JOURNAL OF THE MECHANICAL BEHAVIOR OF BIOMEDICAL MATERIALS 38 (2014) 17–25

Available online at www.sciencedirect.com

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www.elsevier.com/locate/jmbbm

Research Paper

A resorbable bicomponent braided ureteral stent with improved mechanical performance

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ARTICLE INFO

Article history:
Received 6 April 2014
Received in revised form
5 June 2014
Accepted 8 June 2014
Available online 16 June 2014

Keywords:
Bioresorbable ureteral stent
Bicomponent
Braided
Mechanical properties
PGA
PLGA

ABSTRACT

Bioresorbable ureteral stents have the advantage of eliminating the need for a second removal surgery and hence avoiding certain complications. However the inadequate mechanical performance and lack of control over the rate of resorption limit the use of current prototype designs. This paper focuses on a series of resorbable millimeter-sized stents which were fabricated by a unique combination of braiding and thermal treatment processes. Their mechanical properties where optimized by varying the braided structure and different resorbable components. Five different bicomponent structures were fabricated for the stent with different areas and distributions of poly (glycolic acid) (PGA) and poly (lactic-co-glycolic acid) (PLGA) resorbable yarns. Subsequent thermal treatment then converted the PLGA yarns into areas of continuous PLGA polymer film. The morphology, applied compression resistance and recovery and tensile strength tests were conducted on these prototype stents so as to investigate the relationship between their structures and mechanical properties. By selecting the appropriate resorbable biomaterials and altering the design of the braided structure it was possible to generate different sized areas and distributions of 100% braided yarn and 100% polymer film within the same bicomponent tubular structure. The relative total area of braided yarn to polymer film coverage was different for the five different prototype stents as well as between the external and internal surfaces of the bicomponent stents. This relative coverage of the braided yarn to polymer film played an important role in determining the mechanical performance of the stents, including the compression and recovery behavior as well as the tensile properties and failure morphology. The design of Stent C appeared to have the optimal structure for a resorbable ureteral stent with superior applied compression and tensile properties.

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http://dx.doi.org/10.1016/j.jmbbm.2014.06.004
1751-6161/

1. Introduction

Ureteral stents are commonly used in contemporary urologic practice to relieve or prevent ureteral obstruction and promote kidney drainage (Lam and Gupta, 2004; Liatsikos et al., 2009). The concept of a bioresorbable stent was first proposed by Lumiaho et al. in 1999 (Lumiaho et al., 1999), and since that time several investigators have attempted to improve the design (Chew et al., 2010, 2013; Hadaschik et al., 2008; Lingeman et al., 2003a, 2003b; Lumiaho et al., 2000). The main advantage of a bioresorbable stent is that it eliminates the need for a second surgery for device removal (Al-Aown et al., 2010). In addition, because of its degradable nature, it can avoid certain patient complications, such as stent migration, upper urinary tract infection, excessive epithelialization and stent encrustation, hence reducing the morbidity associated with current commercial indwelling ureteral stents (Cevik et al., 2010; Elfaqih et al., 1991; Paick et al., 2003; Paz et al., 2005).

However, there are a number of limitations with the present prototype designs such as their inadequate mechanical properties (Venkatesan et al., 2010) and the lack of control over their rate of resorption (Hadaschik et al., 2008; Lingeman et al., 2003a, 2003b). Bioresorbable ureteral stents should have good biocompatibility and a predictable degradation process with non-toxic byproducts. At the same time they should be flexible, resist compression and kinking, and maintain patency to ensure kidney drainage for their predetermined functional life.

The focus of this study was to demonstrate that a resorbable millimeter-sized stent could be fabricated by a unique braiding and thermal process (Wang et al., 2011, 2013), and by using the appropriate component biomaterials and braided structure it was anticipated that the key mechanical property of compression resistance could be optimized.

It was proposed to include two different resorbable fiber-forming polymers within the braided structure, namely poly (glycolic acid) (PGA) and poly (lactic-co-glycolic acid) (PLGA), which have thermal properties, such as softening temperatures and melting points, in different temperature ranges. This particular selection of polymers was made so as to elicit different behaviors from the two biomaterials during thermal processing. By selecting a heat-treatment temperature below the softening and melting range for PGA(224–226 °C) (Pillai and Sharma, 2010; Shen, 2009), yet above the softening and melting range for PLGA(188–205 °C) (Li et al., 2010; Shen, 2009), the PLGA component would soften and be converted from a fibrous structure to a continuous polymer film, whereas the braided fibrous PGA component would remain unchanged.

Other reasons for selecting these two resorbable polymers was that they have similar rates of resorption (Pillai and Sharma, 2010) and have be shown to lose their mechanical properties during 2–4 weeks when exposed to human urine at 37 °C (Zou et al., 2013). The 2–4 week resorption profile is appropriated for use in most ureteral stent applications. At the same time, the two areas of fibers and polymer film enable the stent to resorb in a predictable and reliable manner both in vitro and in vivo (Zou et al., 2013; Zhang et al., 2014). In addition, both the PGA and PLGA are known to have acceptable biocompatibility, and they have been approved by the FDA for use as surgical sutures (Pillai and Sharma, 2010; Taylor and Bayat, 2003; Ulery et al., 2011).

In these previous preliminary in vitro and in vivo studies (Zou et al., 2013; Zhang et al., 2014), only one bicomponent stent structure was used. The goal of the present study was to optimize the structure in terms of its mechanical properties. By varying the distribution of the PGA and PLGA yarns in the initial braided structure it was proposed to vary the size and distribution of the braided areas and the polymer film within the tubular structure after thermal processing. In this study we fabricated three different bicomponent stent structures with different distributions of the PGA textile and the PLGA film components. In addition, pure braided 100% PGA and pure 100% PLGA film stents were also fabricated to serve as controls so the primary objective of this study was to investigate the relationship between these five structures and their mechanical properties.

2. Materials and methods

2.1. Materials

Resorbable ureteral stents were fabricated from PGA and PLGA multi-filament yarns (Table 1) supplied by Shanghai Tianqing Biomaterials Co. Ltd. The PLGA was a 10/90 copolymer of lactic acid and glycolic acid. We also selected the commercial 6Fr double pigtail Percuflex® Plus biostable polyurethane stent as the control for comparison of the mechanical properties.

2.2. Preparation of prototype ureteral stents

Five different prototype stents (Fig. 1) were braided on a 32 bobbin braiding machine in the Biomedical Textile Materials Research Laboratory at Donghua University, Shanghai, China. All of the stents were braided with the same structure, tension and braid angle around a central core made of a polytetrafluoroethylene (PTFE) cord measuring 1.6 mm in diameter. This removable core ensured that all the stents had a uniform central lumen measuring the same internal diameter of 1.6 mm.

Table 1 – Properties of the multifilament yarns.

Polymer	Fineness (tex)	Number of filaments	Tensile strength(N/tex)	Crystallinity (%)	Melting temperature (°C)
PGA[a]	5.2	12	0.74	59.9	223.8
PLGA[b]	6.1	12	0.40	57.3	202.0

[a] PGA: poly (glycolic acid).
[b] PLGA: poly (lactic-co-glycolic acid).