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A methodology for the customized design of colonic stents based on a parametric model

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ABSTRACT

The choice of necessary stent properties depends mainly on the length of the stenosis and degree of occlusion. So a stent design with variable radial stiffness along its longitudinal axis would be a good option. The design proposed corresponds to a tube-based stent with closed diamond-shaped cells made from a NiTi alloy. By acting independently on different geometric factors, variable geometries can be obtained with different radial force reactions. A design adjustment according to specific requirements, in order to get a better fit to ill-duct and reduces complications, is possible.

A parametric analysis using finite element has been conducted to determine the influence of slot length, number of circumferential slots, tube thickness and shape-factor on stent mechanical behavior, which allow eliminating the need for extensive experimental work and knowing and quantifying the influence of those factors.

The results of finite element simulations have been used, by means of least-squares fit techniques, to obtain analytical expressions for the main mechanical characteristics of the stent (Chronic Expansive Radial Force and Radial Compression Resistance) in terms of the different geometrical factors. This allows the stent geometry to be customized without launching an iterative and costly process of modeling and simulation for each case.

1. Introduction

Large bowel cancer is the most common in the digestive system. Colorectal cancer is the third most common cancer in men and the second most common in women. It is the third malignant tumor in incidence and forth in mortality in the world, after lung cancer (Ferlay et al., 2015) (Fig. 1). Due to its endoluminal growth to 29% of patients with this tumor developed intestinal obstruction (Deans et al., 1994).

Colonic occlusion presents the first reason for emergency colorectal surgery (Frago et al., 2011). Traditional treatment of colonic obstruction is surgery. However, possibilities of surgery are limited, especially when it comes to elderly patients with associated serious diseases, causing high morbidity and prolonged hospitalization and a mortality rate of between 5 and 11% (McArdle and Hole, 2004). Moreover, in many cases it is not possible to restore intestinal continuity, so the patient is left with a permanent colostomy, with the consequent deterioration in their quality of life (Biondo et al., 2005).

Sixty percent of patients with colorectal cancer present with a tumor in the left colon, and up to 25% have complete or partial occlusions at the time of diagnosis (Adamsen and Meisner, 2001). As it is well known metallic self-expanding stents are an option widely used to treat acute obstruction of colon, either for palliation or bridging or transition to surgical intervention, thus avoiding emergency surgery rates of morbidity and mortality, greater than 30% (Adamsen and Meisner, 2001). The stent allows decompression, the complete preparation of the colon and resection surgery in one step (Castaño et al., 2008).

Although the placement of colonic stents is much less invasive, morbidity can be high due to the complications associated with this procedure. To prevent or minimize the complications (perforation, wrong positioning, migration and re-obstruction), it is necessary to make a correct choice of stent to use (Srinivasan and Kozarek, 2014). Since the technical success of a stent for a particular obstructive lesion depends mainly on its mechanical behavior, mechanical modeling is

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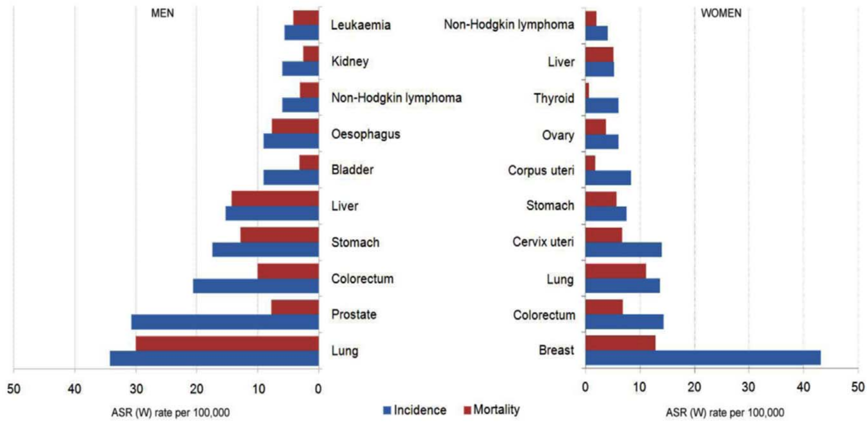

Fig. 1. Malignant tumors with the highest ratio of incidence and mortality in the world (rate per 100,000 population). Ferlay et al. (2015).

required to design the stent structure through a predictive model as does Kim et al. Kim et al. (2008) for braiding stents and Tzamtzis et al. Tzamtzis et al. (2013) for an aortic valve. This will allow custom design stents for each type of obstruction and patient.

