Journal of the Mechanical Behavior of Biomedical Materials 78 (2018) 74–81

Contents lists available at ScienceDirect

Journal of the Mechanical Behavior of Biomedical Materials

journal homepage: www.elsevier.com/locate/jmbbm

Deformation mechanisms of prototype composite braided stent-grafts in bending fatigue for peripheral artery application

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ARTICLE INFO

Keywords:
Stent-graft
Bending fatigue
Deformation

ABSTRACT

Stent-grafts in peripheral arteries suffer from complex cyclic loadings in vivo, including pulsatile, axial bending and torsion. Normal fatigue durability evaluation technologies, however, are majorly based on pulsation and thus are short of accuracy under the complicated stress conditions experienced physiologically. While there is a little research focused on the cyclic fatigue of stent-grafts in bending, it remains an almost total lack of deformation or fatigue mechanisms. In this work, composite braided stent-grafts incorporating Nitinol (NiTi) yarns and polyethylene terephthalate (PET) multifilament yarns were cycled in bending by the self-developed testing system to investigate their deformation behaviors. Deformation mechanisms at the yarn level were discussed, and NiTi yarn crossover structure was considered the primary factor affecting the deformation modes. Four yarn-crossover-based deformation modes (accordion buckling, diamond-shaped buckling, neck propagation and microbuckling) revealed the mechanisms of energy absorption of braided stent-grafts on the mesoscopic scale. Further, mechanical modes were applied to help regulate stent designs.

1. Introduction

Stent-grafts are being widely used to treat peripheral artery disease for reopening the lumen and isolating the blood, in which narrowed arteries hamper blood flow to the extremities. Unfortunately, studies show that structural failure may occur (in turn, functionally), rendering the stenting procedure ineffective. The failure is mostly attributed to the fatigue-induced damage since stent-grafts commonly experience 400 million pulsating cycles and other loading modes over its expected ten-year life span (Cavanaugh et al., 2006). Accordingly, stent-grafts durability remains the principle issue for safe use.

Considerable fatigue researches on stent-grafts have been primarily limited to pulsatile loads, leading to radial cyclic expansion/contraction of the stented artery (Morris et al., 2004; Pelton et al., 2008). Actually, the superficial femoral artery (SFA) experiences a complex loading condition of axial compression and extension, radial compression, bending, and torsion, which all have the potential to cause stent-graft failure (Ganguly et al., 2011; Cheng et al., 2006; Nikanorov et al., 2008; Cheng and Gilwoo Choi, 2010; Kröger et al., 2004). In particular, Alexander Nikanorov has revealed that the artery undergoes significant bending of 48° in knee/ hip flexion (Nikanorov et al., 2008). So fatigue assessment based solely on pulsation may fall far short of accuracy under physiological loading conditions. Besides, ignoring loading modes other than regular pulsation, as the general practice for stent-graft fatigue evaluation, may underestimate the safe lifetime. Indeed, fracture occurrences of some stents implanted in the SFA have been reported to up to 50% after one year (Nikanorov et al., 2008). And it is highly related to long vessel and two major flexion points in the SFA (Pelton et al., 2008; Lee et al., 2007; Umeda et al., 2008). Furthermore, the correlation between stent fatigue fracture and in-stent restenosis has been shown (Xu et al., 2016; Scheinert et al., 2005). All those suggest that bending deformation experienced by stent-grafts is significant and must be included in stent design and life-prediction.

Unlike pulsatile motion and torsion, there is rare literature for the bending fatigue of stent-grafts, although a few studies pertain to morphology changes after bending behavior (Melton and Mercier, 1979; Reinoehl et al., 2000; Mcnichols et al., 1981). However, the microstructure has a substantial effect on the macroscopic mechanics of stent-grafts. Since the amount of energy absorbed is directly related to the way stent structure deforms or collapses.

The main objective of this study was to further the application of bending fatigue in stent-grafts, as well as the relationship between their design and bending durability. In our former study, we have developed a sutureless composite stent-graft that incorporates Nitinol (NiTi) yarns and polyethylene terephthalate (PET) multifilament yarns based on braiding technology, which is aimed at peripheral arteries (Xue et al., 2017). We hereby provided a stent-graft bending lifetime evaluation methodology in vitro. According to this methodology, bending

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https://doi.org/10.1016/j.jmbbm.2017.10.037
Received 24 August 2017; Received in revised form 29 October 2017; Accepted 30 October 2017
Available online 31 October 2017
1751-6161/

durability evaluation was conducted on self-made composite stent-grafts. Bending deformation at the macroscopic and mesoscopic level was investigated, and yarn-crossover-based deformation modes were built (accordion buckling, diamond-shaped buckling, neck propagation and microbuckling). Then main energy absorption mechanisms were identified. Mechanical modes were also applied to help regulate stent structure. The results not only advance the understanding of the bending mechanisms in braids but also point to a new route for optimizing the fatigue properties for stent-grafts.

2. Materials and methods

2.1. Stent-graft preparation

Biomedical grade PET multifilament yarns (Suzhou Suture Needle Company, Suzhou, China), with two different fineness (100D for covered NiTi yarns and 600D for composite stent-grafts), and NiTi wires with the diameter of 0.2 mm (Jiangyin Winbond New Material Technology Co., Ltd, Wuxi, China) were used. Covered NiTi yarns were firstly made by wrapping the core NiTi wire with four 100D PET yarns on 4-bobbin braiding machine at the Biomedical Textile Research Center, Donghua University (Shanghai, China). Then eight covered NiTi yarns were braided with 600D PET multifilament in a certain distribution on 32-bobbin braiding machine (Fig. 1(a)). Stent-grafts with eight NiTi yarns rotating in the same direction were expressed as SG_A, while ones with four NiTi yarns rotating clockwise and the other four counterclockwise were expressed as SG_B. This composite structure avoided problems related to suture fracture, as well as ensured high stent-graft flexibility, preventing kinks in tortuous arteries. Each sample was made into 6 mm in diameter and 80 mm in length. The braiding angle and pitch length (Fig. 1(b)) of stent-grafts were measured, which were illustrated in part 2.4.

