Impact Of Nitinol Stent Oversizing On Outcomes Of Fempop Interventions: How Should Optimal Stent Size Be Determined?

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Nitinol Stent Oversizing
Clinical Considerations

> No clear stent sizing rule.
> Clinicians may exceed limits to obtain acute luminal gain.\(^1,2\).
> Chronic outward force:\(^3\):
  - Damage to arterial walls.
  - Neointimal proliferation.
  - Restenosis.

1 Kirsch et al. 2002. AJNR Am J Neuroradiol
2 Stoeckel et al. 2004. Eur Radiol
3 Saguner et al. 2012. Cardiovasc Intervent Radiol

Nitinol Stent Oversizing
Animal Data

28 Nitinol stents in 14 healthy Yucatan swines.
> Oversizing ratio: 1.2 to 1.9; no post-dilatation.
  - Normal-sized to over-sized threshold: 1.4.
> Follow-up at 6 months:
  - Extent of oversizing correlates with extent of restenosis.

Nitinol Stent Oversizing
Numerical Modelling

> Arterial geometries of 5 PAD patients undergoing 3D rotational angiography of femoro-popliteal artery, 70°/20° knee/hip flexion
> Circular cross section and a constant inner diameter of 5 mm

> Anisotropic, hyperelastic material model with collagen fibre orientations & dispersion
> Astron Nitinol Stent (Biotronik, Switzerland)
> Oversizing ratio: 1.1 – 1.8

*Gokgol et al. 2015. Annals of Biomedical Eng

10 uncoated & 6 TINOX-coated Nitinol stents in healthy mini-pigs
> Oversizing ratio: 1.0 – 2.5; No post-dilatation
> Follow-up at 5 months
  - Increased oversizing and increased stenosis correlated
  - Drug coating had no effect on restenosis


Low OS (1.1-1.3) Mld. OS (1.3–1.6) High OS (1.6-1.9)
Simulation Process

Arterial Stress and Luminal Gain

Conclusions

> Concerns about Nitinol stent oversizing in femoro-popliteal arteries are valid.
> Oversizing yields limited luminal gain but excess circumferential stress.
> Calcified arteries are more tolerant towards stent oversizing when compared with non-calcified segments.
> Measure arterial diameter on duplex sonography prior to stenting!