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Migration resistance of esophageal stents: The role of stent design

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ABSTRACT

Objective: Stenting is one of the major treatments for malignant esophageal cancer. However, stent migration compromises clinical outcomes. A flared end design of the stent diminishes its migration. The goal of this work is to quantitatively characterize stent migration to develop new strategies for better clinical outcomes.
Methods: An esophageal stent with flared ends and a straight counterpart were virtually deployed in an esophagus with asymmetric stricture using the finite element method. The resulted esophagus shape, wall stress, and migration resistance force of the stent were quantified and compared.
Results: The lumen gain for both the flared stent and the straight one exhibited no significant difference. The flared stent induced a significantly larger contact force and thus a larger stress onto the esophagus wall. In addition, more migration resistance force was required to pull the flared stent through the esophagus. This force was inversely related to the occurrence rate of stent migration. A doubled strut diameter also increased the migration resistance force by approximately 56%. An increased friction coefficient from 0.1 to 0.3 also boosted the migration resistance force by approximately 39%.
Summary: The mechanical advantage of the flared stent was unveiled by the significantly increased contact force, which provided the anchoring effect to resist stent migration. Both the strut diameter and friction coefficient positively correlated with the migration resistance force, and thus the occurrence of stent migration.

1. Introduction

Esophageal cancer (EC) is the sixth most common cancer and rarely curable with high morbidity and mortality all over the world [1]. Mostly, the patients suffering from EC are diagnosed at later or advanced stage, which are unfavorable for surgical resection. The survival rate of patients accepting surgical resection is poor with a 5-year survival of 15–34% [2]. Moreover, palliative care of serious illness like malignant stricture is to relieve the symptoms but unable to inhibit the tumor cells, which is the prime concern in curing EC [3]. Stent, a mesh structure serving as a scaffold to open the palliate esophageal stricture and relieve dysphagia, is becoming a common EC treatment option for improving the quality of life of patients [4]. Various self-expanding metal stents have been developed for this purpose. Major complications include stent migration, tumor ingrowth, and tissue perforation [5,6]. Homann et al. [7] investigated 164 self-expanding stents implanted in malignant strictures of the esophagus or the esophagogastric junction, and observed more stent migration and fewer food impactions in patients implanted with covered stents than with uncovered ones. Most existing efforts focus on the covered materials [8] and their anchoring technique [9]. For example, the endoscopic clip at the upper flare of the covered esophageal stent was considered as one promising means to reduce stent migration [9].

The stent shape was also considered as an important factor influencing stent migration. The most common implementation in the design of esophageal stents was the relatively wider proximal and distal ends, which were used to increase the radial force and reduce the risk of stent migration [10]. Sharma et al. [11] have conducted a critical review of the efficacy of esophageal stents and implied that the underlying mechanism of stent migration and tumor in-growth could be clarified quantitatively. Garbey et al. [12] developed a simplified mathematical model to study the influence of flares design, stent length as well as the radial and longitudinal stiffness on the esophageal stent migration. Kajzar et al. [13] illustrated the mechanics of the a stent-esophagus system with focus on the crimping and expansion of esophageal stent. Even though Park et al. [5] classified four levels of stent migration in patients with malignant esophageal stricture, the underlying mechanisms of stent migration away from the esophageal

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stricture, especially the initiation process, remained to be elucidated. Moreover, the quantitative study of stent-esophagus interaction for evaluating stent migration was lacking [14], nonetheless computational modeling of stents has been extensively used for design and analysis [15–18]. Specifically, layered esophageal wall were modeled to illustrate the mechanics of the gastroesophageal junction [19] and the interface mechanics between the muscle layer and the mucosa–submucosa layer [20].

The goal of this work is to characterize the interactions between the stent and esophagus, to shed light on the mechanism of stent migration as well as to design better esophageal stents. We utilized the finite element approach to depict and compare the mechanics of the esophagus with a malignant stricture, after implantation of self-expanding nitinol stents, with and without flared ends. Following the stent deployment in the esophagus, the lumen gain, strut malapposition, Von Mises stress distributions on the wall of the esophagus, and radial contact force between the stent and esophagus were evaluated for both stents. Moreover, both stents were pulled longitudinally at one end to mimic the worst-case scenario for stent migration. The dynamic sliding forces versus the stent displacements were monitored. The obtained results might lead to better design of the next-generation esophageal stents with reduced migration rate.

2. Materials and methods

A three-dimensional geometry of the WallFlex stent (Boston Scientific, Massachusetts, USA) with and without flared ends was constructed as shown in Fig. 1. For the stent without flared ends, the total length was 100 mm and the outer diameter was 18.22 mm. For the flared stent, the middle section had the same diameter as the straight stent with a length of 64 mm, while the flared ends had a diameter of 24.22 mm with a length of 9 mm at each end. Both esophageal stents were braided using 28-strand of wires with the diameter of 0.4 mm and pitch angle of 45° [11].

