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Looped ends versus open ends braided stent: A comparison of the mechanical behaviour using analytical and numerical methods

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ABSTRACT

The present study has two major purposes: firstly, to investigate whether the analytical model proposed by Jedwab and Clerc for assessing the mechanical behaviour of an open ends metallic braided stent is applicable to the looped ends stent design and secondly, to compare the response of the two stent designs subjected to radial compression. We use finite element analysis to evaluate the performance of the two braided stents emulating well established designs: WALLSTENT and WallFlex. We validate the WALLSTENT model analytically. We perform a radial crimping simulation and evaluate the radial forces and stresses induced. This study confirms the validity of using the analytical model in the biomechanical analysis of the WALLSTENT design. However, in case of the WallFlex design, a major difference in the results can be observed in the levels of radial forces and wire peak stresses, justifying the decision of using a different alloy in the fabrication of the WallFlex design.

1. Introduction

Stents are biomedical structures in tubular form used to restore the patency of an occluded hollow passage. The term stent was introduced in the medical literature in 1916 by Jan F. Esser, a Dutch plastic surgeon. Esser used a dental impression compound as scaffolding for tissue when performing facial reconstruction (Ring, 2001). This compound was invented in 1856 by the British dentist Charles T. Stent (1807–1885), and the term stent derives from his name. In 1912, Nobel laureate Alexis Carrel, described experiments where glass and metal tubes covered in paraffin were implanted in canine aortae in order to recover the lumen of diseased vessels. Charles Theodore Dotter reintroduced the concept in 1964 and developed several plastic and metallic designs (Dotter and Judkins, 1964). In early 1980s, he developed a prosthesis made out of shape-memory alloy Nitinol and implanted it into canine peripheral vessels (Dotter et al., 1983; Schatz, 1989). The term stent, as currently used in the medical devices industry, was introduced with the advent of Wallstent, an open ends, braided self-expanding metallic prosthesis invented in the 1980's (Rousseau et al., 1987; Wallsten, 1987; Wallsten and Imbert, 1991). The design quickly became a massive success and its applicability spread from its initial use as a coronary stent to treating peripheral arterial disease and gastrointestinal tract disorders. 30 years later, the initial design is still the benchmark, with current applications in both vascular and nonvascular interventions. However, in the gastrointestinal tract applications, the design evolved. Some of the improvements are: the addition of a polymeric coating to prevent tumour ingrowth, the use of other alloys to improve flexibility and visibility during the testing procedure and ultimately the geometry evolved by replacing the open ends style with a looped and flared ends version in the attempt to reduce the risk of tissue trauma and prevent stent migration.

The braided stent is a self-expanding (SX) design characterised by small diameter delivery system, allowing the stenting procedure to be performed through Minimally Invasive Surgery (MIS). The stent is constructed at the relaxed dimensions and subsequently crimped in order to fit into the catheter for deployment. Once the covering sheath is removed, the SX stent expands to the diameter of the diseased lumen, the radial force pushing the inner wall and restoring the luminal patency. The current study presents a review of the literature, including a classification of materials used and a description of the fabrication method. Furthermore, the literature review includes the current state-of-the-art investigations on the mechanical behaviour of braided stents using analytical and numerical methods.

1.1. Materials

As implantable medical devices, all stents regardless of the deployment method used, must exhibit excellent biocompatibility and corrosion resistance. They should exhibit high radiopacity and should create minimum interference with MRI equipment. Biocompatibility of

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Table 1
Some of the current braided SX stent designs with their characteristics.

Manufacturer	Stent	Material	Description
Abbott	Supera® Peripheral Stent System	Nitinol	SX single wire braided design; diameter 4–7 mm, length 20–200 mm
Boston Scientific	WALLSTENT™ Endoprosthesis	Elgiloy	SX stent; braided wires in a tubular mesh shape; diameters 5–24 mm and deployed lengths 23–145 mm; recapturable; five indications (Iliac Artery, Central Venous, Transhepatic Biliary, Tracheobronchial)
	WallFlex™ Esophageal Stent	Nitinol (silicone coated)	SX stent braided multi-wire design with flares at both ends; fully and partially covered with Permalume; diameter 18–23 mm and length 10–15 mm
Cook Medical	Evolution® Esophageal Stent	Nitinol (silicone coated)	SX single wire braided design; partially and fully covered design with silicone coating; diameter 20 mm, length 80–150 mm
Ella CS	SX-ELLA Stent Esophageal Degradable BD	Polydioxanone (PDO)	SX braided stent with flared ends design and radiopaque markers at both ends; stent integrity and radial force of the stent maintained for 6 – 8 weeks following implantation; completely disintegrated after 11–12 weeks

