presented at: CRT 2020. February 24, 2020. <https://youtu.be/RLSqfrH-qoE>].

The absence of long-term significant advantages of interventional treatment in comparison with optimal drug therapy (Courage and Ischemia) makes it possible to search for novel technological solutions for percutaneous coronary interventions, which include, in particular, the replacement of metal stents.

Relationships and Activities: none.

References

1. Serruys PW, Chevalier B, Sotomi Y, et al. Comparison of an everolimus-eluting bioresorbable scaffold with an everolimus-eluting metallic stent for the treatment of coronary artery stenosis (ABSORB II): a 3 year, randomised, controlled, single-blind, multicentre clinical trial. *Lancet*. 2016;388(10059):2479-91. doi:10.1016/S0140-6736(16)32050-5. Erratum in: *Lancet*. 2017;389(10071):804.
2. Elias J, van Dongen IM, Kraak RP, et al. Mid-term and long-term safety and efficacy of bioresorbable vascular scaffolds versus metallic everolimus-eluting stents in coronary artery disease: A weighted meta-analysis of seven randomised controlled trials including 5577 patients. *Neth Heart J*. 2017;25:429-38. doi:10.1007/s12471-017-1008-x.
3. Wykrzykowska JJ, Kraak RP, Hofma SH, et al. Bioresorbable scaffolds versus metallic stents in routine PCI. *N Engl J Med*. 2017;376:2319-28. doi:10.1056/NEJMoa1614954.
4. Mukherjee D. Device Thrombosis with Bioresorbable Scaffolds. *N Engl J Med*. 2017;376(24):2388-9. doi:10.1056/NEJMe1703202.
5. Ali ZA, Gao R, Kimura T, et al. Three-Year Outcomes With the Absorb Bioresorbable Scaffold: Individual-Patient-Data Meta-Analysis From the ABSORB Randomized Trials. *Circulation*. 2018;137(5):464-79. doi:10.1161/CIRCULATIONAHA.117.031843.
6. Kereiakes DJ, Ellis SG, Metzger DC, et al; ABSORB III Investigators. Clinical Outcomes Before and After Complete Everolimus-Eluting Bioresorbable Scaffold Resorption: Five-Year Follow-Up From the ABSORB III Trial. *Circulation*. 2019;140(23):1895-903. doi:10.1161/CIRCULATIONAHA.119.042584.
7. Räber L, Ueki Y. Bioresorbable Scaffolds: Unfulfilled Prophecies. *Circulation*. 2019;140(23):1917-20. doi:10.1161/CIRCULATIONAHA.119.043773.
8. Smits PC, on behalf of the COMPARE-ABSORB investigators. 3-year results from the COMPARE-ABSORB trial. Presented at virtual CRT 2021, March 13, 2021. https://www.cerc-europe.org/wp-content/uploads/CRT-2021_COMPARE-ABSORB_final-1.pdf.