

## INVITED COMMENTARY

## A Paclitaxel Free Alternative in the War Against Drugs?

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In the current issue of the *European Journal of Vascular and Endovascular Surgery*, Saratzis *et al.* report the results of the direct comparison between interwoven nitinol stents (i.e., Supera) and drug eluting stents (DES) in the femoropopliteal segment using propensity matched analysis.<sup>1</sup> They report that in a heterogeneous single centre population target lesion restenosis, target lesion revascularisation, major amputation, and mortality are similar for the Supera and DES group at a median follow up of two years.

These results are especially relevant given the current controversy with respect to paclitaxel eluting devices. Since the recent meta-analysis of Katsanos *et al.*, reporting an up to 50% increased long term mortality for drug eluting devices was published,<sup>2</sup> restraint use of these devices is advocated. With this in mind, a suitable alternative to fill in this gap would be extremely welcome.

Thus far, Supera interwoven nitinol stents have not been compared directly with DES. The available results of Supera and DES for the treatment of femoropopliteal lesions have been promising, but most studies report on selected patient populations, for instance predominantly claudicants or limited lesion complexity. However, in comparing the results of different studies, the two stent types seem to do equally well in the femoropopliteal area with primary patency rates of roughly 80%–85% and freedom of target lesion revascularisation rates of 85%–90% at 12 months.<sup>3–6</sup> Saratzis *et al.* confirm these observations in a direct comparison, and also that at a median of two years follow up no significant differences between the Supera and DES group were observed.<sup>1</sup>

However, are we now convinced that Supera stents can replace DES in the treatment of femoropopliteal lesions? Target lesion restenosis rates were 32% and 24% for the Supera and DES groups, respectively ( $p = .07$ ) and the need for re-intervention rates were 14% and 9%, respectively ( $p = .12$ ). These differences are not significant, but this can still result from limited power in this considerable, but still not very large, patient population. Furthermore, this study was not specifically designed as a non-inferiority study and even if it used propensity score matching this does not equal randomisation and can, in some instances even increase bias.<sup>7</sup> Another issue in considering the results of Supera stents is the influence of packing on treatment results.<sup>8</sup> The best results are obtained with stent

compression, but no data on stent compression are available in the study of Saratzis *et al.*,<sup>1</sup> and therefore its effect cannot be assessed. However, everybody who has ever used a Supera stent knows that its deployment is somewhat more complex than that of most of the other self expandable stents, which could result in more heterogeneous results or at least requires a learning curve.

After the Food and Drug Administration's (FDA) initial warning, the FDA further analysed the available clinical data on paclitaxel eluting devices and recently published the conclusions of its review panel.<sup>9</sup> It concluded that the available data on paclitaxel coated devices intended to treat femoropopliteal lesions confirm an increase in late mortality rates (between two and five years). However, no clear recommendation was issued as additional data are necessary to provide well balanced advice. Potential alternatives in no-stent areas might be mechanical or laser atherectomy devices. And based on the data of Saratzis *et al.*,<sup>1</sup> interwoven nitinol stents could fill the (temporary) gap left behind by the paclitaxel eluting devices until further data become available.

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