stents refers to their ability to perform their function without causing undesirable effects such as toxin release or harm to the host lumen. Corrosion resistance refers to the ability to resist the corrosion action of bodily fluids. Stent corrosion can have a double impact, firstly because it may lead to the alteration of the mechanical properties of the stent, secondly because corrosion means the release of metallic ions in the body. According to Stoeckel et al. (2002) the SX stent material needs to be flexible but difficult to break, therefore should have a low elastic modulus and a high yield stress. It would also need to facilitate large elastic deformation due to the crimping required prior to deployment. A selection of the current SX stent designs is presented in Table 1. Nitinol, a Nickel-Titanium shape memory alloy, has been progressively used in the design of medical devices since late 1980's due to the advantages offered in comparison to other materials (Poncet, 2000), such as: recoverability from large deformation, ability to resist kinking and crushing, flexibility, ability to generate constant stresses over a large strain range and free recovery. SX stent is one of the most important applications of Nitinol as an implantable medical device. SX stent is able to withstand large deformations with the ability to recover its original geometry upon unloading (Stoeckel et al., 2004). Another metallic alloy used for manufacturing SX braided stents is ASTM F1058, a Cobalt-Chromium-Nickel alloy marketed as Elgiloy or Phynox. Elgiloy exhibits excellent biocompatibility and corrosion resistance. The alloy has good mechanical properties, high strength and good fatigue resistance (Clerc et al., 1997). Elgiloy is non-ferromagnetic which leads to improved MRI-compatibility. The biodegradable (BD) and bioresorbable (BR) polymeric stents enable temporary stenting and are fabricated from various synthetic polymers such as Polydioxanone (PDO).

1.2. Fabrication – Braiding

Braiding is a traditional form of fabric construction and consists in intertwining yarns or fibres in different directions to form flat braids, tubular braids and solid 3D structures (Corbman, 1983; Adanur, 1995). Due to their construction, braids have some unique characteristics such as high level of conformability, torsional stability and damage resistance (Braiding, 1987). Braided stents are small diameter tubular structures consisting of two sets of interlacing, spiralling strands, one set clockwise and the other anti-clockwise direction, both lying on the bias relative to the longitudinal axis of the braid. Braided stents can be manufactured on custom-made braiding machines, Boston Scientific's WALLSTENT and WallFlex being some examples. WALLSTENT is fabricated by interlacing a set of wires in a continuous tube geometry from which the individual stents are cut to specification, leaving the ends of the wires exposed, therefore the “open ends” name of the design. WallFlex also features a multi-wire design, however, on both ends of the stent there are closed loops (at one end the wires being bonded with the help of laser fusing technology) which gives the design the name “looped ends”. Braided stents can also be fabricated manually using a single piece of wire. The seamless design enables crown forming at the extremities of the stent and can be produced on cylindrical or stepped mandrels. Examples are Cook's Evolution Nitinol stent and Ella CS's SX-Ella Esophageal BD PDO stent. The braided stents are produced in the expanded dimensions, followed by electropolishing in order to remove the oxides formed during the manufacturing process (De Scheerder et al., 1998). Braided stents provide excellent coverage and flexibility; however, they shorten substantially after expansion.

1.3. Additions

Current generation stent designs, including the braided type are enhanced in order to improve radiopacity, reduce in-stent restenosis and facilitate stent removal. Radiopacity or X-ray visibility is a very important topic for implantable medical devices and stents in particular, because stent visibility facilitates accurate positioning of the device during deployment, detection and monitoring of the stent position. A stent must absorb more X-rays than the surrounding tissue in order to be fluoroscopically visible. Nitinol is slightly more radiopaque that stainless steel, but far less than other materials such as tantalum, gold or platinum (Poncet, 2000). The trend in stent design is minimal thickness of the struts, therefore, when the thickness of the wire or struts cannot be increased to facilitate visibility, the radiopacity issue is addressed by attaching radiopaque markers made from materials with higher atomic weight (e.g. tantalum, gold, platinum) at both ends of the stent, which is the case of WALLSTENT. Another way is to use an alloy with a higher visibility and in case of some of the WallFlex stents, the use of Platinol (a Nitinol wire with a Platinum core), delivering enhanced full-length radiopacity. Certain conditions where there is a discontinuity in the lumen, such as a rupture or fistula, remain a problem in interventional therapy. A solution to this problem is to apply a polymer material such as silicone to the stent surface as a coating. The addition of the coating reduces tissue hyperplasia and the risk of thrombosis and enables stent removal if repositioning or a temporary placement is required. SX braided stents designed for esophageal, biliary and colonic applications are available partially and fully covered. An example is: ‘WallFlex Billiary’ (Boston Scientific), where the stent is covered with a silicone coating.

1.4. Finite element analysis of SX braided stents

Despite the advantages in using finite element analysis (FEA) in stent design, research literature dedicated to SX braided stents is limited, most of the researchers concentrating their efforts in studying the laser-cut SX designs. The lack of scientific efforts in the area of SX braided stents may be due to the complexity of the geometrical model and the subsequent numerical analysis. In terms of material models, a generic linear elastic type has been implemented for Elgiloy, while for Nitinol, user defined models covering its super-elastic behaviour were developed. FE models for polymeric stents are almost non-existing. In 2007, Zahora et al. were the first to investigate FE modelling of a