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SHARING EXPERTISE

LOCOMOTIVE ALL COMERS STUDY

VascuFlex® Multi-LOC

First clinical experience with the Multi-LOC multiple stent delivery system for focal stenting in long femoro-popliteal lesions

Amendt K, Beschorner U, Waliszewski M, Sigl M, Langhoff R, Thalwitzer J, Redlich U, Vogel B, Härtel D, and Zeller T. Vasa 2017;46(6):1–10.

OBJECTIVES

The LOCOMOTIVE study is a non-randomized, prospective, multi-centre, post market assessment study. It investigates the clinical outcomes of the new multiple stent delivery system VascuFlex® Multi-LOC in patients with femoro-popliteal lesions. This study will be complemented by the LOCOMOTIVE EXTENDED study which will target a total of up to 500 patients in Europe and Asia.

METHODS

In this first analysis, a total of 75 patients with symptomatic Peripheral Arterial Disease in femoro-popliteal lesions were recruited. Primary Endpoint was the 'all cause' TLR at six months and secondary endpoints includde the ABI, patency and walking distance at 6 and 12 months.

FINAL RESULTS AT 6 MONTHS

The majority of the 176 individually treated lesions had long and complex morphologies (51.1 % (90/176) TASC C/D) with a mean lesion length of 14.5 ± 9.0 cm. Overall 47 ± 18 % of lesion lengths could be saved from stenting. At six months, the patency was 90.7 % (68/75) and all-cause TLR rates were 5.3 % (4/75) in the overall cohort.

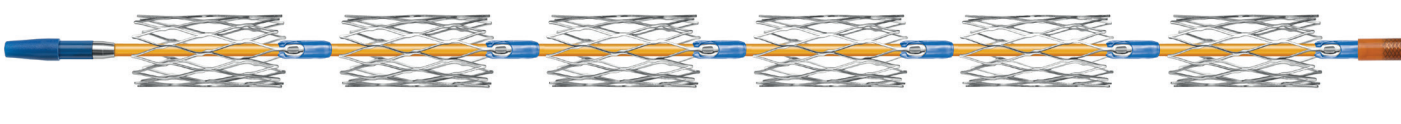
CONCLUSION

The first clinical experience at six months suggests that VascuFlex® Multi-LOC was safe and effective to treat femoro-popliteal lesions of considerable length (14.5 ± 9.0 cm). Almost half of the lesion length could be saved from stenting while vessel patency was high and TLR rates were acceptably low given the complexity of included patients ands lesions.

PRELIMINARY RESULTS AT 12 MONTHS

At 12 months, the patency was 86.7 % (52/60) and all-cause TLR rates were 9.3 % (7/75) in the overall cohort.

TLR **9.3 %** at 12 months (n=75)	TASC C/D lesions **51.1 %**	Procedural success **100 %**
Patency **86.7 %** at 12 months	Mean lesion length **14.5 cm**	Lesion length saved from stenting **47.0 %**



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V-VS17062