

Optimization of a new venous stenosis treatment self-expanding nitinol stent using a multi-scale tribological approach from catheter to the veins

A. Sallami², P. Malecot^{3,4}, M. Fontaine¹, S. David², C. Moureaux², **P. Stempflié**^{1,*}

¹ SUPMICROTECH, CNRS, institut FEMTO-ST, F-25000 Besançon, France

² Cisteo MEDICAL, 1 rue Anne de Pardieu, F-25000 Besançon, France

³ Université de Bretagne Sud, CNRS, IRDL, F-56100 Lorient, France

⁴ Académie militaire de Saint-Cyr Coëtquidan, CReC Saint-Cyr, F-56380 Guer, France

*Correspondence: philippe.stempfle@ens2m.fr

Ni-Ti alloys – common shape memory alloys (SMAs) so-called nitinol [1] – are known to have the ability to recover their original shapes, even after significant externally loads are applied, owing to the existence of an austenite-to-martensite reversible phase transformation allowed by a simple unloading. This super-elastic behaviour (SE) – combined with its bio-compatibility – naturally leads nitinol to be an interesting candidate for various applications in medicine [2].

The present work focuses on a new patented one-piece double cross-sectional stent used in the treatment of venous stenosis, affecting vena cava, iliac veins and their bifurcations [2, 3]. Owing to the diameters of the targeted veins, this unique stent displays two sections of different diameters once deployed, which are connected together by a compliant area. Since the SE nitinol stent is placed in veins by catheterization their sections are first reduced into a wire form to be inserted within a polytetrafluoroethylene (PTFE) catheter displaying both a low friction and a good biocompatibility. Once positioned in the diseased vein, stent then returns to its shape on its own, taking advantage of its SE behaviour to expand the diseased vein. However, numerous antagonistic tribological challenges arise during this release because the stent: (i) first needs to slide easily along the guide-wire (catheter), in order to avoid any stick-slip occurrence leading to PTFE abrasion wear [3], and (ii) should not be enabled to slide any more once located within the veins [4].

The first issue has been recently studied by using an original multi-scale approach [3]. The latter combines X-ray tomography, optical topography with the Persson's contact theory in both static and dynamic cases in order to track the evolution of the real contact area during the sliding process. Various stent designs have been then deducted and optimized to reduce friction throw the catheter. The present work actually addresses the second tribological issue by extrapolating the above approach in order to follow the evolution of the static real contact area during stent deployment within both the illiac and cave veins. The ultimate local normal contact pressures can be evaluated as function of the stent topography to both (i) insure the non-sliding conditions of stent within the veins [4] and, (ii) avoid any vein lesions by limiting the normal pressure exerted by the stent on the veins [5].

As these results directly influence the design and the surface treatment of each stent's part, this work will describe the optimized double structure displaying in the same time: (i) a very low rigidity in the catheter in order to promote sliding [2,3] and, (ii) a maximum contact area in the vein limiting both the radial pressure and the risk of slipping once deployed [4,5].

[1] W.J. Buehler et al, J. Appl Phys., vol. 34, N°5, (1963), 1475-77

[2] A. Sallami et al, X ECCOMAS SMART 2023, D.A. Saravanos et al (Eds)

[3] A. Sallami et al, submitted to Tribology International, May 2024

[4] K. Gibson, MEDTRONICS Medical Affairs Corner, (2021)

[5] A.C. Dunn et al, Tribology Letters 27, 233-238, (2007)

Keywords: Self-expanding Nitinol Stent, Frictional law, Real contact area, Persson's contact theory