BioMimics 3D helical stent imparting curvature in calcified vessels
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Background
The BioMimics 3D stent is designed on the principles underlying the latest generation of Nitinol stent technology for use in the femoropopliteal artery e.g. radial support, excellent flexibility, durability, clear visualisation and delivery accuracy, but with the addition of three-dimensional helical centreline geometry. The purpose of this helical geometry is to generate swirling blood flow within the stented segment. Pre-clinical studies have indicated that the introduction of swirling blood flow reduces neointimal formation when compared to a straight stent [1].

Aim
The goal of this analysis of data from the Mimics randomised control trial is to assess if the non-planar curvature imparted by the BioMimics 3D stent was changed by the presence of moderate-severe calcium.

Methods
The Mimics study enrolled 76 patients with symptomatic peripheral arterial disease randomised 2:1 to BioMimics 3D (helical) or straight control stent [2]. For the helical and straight stent groups respectively, 52% (26/50) & 58% (15/26) (p = 0.47) had moderate-severe calcification (core lab data). Using bi-planar X-ray images (AP and lateral projections), stent centreline curvature was quantified for each device implanted. Stented vessel curvature was evaluated continuously along the segment length using a method described in O’Flynn et al. 2007 [3]. Differences in curvature between groups was evaluated using the Student t-test. Primary stent patency was determined by the Core Lab (coreLab Bad Krozingen) and defined as freedom from > 50% stenosis identified by formal angiography or duplex ultrasonography (PSVR > 2.0) since the index procedure.

Results
There was more non-planar curvature measured in the BioMimics 3D stent group than the straight control group (p = 0.02).* Furthermore, there is no statistically significant drop-off in the level of curvature in the BioMimics 3D stent when the none-mild and moderate-severe groups are compared (p=0.14). Primary patency was observed to be independent of the degree of calcification in the BioMimics 3D group (log rank test p = 0.73). This supports the rationale for BioMimics 3D use within heavily diseased femoropopliteal segments.

Conclusions
The BioMimics 3D stent is as effective at imparting non-planar curvature in calcified vessels as it is in non-calcified vessels. Primary patency was observed to be independent of the degree of calcification in the BioMimics 3D group.

References