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MILES-UK: Nine-month clinical outcomes of biodegradable polymer ultrathin sirolimus-eluting stent in an all-comer UK population undergoing percutaneous coronary intervention

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(on behalf of the MILES UK study investigators)

Potential conflicts of interest

Speaker's name : Ian Menown

☑ I have the following potential conflicts of interest to declare:

Receipt of Grant/ Research support: Meril Life Sciences

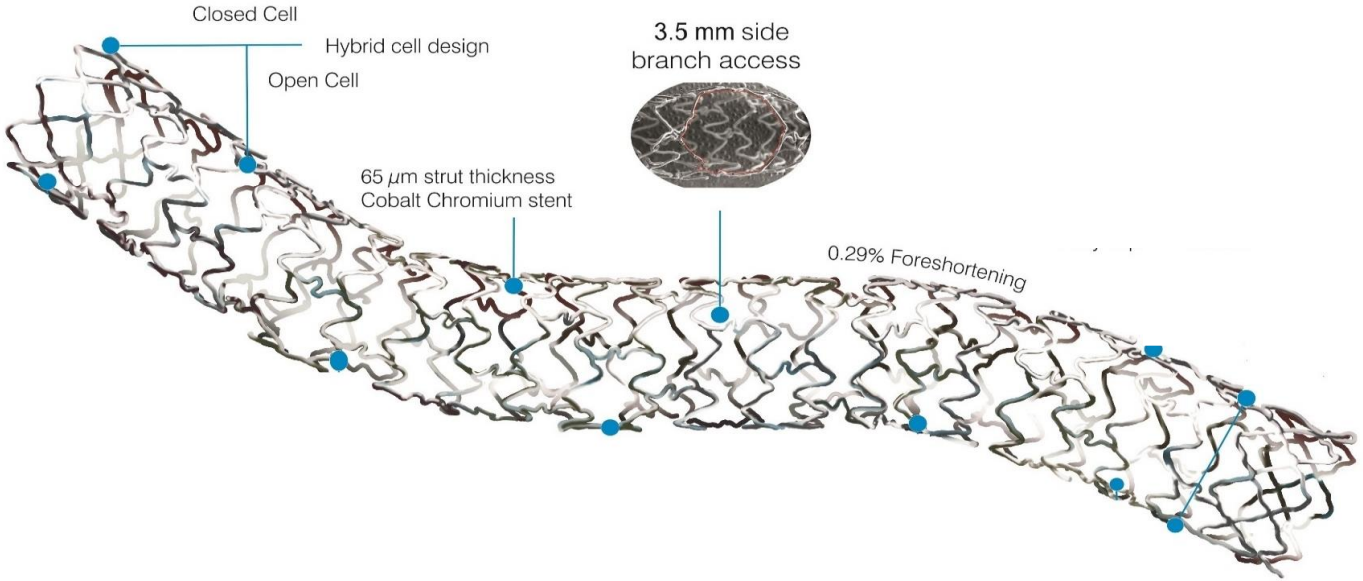
Why this study?

- Thin stent struts may be associated with reduced vessel injury and use of biodegradable polymers may further improve long term outcomes.

- However, data with earlier stent designs has been inconsistent and thus further studies are required.

What did we study?

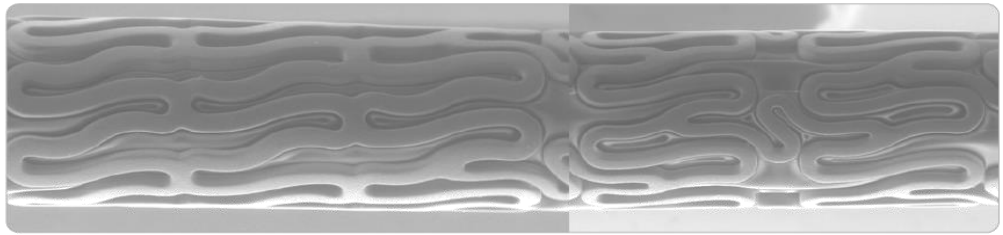
- Ultra-thin (**65µm**) strut cobalt chromium sirolimus eluting stent (**BioMime**)
  Good radial strength (collapse pressure 1.1bar), <3% recoil, 0.29% foreshortening



- Thin (2µm), flexible co-polymer layer PLLA/PLGA (BioPoly™), non-thrombogenic, elutes sirolimus (1.25 µg/mm^2), rapidly biodegrades <60days

