BIOMAG-I

Temporal Changes in Coronary Plaque as Assessed by an Artificial Intelligence Based OCT: From the FIH Trial on Freesolve™ Scaffold[1]

Conclusions

- Freesolve RMS **promotes the healing of the vessel coronary wall** demonstrated by the decrease in the lipid area and the increase in fibrous tissue 12 months after implantation.*[1]
- There is a **reduction of more than 20% in lipid area** between baseline and 12-month follow-up.[1]
- There is an **increase of 36% in fibrous tissue** between baseline and 12-month follow-up.[1]
- Regardless of the plaque composition at baseline, **Freesolve triggers the thickening of the fibrous cap which contributes to plaque stabilization and may mitigate the risk of plaque rupture**.[1]

Aim of the study

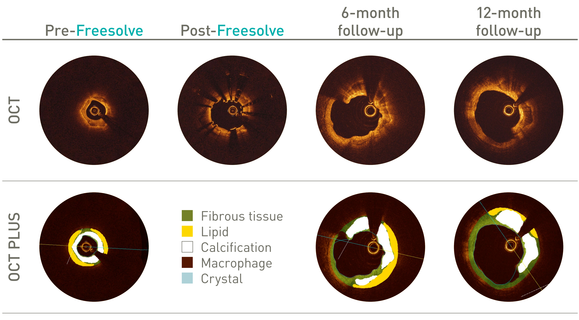
- To assess the impact of the baseline plaque composition on the Freesolve RMS luminal late loss.
- To compare the serial plaque changes between baseline and 6-month and 12-month follow-up.

Methods

A total of 116 patients were enrolled in the BIOMAG-I trial. Patients were imaged with OCT pre- and post-Freesolve RMS implantation and at 6 and 12 months. OCT has a unique resolution to permit coronary plaque content characterization. In this analysis the investigators utilised the OCTPlus software, which uses artificial intelligence to assess the composition (i.e., lipid, calcium, fibrous tissue) of the plaque.

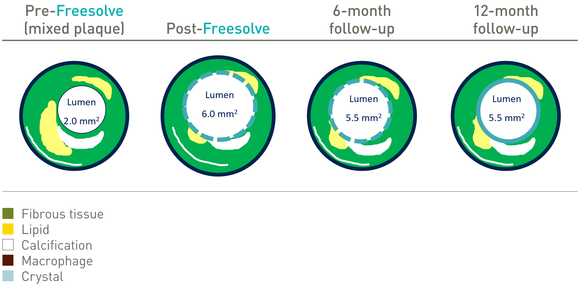
Results[1]

- Serial changes in coronary plaque composition in response to Freesolve RMS implantation.
- There was a reduction of 24.8% and 20.9% in lipid area between the OCT taken before the Freesolve RMS implantation (pre-PCI) and the 6- and 12-month follow-up.
- Conversely, the fibrous tissue increased by 48.4% and 36.0% between the OCT taken before the Freesolve RMS implantation (pre-PCI) and the 6- and 12-month follow-up.



The OCTPlus software color-coded each frame to represent the different tissue composition (i.e. green represents the fibrous tissue, yellow represents the lipid tissue, etc.).

Note: The frame after the implantation is not presented because the struts produce an artefact that it is misinterpreted by the software.



Regardless of the plaque composition at baseline, Freesolve RMS triggers the thickening of the fibrous cap which contributes to plaque stabilization and may mitigate the risk of plaque rupture. This is an important point since rupture and thrombosis of lipid-rich atherosclerotic coronary artery lesions (known as vulnerable plaques) is the most frequent cause of acute coronary syndrome and sudden cardiac death.[2]

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* Based on OCT analyses.

1. Garcia-Garcia et al. European Heart Journal - Cardiovascular Imaging, Volume 25, Issue 4, April 2024, Pages 491–497, https://doi.org/10.1093/ehjci/jead299; 2. Seung-Jung Park et al. The Lancet. Published online April 8, 2024. https://doi.org/10.1016/S0140-6736(24)00413-6.

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