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Fiber-reinforced silicone for tracheobronchial stents: An experimental study

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ABSTRACT

A trachea is a tubular structure composed of smooth muscle that is reinforced with cartilage rings. Some diseases can cause sagging in smooth muscle and cartilaginous tissue. The end result is reduction (narrowing) of the trachea diameter. A solution to this problem is the use of tracheal stents, which are small tubular devices made of silicone. One is inserted into the trachea to prevent or correct its constriction. The purpose of tracheal stent use is to maintain cartilage support that would otherwise be lost in the airway.

Current tracheal stent models present limitations in terms of shape and characteristics of the silicone used in their production. One of the most important is the large thickness of the wall, which makes its placement difficult; this mainly applies to pediatric patients. The wall thickness of the stent is closely related to the mechanical properties of the material.

This study aims to test the reinforcement of silicone with three kinds of fibers, and then stents that were produced using fiber with the best compressive strength characteristics. Silicone samples were reinforced with polypropylene (PP), polyamide (PA), and carbon fiber (CF) at concentrations of 2% and 4% (vol%), which then underwent tensile strength and Shore A hardness testing. Samples with fiber showed good characteristics; surface analyses were carried out and they were used to produce stents with an internal diameter of 11 or 13 mm and a length of 50 mm. Stents underwent compression tests for qualitative evaluation. Samples with 2% and 4% CF blends showed the best mechanical performance, and they were used to produce stents. These samples presented similar compressive strengths at low deformation, but stents with a 4% CF blend exhibited improved compressive strength at deformations greater than 30–50% of their diameter ($P \leq 0.05$). The addition of 2% and 4% CF blends conferred greater mechanical strength and resistance to the silicone matrix. This is particularly true at low deformation, which is the condition where the stent is used when implanted. In the finite element compression strength tests, the stent composite showed greater compression strength with the addition of fiber, and the results were in accordance with mechanical compression tests performed on the stents.

In vivo tests showed that, after 30 days of post-implantation in sheep trachea, an inflammatory process occurred in the region of the trachea in contact with the stent composite and with the stent without fiber (WF). This response is a common process during the first few days of implantation.

1. Introduction

Biomaterials are currently defined as any synthetic or natural material used in a medical device intended to interact with biological systems (Binyamin et al., 2010). The choice of the best biomaterial for different applications is based on several requirements, including the absence of a sustained inflammatory response following in vivo implantation, a degradation time that allows regeneration or cure of the compromised site, mechanical properties that do not compromise the regeneration or the re-establishment of the compromised site (Oliveira et al. (2010)) and biocompatibility. A major aspect of biocompatibility concerns the surface of the materials to be implanted, which should not be recognized as a foreign body during the first two-to-four weeks following implantation (Anderson et al., 2008; Maia et al., 2010; Maiti et al., 2016).

Medical grade polydimethylsiloxane (silicone) is among the most

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widely used synthetic biomaterial for medical applications. Compared with natural biomaterials (bone, corneas, and collagen), synthetic biomaterials present several advantages: they are easier to obtain and they are more controllable in terms of reproducibility of results, safety, cleanliness, and their speed of manufacture. Disadvantages include a higher probability of inflammatory response and a higher cost, even though these limitations are becoming increasingly more manageable (Franca et al., 2005; Fischer et al., 2016).

Silicone is stable at high temperatures, has excellent biostability, experiences minimal deterioration of its properties over time, has good elasticity, and it is hydrophobic (Chen et al., 2013). It is particularly suitable for use in stents. Stents are currently a major resource for the treatment of cardiac, biliary, and tracheal conditions among others (Yaszemski et al., 2004). Because their purpose is to keep vessels open, stents must be made of a material that ensures sufficient resistance without risk. Migration and ease of handling should to be avoided, especially in the case of stents that are only temporarily kept in place. This is the case for many patients that receive tracheobronchial stents.

The Dumon stent, which is a well-known tracheal stent that is used as model for other stents, is available for both malignant and benign lesions. Our group has developed a silicone stent for tracheal applications (HCPA-1), which presented an effective improvement in the quality of life of patients with benign and malignant tracheal stenosis (Saueressig et al., 2010). This is currently the only tracheobronchial stent made in Brazil, and is commercially available as the Medicone stent (Medicone). Its use has been part of a national project, with support from the Brazilian Ministry of Health, involving teaching hospitals in several regions. However, all current models present limitations in terms of shape and mechanical characteristics of the silicone used in their production.