The esophagus was assumed to be a uniform cylinder with a length of 150 mm, an inner diameter of 16 mm, and a wall thickness of 3 mm [14]. The simplified esophagus tube has been used for understanding the food transport [21], and stent-esophagus system [13]. The eccentric-shaped tumor with a maximum thickness ratio of 2:1 spanned across the 60 mm of esophagus and resulted in a minimum lumen diameter of 6 mm, i.e., a diametrical stenosis ratio of 62.5% (Fig. 1b). The tumor length was shorter than the middle section of the flared stent, and this warranted the same stent-tumor interaction for both stent deployments. After preliminary simulations, we constructed half of the model by applying symmetry boundary conditions along the z plane ($U_z = UR_x = UR_y = 0$) in order to reduce the computational time.

The stent was made of nitinol which underwent phase transformation between austenite and martensite during one loading cycle [22]. The superelastic behavior of shape memory alloys can be simply understood as the phase transformation of austenite and martensite under stress. Based on free energy function and dissipation potential, the model is assumed that there is a relationship between the martensitic constant φ_M and the austenite constant φ_A:

$$\varphi_M + \varphi_A = 1 \tag{1}$$

The elastic modulus of Nitinol can be represented as a linear function of martensite volume fraction

$$E_f = \varphi_M E_M + (1 - \varphi_M)E_A \tag{2}$$

where E_f, E_M and E_A are the elastic modulus of alloy, martensite and austenite, respectively.

The stress-strain relation is given according to the generalized Hooke's law as follows:

$$\sigma_f = C_f(\varepsilon - \alpha(T - T_0) - \varepsilon_{tr}) \tag{3}$$

where ε is the total strain the SMA, T_0 is the reference temperature, ε_{tr} is the phase transformation strain, α is the thermal coefficient, σ_f and C_f are the stress and elastic tensor, respectively. Therefore, an incremental constitutive law can be expressed as:

$$\Delta\sigma_f = C_f(\varphi_M)(\Delta\varepsilon - \alpha(\varphi_M)\Delta T - \omega\Delta\varphi_M) \tag{4}$$

The main parameters of the constitutive model of nitinol alloy under isothermal conditions were listed in Table 1 [23]. The constitutive model was implemented through a built-in ABAQUS user material subroutine (UMAT) [24].

The hyperelastic behavior of the tissue, including both esophagus and tumor, were adopted from the published experimental datasets [23,25], which were fitted using the reduced polynomial constitutive equation below:

$$U = \sum_{i,j=1}^{3} C_{ij}(I_1 - 3)^i(I_2 - 3)^j \tag{5}$$

where, I_1 and I_2 are the first and second invariants of the Cauchy-Green tensor and

$$I_1 = \lambda_1^2 + \lambda_2^2 + \lambda_3^2 \tag{6}$$

$$I_2 = 1/\lambda_1^2 + 1/\lambda_2^2 + 1/\lambda_3^2 \tag{7}$$

The obtained material coefficients C_{ij} are listed in Table 2.

The stent crimping process was simulated by applying radial inward displacement on the outer surface of the stent. The self-expanding process was captured by removing the displacement constrains. No relative movement between braided wires was allowed to mimic the role of the cover on the stent. The residual stresses of the esophagus tissue under physiological loading conditions were not considered for this comparative study [26]. The friction coefficient of 0.1 was adopted for the contact between the stent wires and tissue [27]. The mesh convergence study was conducted, and the esophagus and tumor was meshed with 125,000 and 21,456 elements (C3D8R), respectively. The stent was constructed by 11,200 B31 elements which are two-node

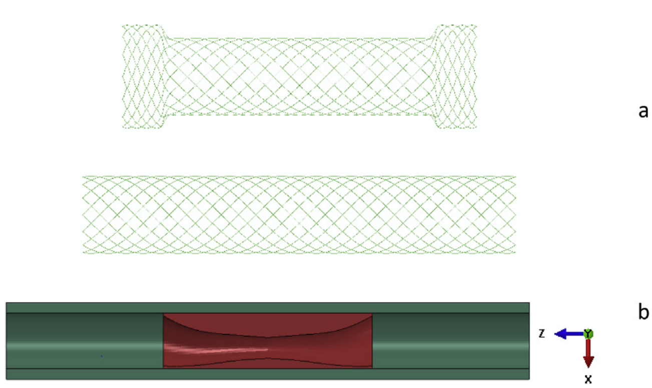

Fig. 1. (A) Configurations of the flared stent and straight one; (b) Tumor restricted Esophagus.

Table 1
Material constants of Nitinol.

Property	Value	Definition
E_A	50 GPa	Austenite elasticity
E_M	37 GPa	Martensite elasticity
σ_M^s	400 MPa	Starting transformation stress of loading
σ_M^f	650 MPa	End transformation stress of loading
σ_A^s	350 MPa	Starting transformation stress of unloading
σ_A^f	80 MPa	End transformation stress of unloading
ε_L	0.055	Maximum residual strain