2.2. Qualitative bending fatigue

Patients' arteries suffer from greater bending when sitting than walking. However, there was no standard available regarding stent-graft bending fatigue test. So an accelerated bending fatigue test to simulate people's sitting by a fatigue testing system was developed based on Nikanorov, A.'s in vivo observation (Nikanorov et al., 2008) and Lin J's in vitro exploration (Lin et al., 2016) (Fig. 1(c)). One extremity of stent-graft was fixed on the horizontal terminal while another was attached to the vertical one, transforming forward and afterward. Its cyclic motion caused repeated bending of stent-grafts from 40° to 130°. Bending durability evaluation was performed at 1 Hz in a cube glass chamber full of phosphate buffered saline (PBS, pH = 7.2) (Chen et al., 2015). The tests were set at 7 days (6.048×10^5 cycles) and 30 days (2.592×10^6 cycles). Devices without any loading were used as controls (0 day) represented by SG_A or SG_B. Fig. 2 reveals stent-graft deformations throughout the bending fatigue experiment.

2.3. Quantitative bending performance

Stent-grafts were cycled on fatigue testing system qualitatively. Radial compression instrument (Model LLY-06D, Laizhou Digital Instrument Co., Ltd, Shandong, China) was improved and employed to measure single cycle bending performance quantitatively of stent-grafts (Hirdes et al., 2013), hoping to reflect their cycled bending properties. One end of the stent was fixed while another was left flexible and loaded by the press foot. The press foot first went to bend stents until deformation angel of 40° and then unloaded stents. Forces were recorded by a sensor (capacity: 100 cN, total error: < 0.02 Rated Output, accuracy: 0.001 cN) in the press foot, connected to the computer. All tests were conducted under standard environmental conditions (20 ± 1 ℃, relative humidity (RH) 65 ± 2%). The photograph of the experimental system is illustrated in Fig. 3. Load vs. displacement (L–D) curves were gotten, and functional properties were calculated accordingly. The maximum load value was defined as the bending force of testing samples. Besides, the exerting load inevitably introduces related deformation and irreversible plastic energy (Kahirdeh and Khonsari, 2015), 80–90% of which is transformed into thermal energy related to yarn friction. Others are restored in stent-grafts, affecting the crystal lattice of polymers. The plastic energy (E) was calculated from the L–D curves as follows:

$$E = \int_0^L [f(x) - g(x)]dx \tag{1}$$

Where: $f(x)$ and $g(x)$ represent functions of the bending and recovery curves, respectively.

2.4. Surface topography

Fatigue damage to stent-grafts was assessed macroscopically. A digital camera (Canon 700D, Canon China Co., Shanghai, China) and a stereomicroscope (PXS8-T, Shanghai Cewei Photoelectric Technology Co., Ltd, Shanghai, China) were used to observe the stent fracture or yarn breakage. Serious attention was then paid to metal and polymer under scanning electron microscope (Jeol Ltd., Tokyo, Japan) at a 10 kV accelerating voltage.

The photographs were analyzed by ImageJ image processing software. Stent-grafts shape retention was assessed via calculating the angle between its longitudinal axis and flexuous parts. They were also used to

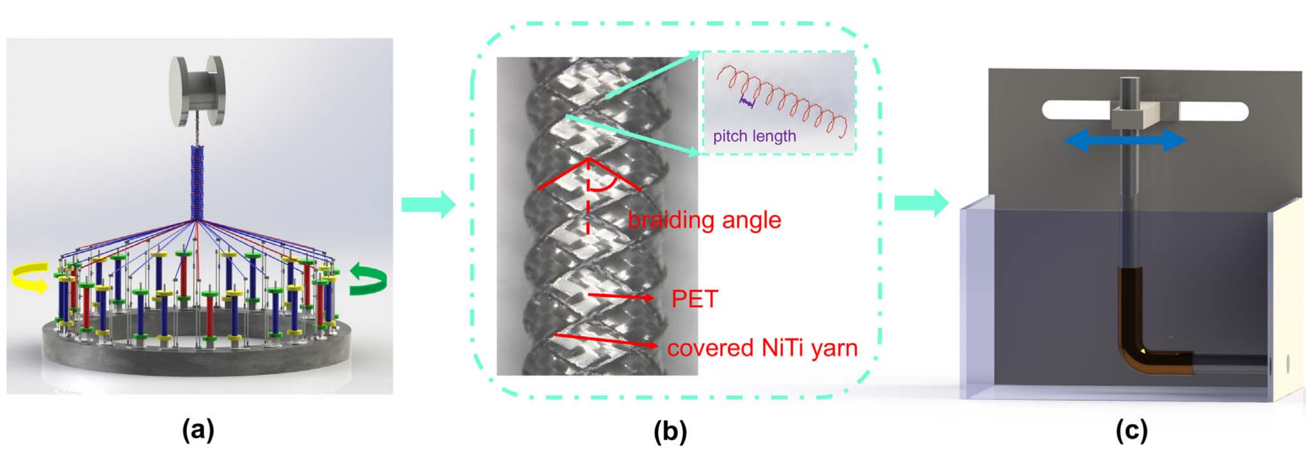

Fig. 1. Schematic diagram of stent-grafts bending fatigue measurement. (a): composite stent-grafts manufacture (blue lines represent PET and red lines represent covered NiTi yarns); (b): parameters of composite stent-grafts; (c): bending fatigue testing system (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.).