Sponsored by BIOTRONIK

How Does Stent Size Selection Play a Role in SFA Stenting Outcomes?

Findings from the BIOFLEX-I evaluation of COF.

BY MARIANNE BRODMANN, MD

A self-expanding stent's chronic outward force (COF) is dependent on the stent's design and materials, the structure of the lesion, as well as the implanted stent's selected size for the target vessel diameter. Self-expanding stents should generally be at least one size larger than the vessel diameter to ensure adequate contact with the vessel wall; however, the greater the size ratio, the more COF is exerted onto the vessel wall, which can result in

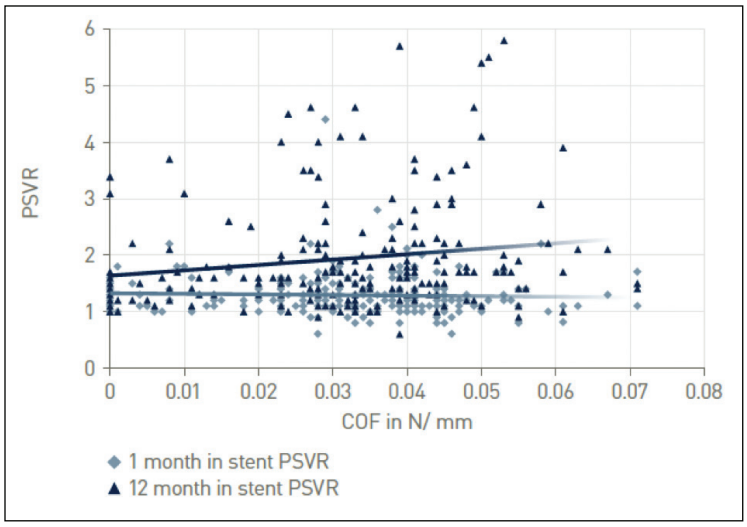

Figure 1. PSVR in dependence of COF at 1 and 12 months.

mechanical stress that may increase neointimal hyperplasia and restenosis.[1*] To evaluate the role of stent sizing and the resulting COF in clinical outcomes, a secondary evaluation was performed from a cohort of patients in the BIOFLEX-I study.[2]

BIOFLEX-I was a prospective, nonrandomized, multicenter, core lab–adjudicated study that evaluated the safety and efficacy of the Pulsar® self-expanding stent† (BIOTRONIK) in 302 patients with superficial femoral artery and proximal popliteal peripheral artery disease lesions. Duplex ultrasound was performed at 30-day and 6- and 12-month follow-up. These measurements were then used to do a secondary evaluation to explore the clinical impact of COF.

BIOFLEX-I EVALUATION OF COF

Available core lab–adjudicated angiographic imaging taken immediately after Pulsar stent implantation were analyzed to determine each individual vessel diameter and stent oversizing. Identified stent oversizing was then correlated with COF as measured in bench testing, and this determined amount of COF was correlated with measured peak systolic velocity ratio (PSVR) at 1, 6, and 12 months (Figure 1).

Pearson's correlation coefficient showed significance at 1 and 12 months (−0.196; $P = .008$). At 1 month, the PSVR was lower in those stents sized to exert greater COF; however, the sign of correlation was swapped at 12 months, with the lower COF stents showing lower PSVR. Thus, it was found that COF (in addition to smoking) was one of the most significant predictors for deterioration of PSVR ($P = .024$).

DISCUSSION

The data gathered from BIOFLEX-I show a trend that supports previous studies suggesting that oversizing can have a negative impact on clinical results. While theoretically it would seem likely that substantially increasing luminal diameter via oversized stent implantation would optimize outcomes, there has been a demonstrated threshold for when the resulting intramural stress from oversizing will trigger neointimal hyperplasia and subsequently may cause early restenosis.[3] Another study demonstrated that higher oversizing is associated with a significant increase in wall shear stress but resulted in no significant increase in luminal gain.[4] Particularly in calcified lesions, oversizing has been found to be associated with risk of tissue failure and is advised to be avoided.[5] The Zilver PTX global clinical program also showed that stent oversizing > 30% was a significant factor impacting target lesion revascularization ($P = .043$).[6]

CONCLUSION

As suggested by secondary evaluation from BIOFLEX-I, at 12 months, high COF appears to be a significant risk factor for restenosis (shown as high PSVR; $P = .024$). Long-term, low COF seems to result in less restenosis and potentially fewer reinterventions.[2] This should be considered when selecting size and stent for implantation in the lower limb to optimize the amount of exerted radial force; avoiding oversizing could potentially improve clinical outcomes.[3] The Pulsar stent, which has shallow expansion curves and low COF, has been associated with better outcomes compared to higher COF alternatives.[7] Further research is needed to clarify the relationship between stent forces, size selection, and clinical outcomes. ■

1. Zhao HQ, Nikanorov A, Virmani R, et al. Late stent expansion and neointimal proliferation of oversized nitinol stents in peripheral arteries. Cardiovasc Intervent Radiol. 2009;32:720-726.
2. Burket M. BIOFLEX-I increased outward force of SE-BMS in the SFA. Presented at: Charing Cross Symposium 2019; April 16, 2019; London, United Kingdom.
3. Ballyk PD. Intramural stress increases exponentially with stent diameter: a stress threshold for neointimal hyperplasia. J Vasc Interv Radiol. 2006;17:1139-1145.
4. Gokgol C, Diehm N, Nezami FR, Buchler P. Nitinol stent oversizing in patients undergoing popliteal artery revascularization: a finite element study. Ann Biomed Eng. 2015;43:2868-2880.
5. Gokgol C, Diehm N, Buchler P. Numerical modeling of nitinol stent oversizing in arteries with clinically relevant levels of peripheral arterial disease: the influence of plaque type on the outcomes of endovascular therapy. Ann Biomed Eng. 2017;45:1420-1433.
6. Dake M. Insights from Global Zilver PTX experience: what are the predictors for clinical failure and TLR? Presented at: LINC 2019; January 23, 2019; Leipzig, Germany.
7. Funovics M. Differences in clinical outcomes of low COF stent vs high COF stent proven in clinical practice. Presented at: CIRSE 2019; September 7-10, 2019; Barcelona, Spain.

*As demonstrated in preclinical studies using comparable stents.
†Clinical data obtained with Astron Pulsar and Pulsar-18, predecessors of Pulsar-18 T3; stent of Pulsar-18 is identical compared to Pulsar-18 T3.

Marianne Brodmann, MD
Division of Angiology
Medical University Graz
Graz, Austria
marianne.brodmann@medunigraz.at
Disclosures: Receives honoraria from BIOTRONIK.