A prospective multicentre randomized all-comers trial to assess the safety and effectiveness of the ultra-thin-strut sirolimus-eluting coronary stent Supraflex: 2-year results of the TALENT trial

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Background and purpose: Supraflex is a sirolimus-eluting stent with a biodegradable polymeric coating and 60um ultra-thin struts. In the TALENT study, we found the Supraflex stent was non-inferior to the Xience stent for a device-oriented composite endpoint (DOCE, defined as cardiac death, target-vessel myocardial infarction, or clinically indicated target lesion revascularisation) at 12 months in an all-comer population. Additionally, per-protocol analysis showed a significantly lower clinically indicated target lesion revascularisation (CI-TLR) in the Supraflex group than in the Xience group. We now present the 2-year follow-up results.

Methods: The TALENT study was a prospective, randomised, single-blind, multicentre study across 23 centres in Europe. Eligible participants underwent percutaneous coronary intervention in an all-comers fashion in vessels of 2.25–4.5 mm. Patients were randomized (1:1) to implantation of either Supraflex or Xience (NCT02870140).

Results: Between October 21, 2016 and July 3, 2017, 720 patients with 1046 lesions were randomly assigned to Supraflex, and 715 patients with 1030 lesions to Xience. At 24 months, DOCE had occurred in 49 patients (6.9%) in the Supraflex group and in 56 patients (7.9%) in the Xience group (absolute difference –1.0% [95% CI: –3.7 to 1.7], Plog-rank=0.491). Per-protocol analysis at 24 months showed CI-TLR occurred in 21 and 30 patients in the Supraflex and Xience, respectively (3.3% versus 4.5%, absolute difference –1.2%, [95% CI: –3.3 to 0.9], Plog-rank=0.267).

Conclusion: In an all-comer population, at 2-year follow-up, the use of Supraflex stent was at least as safe and efficacious as Xience stent. However, the significantly lower rate of CI-TLR shown in patients treated with Supraflex at 1-year was no longer retained in the 2-year results. Whether theoretical advantage of ultra-thin strut drug eluting stents Supraflex can translate into clinical benefit or not will be further elucidated through a total of 3 years of follow-up.