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Mechanical properties of different airway stents

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ABSTRACT

Airway stents improve pulmonary function and quality of life in patients suffering from airway obstruction. The aim of this study was to compare main types of stents (silicone, balloon-dilated metal, self-expanding metal, and covered self-expanding metal) in terms of their mechanical properties and the radial forces they exert on the trachea. Mechanical measurements were carried out using a force gauge and specially designed adaptors fabricated in our lab. Numerical simulations were performed for eight different stent geometries, inserted into trachea models. The results show a clear correlation between stent diameter (oversizing) and the levels of stress it exerts on the trachea. Compared with uncovered metal stents, metal stents that are covered with less stiff material exert significantly less stress on the trachea while still maintaining strong contact with it. The use of such stents may reduce formation of mucosa necrosis and fistulas while still preventing stent migration. Silicone stents produce the lowest levels of stress, which may be due to weak contact between the stent and the trachea and can explain their propensity for migration. Unexpectedly, stents made of the same materials exerted different stresses due to differences in their structure. Stenosis significantly increases stress levels in all stents.

1. Introduction

Airway stents can improve the pulmonary function of patients suffering from central airway obstruction and have the potential to save or prolong patients' lives. Airway stents are designed to restore airway patency and to mimic normal airway anatomy and physiology [1].

In general, airway stents can be classified into four types: silicone, balloon-expandable metal, uncovered self-expanding metal and covered self-expanding metal. When selecting a stent for a given patient, the clinician must take into account several considerations: whether the stent is permanent or temporary, whether the procedure requires general or local anesthetic, the stent's likelihood of migration, and whether it encourages tissue growth [1].

Each type of stent is associated with advantages as well as disadvantages [2], and, thus far, no data have indicated clear superiority of one type over another [3]. Silicone stents can be easily removed and replaced as needed [4,5]. However, they have several major drawbacks, including a high migration rate, a low lumen-to-wall thickness ratio, difficulty in clearing secretions, and the need to carry out rigid bronchoscopy for their apposition [5–8]. Metallic stents, usually made of steel or nitinol, can be placed via flexible bronchoscopy, under local anesthesia [6]. Balloon-expandable metallic stents are dilated by a balloon to the correct diameter at the target site. These stents lack the capacity for elastic re-expansion and therefore risk being crushed or becoming deformed with coughing; thus, they are not recommended for use in the central airways. However, they are often used in children, since they are available in sizes suitable for pediatric application [9]. Self-expanding metal stents have a shape memory that enables them to be restored to a predetermined configuration when released from a constraining delivery catheter [6]. These stents can be made of steel or nitinol and can either be uncovered or covered with thin polyurethane membranes. They are associated with lower likelihood of migration and less interface with cilia, and their walls are thinner, so their inner diameter is wider. However, they are difficult to remove due to the growth of airway epithelium around them, they can impair mucociliary clearance, are associated with recurrent lumen obstruction, with greater bacterial colonization and are also susceptible to metal fatigue and fracture over time [6,10,11]. Covered self-expanding metal stents are associated with a lower risk of tumor in-growth and granulation tissue formation. A disadvantage of this type of stent is that radial forces acting on the stent may cause necrosis of mucosa and fistula formation. These stents even collapse if the external force is too high, and granulation tissue at the uncovered ends may block the bronchus [10,3].

In order to be suitable for long-term use, stents must be able to respond to cough pressures by undergoing reversible reduction of the cross-sectional area [12]. A numerical study on the human healthy

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trachea has shown that the trachea wall is subjected to maximal stress levels of 3.3 kPa in tension (inspiration) and 5.25 kPa in compression (expiration). During coughing these maximal and minimal values increase to 6 kPa and 7.25 kPa, respectively [12]. In the same study, stent-trachea models, silicone (Dumon) and metallic (Ultraflex), revealed that the presence of a stent prevents tracheal muscle deflections, especially during coughing. In addition, compared with the metallic stent-model, the silicone stent-model was shown to contain larger regions that are predisposed to sliding, leading to the conclusion that stent type selection plays an important role in improving clinical outcomes. Several numerical studies examined changes in airway flow and pressure during airway obstruction [13,14] and after stent placement [15]. Other studies employed finite element analysis to evaluate flow pattern, wall stress and deformation in healthy and stenosis trachea [16], to evaluate the influence of silicon stent-model on the trachea wall during inspiration and expiration [17] and to examine the influence of the same silicone stent-model on the trachea movement during swallowing [18].

However, while airway stents can be life-saving and life prolonging, numerical and mechanical evaluation of mutual stress relationships between different airway stents and the trachea, has gained little attention. Of this relationship, the effect of the radial forces exerted by the different stents on the airways is of particular importance since radial forces are known to cause tissue growth around and inside the stent, a main drawback of airway stents [3,10].

The main objective of this study, therefore, was to evaluate, based on numerical simulation, the radial forces exerted on the trachea by different airway stents. This comparison might assist in selecting, for a given procedure, the most suitable commercially available airway stent. In addition, the mechanical functions of the four main types of airway stents were compared through mechanical measurements of radial stresses and strains.

