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Comparison of femoropopliteal artery stents under axial and radial compression, axial tension, bending, and torsion deformations

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ABSTRACT

High failure rates of Peripheral Arterial Disease (PAD) stenting appear to be associated with the inability of certain stent designs to accommodate severe biomechanical environment of the femoropopliteal artery (FPA) that bends, twists, and axially compresses during limb flexion. Twelve Nitinol stents (Absolute Pro, Supera, Lifestent, Innova, Zilver, Smart Control, Smart Flex, EverFlex, Viabahn, Tigris, Misago, and Complete SE) were quasi-statically tested under bench-top axial and radial compression, axial tension, bending, and torsional deformations. Stents were compared in terms of force-strain behavior, stiffness, and geometrical shape under each deformation mode. Tigris was the least stiff stent under axial compression (6.6 N/m axial stiffness) and bending (0.1 N/m) deformations, while Smart Control was the stiffest (575.3 N/m and 105.4 N/m, respectively). Under radial compression Complete SE was the stiffest (892.8 N/m), while Smart Control had the lowest radial stiffness (211.0 N/m). Viabahn and Supera had the lowest and highest torsional stiffness (2.2 μN m/° and 959.2 μN m/°), respectively. None of the 12 PAD stents demonstrated superior characteristics under all deformation modes and many experienced global buckling and diameter pinching. Though it is yet to be determined which of these deformation modes might have greater clinical impact, results of the current analysis may help guide development of new stents with improved mechanical characteristics.

1. Introduction

Peripheral Arterial Disease (PAD) affecting the femoropopliteal artery (FPA) is usually due to chronic atherosclerotic obstruction that reduces blood flow to the lower extremity. PAD affects more than 200 million individuals worldwide, and is associated with significant morbidity, mortality and decreased quality of life (Fowkes et al., 2013). Endovascular stenting of the FPA is an increasingly popular minimally invasive procedure that utilizes Nickel-Titanium (NiTi) alloy-based self-expanding stents that form a metal scaffold in the artery to improve its patency after balloon angioplasty. Though FPA stenting is one of the most common procedures performed outside of the heart, it carries one of the highest rates of reconstruction failure, with many patients developing recurrent disease requiring re-intervention in as little as two years (Schillinger et al., 2007).

Although the mechanisms underlying endovascular reconstruction failure are likely multifactorial, it is believed that the dynamic mechanical environment of the FPA in the flexing limb contributes significantly to this process (Ansari et al., 2013; MacTaggart et al., 2014). Requirements for stent design are not well standardized, which may contribute to large variabilities in clinical outcomes as evidenced by industry-supported and industry-independent clinical trials demonstrating 43–83% one year patency rates (Rundback et al., 2015). Furthermore, studies demonstrate major differences in stent fracture rates (Higashiura et al., 2009; Scheinert et al., 2005; Werner, 2014), suggesting that stent design may play a major role in this process.

Empirically, ideal FPA stent designs need to accommodate tension/compression, bending, and torsion of the artery with minimal resistance, while also ensuring necessary resistance to radial compression and long-lasting fatigue performance. Though optimal stent evaluation should include clinical data, human research trials are challenging and require large sample sizes due to heterogeneity of PAD patient populations, differences in anatomical and lesion characteristics, and technical differences in procedures (Mohsen et al., 2013; Nakazawa et al., 2009; Scheinert et al., 2005). Benchtop mechanical stent testing allows direct evaluation of the device without the interference of patient-dependent factors, thereby eliminating the need for large sample sizes. While such tests do not necessarily replicate the complex loads and conditions experienced by the stent *in vivo*, they can be used to understand key mechanical characteristics of different designs, and these

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experimental data are critical for computer aided design work and validation of computational models.

Published benchtop mechanical studies are mostly limited to small numbers of stent models (Duda et al., 2000; Gong et al., 2004; Stoeckel et al., 2004; Gore and Associates, 2007), many of which are currently off the market or have been replaced with newer generation devices. In addition, FPA deformation magnitudes experienced with limb flexion, and therefore the loading conditions for the benchtop tests, have not been completely understood and quantified. Recent data on axial compression, bending and torsion of the FPA in walking, sitting and gardening postures (Desyatova et al., 2017; MacTaggart et al., 2014; Poulson et al., 2017), demonstrate that values of FPA deformations used for current stent design and preclinical testing (Ansari et al., 2013), may be significantly underestimated, potentially contributing to poor clinical performance of many FPA stents.

The goal of this study was to perform comprehensive benchtop mechanical comparison of 12 currently used PAD stents under the most severe deformations experienced by the FPA during flexion of the limb. Quantitative and qualitative head-to-head assessments of stent performance under axial tension, axial compression, bending, radial compression, and torsion are detailed and the benefits and drawbacks of different stent designs are discussed.