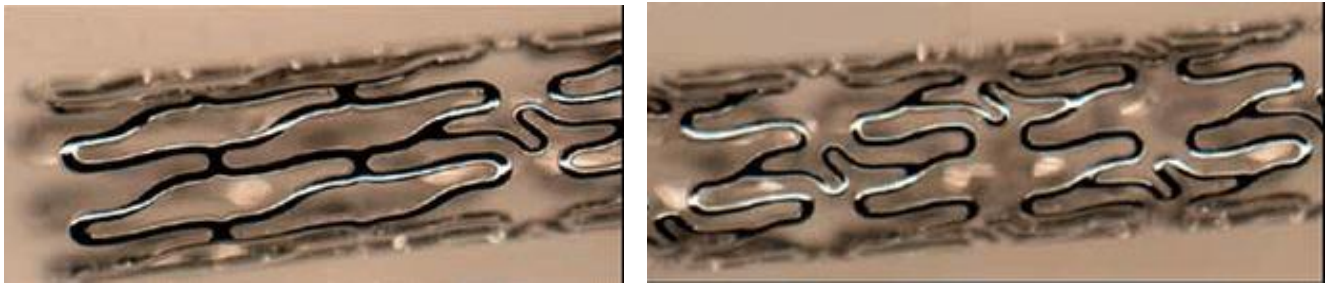
Hybrid cell design and stent expansion

Hybrid design: closed cells at ends to reduce edge injury and open cells in centre to optimise conformability



Closed cell design (ends)

Open cell design (centre)



Hybrid cell design and stent expansion

Hybrid design: enables balloon expansion from the centre instead of the ends which may reduce edge injury

Crimped stent

Morphology Mediated Expansion

Fully expanded stent

How was the study executed?

All-comers patients from 14 UK sites undergoing PCI enrolled into a prospective, non-randomized, multi-centre, open-label study (IRAS No. 135437)

Inclusion of patients with complex anatomy encouraged (long lesions, bifurcations, CTOs)

Clinical follow-up at 1, 9, 12, 24 and 36 months

1^0 efficacy endpoint: 9 month incidence of target vessel failure (cardiac death, MI, or TVR)
1^0 safety endpoint: 9 month incidence of definite or probable stent thrombosis (ARC definition)

Baseline Demographics and Clinical Characteristics

	N=752
Age (Mean ± SD), years	64.77±12.22
Male	71.5%
Smoking	43.3%
Hypertension	59%
Dyslipidemia	58.8%
Diabetes mellitus	20.7%
Acute coronary syndrome	34%
Multi-vessel disease	40.4%
Previous MI	19.6%
Previous PCI	22.2%
Previous CABG	4.7%

Lesion and Procedural Characteristics

Characteristics	n=954 lesions treated
Lesions per patient	1.27
Stents per patient	1.42
LMCA	5.7%
RCA	61.2%
LAD	25.7%
LCx	7.2%
SVG	0.2%
Visible thrombus	6.0%
Bifurcation	13.4%
CTO	6.1%
Lesion length (mean±SD)	25.69mm±17.25
Stent Diameter, (mean±SD)	3.08mm±0.52

Cumulative Clinical Outcomes at 9months f/up

Variables, n (%)	In-Hospital (n=752)	1 month (n = 728)*	9 months (n=578)*
Death	1 (0.13)	3 (0.41)	9 (1.56)
Cardiac Death	1 (0.13)	3 (0.41)	6 (1.04)
Non-Cardiac death	0 (0.00)	0 (0.00)	3 (0.52)
MI	2 (0.27)	4 (0.55)	5 (0.87)
TVR (ischaemia driven)	2 (0.27)	3 (0.41)	6 (1.04)
Stent Thrombosis (ARC def/prob)	1 (0.13)	2 (0.27)	5 (0.87)
Cumulative TVF*	**3 (0.40)**	**7 (0.96)**	**12 (2.08)**

(*from 728 and 578 patients reaching follow-up)

Conclusions

- Use of an ultra-thin strut biodegradable polymer sirolimus-eluting stent in all-comers patients undergoing PCI was associated with good clinical efficacy and safety at 9 months in this relatively complex patient cohort.
- Outcomes are consistent with Biomime *meri-T* trial data.
- Follow up data up to 3 years are awaited with interest.

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