Therefore, the objectives of the present study are: (1) to analyze the reinforcement test for silicone with polypropylene (PP), polyamide (PA), or carbon fibers (CF), and to compare these fibers in terms of their mechanical properties; and (2) to produce stents using fibers with better characteristics and to perform tests in vivo.

2. Materials and methods

This work was done in two phases: (1) using non-biomedical silicone to evaluate mechanical properties; and (2) using biomedical silicone to analyze physiological properties. The phases are described below.

2.1. Phase 1

Samples of NE-140 silicone (Dongjue Silicone - Nanjing Co., Ltd., Jiangsu, China), with mechanical properties similar to biomedical grade silicone, were used in phase 2 (item 2.2), and were reinforced with three types of fibers: PP, PA, and CFs. The properties of these fibers are described in Table 1. All tests were performed in WF samples to compare the samples. The selection of fibers was based on results described in literature for other kinds of applications (Santos, 2002; Hin, 2004).

Table 1
Property of fibers used for reinforcement of silicone.

Characteristics	Polypropylene (PP)	Polyamide (PA)*	Carbon fiber (CF)
Manufacturer	Polystar – Brazil	Fairway – Brazil	Hexcel - USA
Density (g/cm^3)	0.9	1.18	1.84
Mean diameter (μm)	16.3	10.7	7.3
Tensile strength (GPa)	0.093	0.216	3.03
Elastic modulus (GPa)	3.4	6.7	232
Elongation (%)	40.8	4.2	0.56

Adapted from Santos (2002).

2.1.1. Preparation and characterization of samples

Samples containing 2% and 4% fiber blends were added to each 100 phr (part per hundred rubber) of silicone. Silicone and the fibers were mixed according to the American Society for Testing and Materials (ASTM) standard D3182 (ASTM Standard D, 3182, 2012). Coupling agents were not used. The composite was mixed in an open two-roll mixer for 60 min to homogenize the mixture at room temperature.

Cross-link characteristics of the composite were determined using an MDR 2000 Moving Die Rheometer (Alpha Technologies, Akron, OH, USA) based on ASTM standard D5289 (ASTM Standard D, 5289, 2012). The cross-link properties were determined from different cross-link curves, which were set at 180 °C.

2.1.2. Mechanical properties

The mechanical performance of silicon without fibers and the composite samples were evaluated in terms of their tensile strength and using Shore A hardness testing. An Instron® 5900 Series Universal Testing Machine (Instron, Norwood, MA, USA) was used to determine the tensile strengths based on the ASTM standard D412 (ASTM Standard, D412, 2013), where samples C-type were used. Hardness tests were performed using a Shore A durometer (Mitutoyo, Kawasaki, Japan) according to the ASTM standard D2240 (ASTM Standard D, 2240, 2010).

2.2. Phase 2

Samples of MED-4735 Part A and B medical grade silicone (NuSil Technology LLC, Carpinteria, CA, USA) were produced with the fibers selected during phase 1. All procedures and tests, as previously described for phase 1, were repeated for phase 2. In phase 1, silicone samples without fiber (WF) were used to compare the results.

2.2.1. Surface evaluation

Samples produced with medical grade silicone demonstrate hydrophobicity, biocompatibility, and cell viability. Before the tests, samples were sterilized with ethylene oxide following the procedure by Gautriaud et al. (2010). This method of sterilization did not present significant negative effects on silicone for medical use compared to other sterilization techniques (such as irradiation). Hydrophobicity was tested by measuring the contact angle using a Labometric LB-DX device (Labometric Ltd., Miami, FL, USA) and distilled water. For assessment of biocompatibility, samples were immersed in simulated body fluid (SBF) for 10 days and evaluated periodically. Cell viability tests were performed using a method based on the ISO 10993-5:1992 standard (ISO, 10993-5, 1992). All samples were placed directly in contact with the HepG2 growth medium, where the cells were cultured. Latex was used as negative control because it is a cytotoxic material (i.e., it prevents cell growth).

2.2.2. Stent production

Stents were produced through molding using medical grade silicone and composite samples. Their design was based on the Brazilian tracheobronchial stent, which is also known as the Medicone stent (Medicone). Stents were produced with an internal diameter of 11 or 13 mm, a wall thickness of 0.8 and 1 mm respectively, and a length of 50 mm. Dimensions are identical to those of the Medicone stent, except for the thickness, which is 20% lower in this study.

2.2.3. Compression tests

Stents underwent compression tests for evaluation of their elastic deformation. The test involved deformation to 50% of the internal diameter, i.e., to 5.5 mm for stents with an internal diameter of 11 mm and to 6.5 mm for those with an internal diameter of 13 mm. Measurements of force and deformation were obtained for 10 samples