2. Methods

2.1. Stent models

Twelve stent models frequently used to treat PAD were mechanically tested under axial tension/compression, three-point bending, radial compression, and torsion deformations. Stents included Absolute Pro and Supera (both Abbott Vascular), Lifestent (Bard), Innova (Boston Scientific), Zilver (Cook), Smart Control and Smart Flex (both Cordis), EverFlex (Covidien), Viabahn and Tigris (both Gore), Misago (Terumo), and Complete SE (Medtronic). All stents were indicated for a 6 mm artery, however the actual diameters ranged from 6.15 to 7.50 mm (average 6.99 ± 0.45 mm). Since all stents pass quality checks after manufacturing, and fatigue behavior was not a part of the current study, one sample of each stent type was considered sufficient for quasi-static analysis. However, if the stent experienced plastic deformations under any of the testing modes, a new sample of the same dimensions was used for consecutive tests. This was the case with the Tigris stent that has polymer connectors that can undergo plastic deformations when overstretched.

2.2. General characteristics of testing protocols

All stents were mechanically tested at 37 °C. Stents were ~ 40 mm in length and measurements were obtained in the middle of the sample, usually at least 5–10 mm away from edges to minimize edge effects. Mechanical tests were performed in the same sequence for all stents: axial tension and compression, three-point bending, radial compression, and torsion. All tests were displacement-controlled and performed in a cyclic manner with ascending peak displacements. Only the last cycle with the highest peak deformation is presented in the results for each test. Peak displacements varied between stents due to some variation in span lengths and limitations of the load-cell capacity. Neutral positions of the Viabahn and Tigris stents were assumed with PTFE fabric and polymer interconnectors fully extended.

2.3. Axial tension and compression

Axial tension and compression tests were performed with CellScale biotester (Waterloo, Ontario, Canada) in displacement-controlled mode and in a temperature-controlled water bath. All stents were mounted on cylindrical supports and fixed around the perimeter with plastic barbed teeth clamps (Fig. 1), which resulted in complete restriction of radial and torsional deformations at the supports. Span lengths between the supports varied from 19.5 mm to 27.1 mm. Tests were performed at 0.467 mm/s displacement rate and forces were measured with 2.5 N, 5.0 N, 10.0 N, or 23 N load cells, depending on the forces generated during the test. Axial stiffness was calculated for the linear and non-linear segments of the force-displacement curve as slopes of linear fit to the first and last 20% of the loading curve.

2.4. Three-point bending

Three-point bending tests were performed in a horizontal plane using the CellScale biotester. Stents were supported vertically by a 36.5 mm wide smooth base plate, and horizontally by two 6 mm-diameter pillars located 34 mm apart, with no restriction on rotation or lateral displacement (Fig. 1). Deformation was applied to the mid-span of the stent through a 10 mm high and 6.35 mm wide rounded-tip loading pin. Displacement-controlled tests were performed in a temperature controlled water bath with 1.0 mm/s displacement rates. Forces were measured with 2.5 N or 5.0 N load cells. Bending stiffness was calculated similarly to the axial stiffness, but using the first and the last 30% of the force-displacement curve.

2.5. Radial compression

Radial compression tests were performed with 40 mm wide v-shaped clamps mounted on the force transducers of the CellScale biotester (Fig. 1). No external supports were used for the stents. Cyclic tests with 1 mm, 2 mm, 3 mm, 4 mm, and 5 mm travel of v-clamps were performed with 0.125 mm/s displacement rates on stent sections placed in a heated water bath and displacements of the v-clamps were used to calculate reduction of the cross-section assuming that stent remained circular. Forces were measured with 5 N, 10 N, or 23 N load cells. Radial stiffness was calculated similarly to the axial stiffness using the first and last 20% of the curve.

2.6. Torsion

Torsion tests were performed in a temperature-controlled air chamber using a TA Electroforce 5175 BioDynamic tester (New Castle, DE, USA) equipped with a 2.82 N m torsional load cell. Stents were mounted using tapered supports and were fixed with a non-adhesive Parafilm tape. The tape completely restricted stent deformations at the supports. The average span between the supports was 23.0 ± 1.4 mm which corresponds to the distance between intra-arterial markers used to measure limb flexion-induced FPA torsion (Desyatova et al., 2017) (Fig. 1). During the test axial deformations were restricted. Consecutive cyclic tests with 30°/cm, 45°/cm, 60°/cm, 75°/cm, and 90°/cm maximum rotations in both clockwise and counterclockwise directions were performed at 5°/s rotational speed. Torsional stiffness was calculated similarly to the bending stiffness using the first and the last 30% of the torque-rotation curve.

3. Results

3.1. Axial tension and compression

Axial tension test results are summarized in Fig. 2. Panel A provides force (N)–strain (%) relations under tension up to 160% of initial length, while panel B compares stiffness (N/m) of all stents in tension. Viabahn, Smart Flex, Tigris, and Smart Control stent responses in tension were non-linear, while other stents demonstrated mostly linear behavior (Fig. 2A). At 11% strain Tigris stent started developing significant plastic deformation within its polymer interconnectors, and the associated yielding load was ~ 5 N. Viabahn and Smart Flex stents became stiffer with increasing loads, while the Smart Control stent became softer. The highest stiffness in tension was demonstrated by the