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Title: Mechanical properties of a biodegradable self-expandable polydioxanone monofilament stent: In vitro force relaxation and its clinical relevance

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Abstract: Biodegradable stents are promising treatments for many diseases, e.g., coronary artery disease, urethral diseases, tracheal diseases, and esophageal strictures. The mechanical properties of biodegradable stent materials play a key role in the safety and efficacy of treatment. In particular, insufficient creep resistance of the stent material could result in premature stent collapse or narrowing. Commercially available biodegradable self-expandable SX-ELLA stents made of polydioxanone monofilament were tested. A new, simple, and affordable method to measure the shear modulus of tiny viscoelastic wires is presented. The important mechanical parameters of the polydioxanone filament were obtained: the median Young's modulus was (E) over tilde = 958 (922, 974) MPa and the shear modulus was (G) over tilde= 357 (185, 387) MPa, resulting in a Poisson's ratio of nu = 0.34. The SX-ELLA stents exhibited significant force relaxation due to the stress relaxation of the polydioxanone monofilament, approximately 19% and 36% 10 min and 48 h after stent application, respectively. However, these results were expected, and the manufacturer and implanting clinician should be aware of the known behavior of these biodegradable materials. If possible, a biodegradable stent should be designed considering therapeutic force rather than initial force. Additionally, new and more advanced biodegradable shape-memory polymers should be considered for future study and use.

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