2. Materials and methods

2.1. Mechanical measurements

The mechanical properties of several different airway stents (A–E; summarized in Table 1) have been measured using an experimental setup consisted of a force gauge (Mark 10) and specially designed polyester film adaptors produced in our lab (Fig. 1). An adaptor was fitted to each stent such that its dimensions corresponded to the stent's circumference (Table 1). A stress-strain curve was obtained for each stent under evaluation, under a range of radially applied forces. Specifically, each of the tested stents was placed with its adaptor in the force gauge, and a gradually increasing radial force was applied to the stent until the adaptor tore. The measured parameters were vertical forces and vertical displacements. The radial stress σ was calculated based on the force data as follows:

$$\sigma = \frac{F_y}{2\pi rl} \quad (1)$$

where F_y is the applied vertical force, and r and l are, respectively, the external radius and the length of the stent. The strain ε was calculated as follows:

$$\varepsilon = \frac{\Delta l_y}{2\pi r} \quad (2)$$

where Δl_y is the vertical displacement. Since, the adaptor was stiffer than the stent, its stretching was neglected. Once the stress-strain curves were plotted, their linear regions were extracted and compared. The measured mechanical properties of the smooth silicone stent were also compared to the properties obtained by the numerical simulations described in Section 2.2 below.

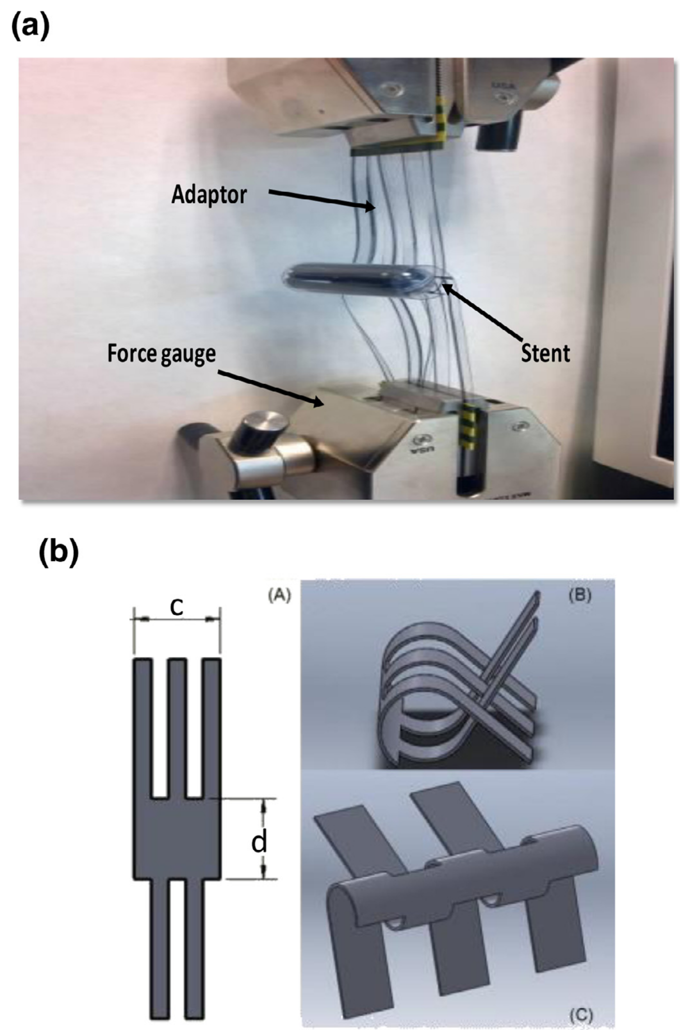

Fig. 1. (a) The experimental setup. (b) The polyester film adaptor (A) interior view, (B) lateral view and (C) posterior view.

2.2. Numerical simulations

Numerical simulations of about 100 different cases were carried out on a combined model of airway stent within the trachea. The simulations were done to investigate the influence of different stent diameters, geometries and materials on the radial stress levels that the stent exerts on different trachea models.

2.2.1. Modeled stents types

Eight different types of stents were examined (Table 1): internally-covered self-expanding metal stent (A); externally-covered self-expanding metal stent (B); two uncovered self-expanding metal stents (zigzag (C) and wallstent (D)); studded silicone (E) and smooth silicone (F) stents; and two balloon-expandable metal stents (G and H).

2.2.2. Stent models dimensions and materials

The dimensions, geometries and materials of the modeled stents were comparable to those of existing stents. To allow comparison among the different stents, a length of 50 mm and a diameter either of 14 mm, 15 mm or 16 mm were assigned for each stent. The stents were assumed to be composed of various types of materials, as detailed in Table 2. The materials were: nitinol (55Ni-45Ti) austenite, cobalt alloy (elgiloy), cobalt alloy (40Co-20Cr), stainless steel (316 L), and silicone