Colon stents were introduced in the early 90s. In 1990 Dohmoto et al. Dohmoto et al.,(1990) present the treatment of a malignant rectal obstruction placing an expandable metal stent and in 1994, Tejero et al. Tejero et al. (1994) reports two cases of acute malignant obstruction treated successfully with the placement of a stent prior to elective surgery. In 1996 is presented the first prototype of self-expanding colonic stent made of nitinol (Bashir et al., 1996). Since then, the field of colorectal stent placement has evolved substantially with the introduction of new stent models and more versatile deployment systems. Self-expandable metallic stents (SEMSs) are widely used to treat malignant colonic obstruction (Moroi et al., 2014).

Stents design principally has two different manufacture strategies: braided or knitted wire-based stents, and tube-based stent designs (Stoeckel et al., 2004) to which a laser cuts are practiced and shaped until its final-repose configuration. They can also be classified according to whether covered or uncovered. Although the tendency is to design them covered to prevent tumor growth and thus reduce the risk of restenosis, in practice they have not shown clear advantages over other (Zhang et al., 2012). Tumor ingrowth occurred more frequently in the uncovered group, while late migration is more common in the covered stents. In (Lee et al., 2007) reported an increase of late migration (40%, P=0.005) and greater loss of stent function (60%, P=0.0018) with covered stents.

Different designs of colorectal stents are available for clinical use. The characteristics of some of the most extended and used like Ultraflex®, Wallstent® and colonic Wallflex® are included in Table 1. However, to the authors' knowledge, in literature no quantitative data may be found to characterize the behavior of the different types of colonic stents. A small number of studies have investigated the influence of design parameters for helical coils (Huo et al., 2014) and braided stents (Kim et al., 2008; Rebelo et al., 2015) on the mechanical behavior. Experimental bench testing to understand the properties of self-expandable metallic stents for different biliary and airway endoprosthesis have been reported (Isayama et al., 2009; Ratnovsky et al., 2015). Finite element analysis is commonly used in contrasting the main mechanical parameters (radial and axial strength, flexibility, etc.) of different stents (Grogan et al., 2012; McGrath et al., 2014; Petrini et al., 2004; Migliavacca et al., 2002; Etave et al., 2001).

This study employs a finite element (FE) approach in order to get a simulated bench testing data (Radial Compression Resistance and Chronic Radial Expansion Force) to develop a methodology for the design of customized self-expandable NiTi colonic stents adapted to each patient-specific case, taking like base a laser cutting tube stent design, by controlling geometry parameters. Finite element simulations are used to analyze the behavior of a predefined set of geometric configuration in order to establish an extrapolation technique that allows designing new stents adapted to the requirements of individual specific patients.

2. Material and methods

2.1. Stent model

The geometric typology used in this study is a tube-based stent with closed diamond-shaped cells (Palmaz-Schatz type), which correspond to basic geometry module used by the authors to design and manufacturing a prototype of colonic stent (Domingo et al., 2005; Domingo et al., 2007). In previous comparative analysis of stents for treatment of colorectal obstruction (Domingo et al., 2007) and by means of experimental animal testing (Puértolas et al., 2013), it was shown that stents based on closed cells with arms joined by rigid nodes develop higher radial force response, necessary for reopening occlusive colonic strictures where greater strength is required.

The geometrical pattern adopted allows manufacturing the initial

Table 1
Main available commercial colorectal stents (Feo and Schaffzin, 2011).

Stent name	Material	Length(mm)	Diameter flare (mm)	Diameter body (mm)	Manufacturer
Ultraflex precision colonic stent®	Nitinol	57, 87, 117	30	25	Boston Scientific
Wallflex Colonic TTS®	Nitinol	60,90,120	25	22 or 25	Boston Scientific
Wallstent Enteral TTS®	Elgiloy	60,90	NA	20 or 22	Boston Scientific
Colonic Z stent®	Stainless steel	40, 60, 80, 100, 120	35	25	Wilson-Cook
Niti-s Colorectal stent®	Nitinol	60,80,100 Covered, uncovered	28–30	20, 22, 24	Taewoon-Medical Co., Ltd.
TTS Niti-s Colorectal stent®	Nitinol	60,80,100	28	20	Taewoon-Medical Co., Ltd.
Hanarostent colorectal®	Nitinol	Covered: 60, 90, 110, 130 Uncovered: 80, 110, 140	NA NA	18, 22 18, 22	MI Tech Co. Ltd.

NA=not available.