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Yanli Wang

Pengfei Dong

Jingyao Ke

Xiang Shen

Zongming Li

See next page for additional authors

Authors
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Research Article

Yanli Wang, Pengfei Dong, Jingyao Ke, Xiang Shen, Zongming Li, Kewei Ren, Xinwei Han*, and Linxia Gu*

Experimental evaluation of self-expandable metallic tracheobronchial stents

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Abstract: The self-expandable metallic stents have been widely used in tracheobronchial obstruction or fistulation, including the J-shaped and Y-shaped stents, named after the shape of the branch-stem junction of the stent. However, there is scarce data on the mechanical performance of these tracheobronchial stents, which is essential for optimal stent implantation. In this work, eight self-expandable metallic tracheobronchial stents in three types (*i.e.*, straight, J-shaped, and Y-shaped), with or without cover, were characterized. The compression resistance of the stems was investigated through both compression and indentation tests. The bending resistance of the branches in the J-shaped and Y-shaped stents was assessed through the bending test. Our results demonstrated that the covered stents exhibited a significantly higher compression resistance and bending resistance than the uncovered ones. The branches had a minimal impact on the compression resistance of the stem. The branch of the J-shaped stent showed a significantly lower bending resistance than the Y shaped one. This work provides a testing framework for the J-shaped and Y-shaped stents, which could shed some light on the optimal design of stent with branches.

Keywords: self-expandable metallic tracheobronchial stent, Y-shaped, J-shaped, covered stent, bending resistance

***Corresponding Author: Xinwei Han:** Department of Interventional Radiology, The First Affiliated Hospital, Zhengzhou University, Henan, China; Email: hanxinwei2006@163.com
***Corresponding Author: Linxia Gu:** Mechanical and Materials Engineering, College of Engineering, University of Nebraska-Lincoln, United States of America; Department of Biomedical and Chemical Engineering and Sciences, Florida Institute of Technology, United States of America; Email: gul@fit.edu
Yanli Wang: Department of Interventional Radiology, The First Affiliated Hospital, Zhengzhou University, Henan, China Pengfei Dong: Mechanical and Materials Engineering, College of Engineering, University of Nebraska-Lincoln, United States of America
Pengfei Dong: Mechanical and Materials Engineering, College of Engineering, University of Nebraska-Lincoln, United States of America.
Yanli Wang and **Pengfei Dong** contributed equally to this paper
Jingyao Ke: Mechanical and Materials Engineering, College of Engineering, University of Nebraska-Lincoln, United States of America
Xiang Shen: School of Mechanical Engineering, Jiangsu University, Zhenjiang, Jiangsu, China
Zongming Li, Kewei Ren: Department of Interventional Radiology, The First Affiliated Hospital, Zhengzhou University, Henan, China

1 Introduction

Tracheobronchial obstruction or fistulation is potentially life-threatening and requires immediate therapy to restore the airflow. The traditional Y-shaped silicon stent was used for the central airway obstruction, but was limited by its noncompliant structure [1]. The self-expandable metallic stents, originating from treating the blocked artery, have become widely used for tracheobronchial obstruction and fistulation during the last two decades [2–4]. Different structures of self-expandable metallic stents were developed: straight stent without a side branch [5], J-shaped stent with one branch [6], and Y-shaped stent with two branches [7]. The deployment of the J-shaped or Y-shaped stents in the bifurcation lesions will lead to a more complex mechanical response in the lesion compared with the deployment of the straight stent [8]. These stents are usually covered with a silicon membrane to mitigate the tissue ingrowth [9], as well as to facilitate the stent removal [10]. The adverse effect of the covered stent is the higher risk of migration. The partially covered stent was designed to take advantage of the merits of both the covered stent and the bare-metal one [11].

The mechanical performance of the tracheobronchial stent is essential for serving as a scaffold to restore the airflow. The radial strength, bending resistance, and torque resistance were characterized for stent implantation in arteries [12–14]. Ratnovsky *et al.* measured the radial strength of the straight tracheal stents using a specially designed adaptor [15]. Regardless of scarce testing data available for the tracheobronchial stents, the characteriza-

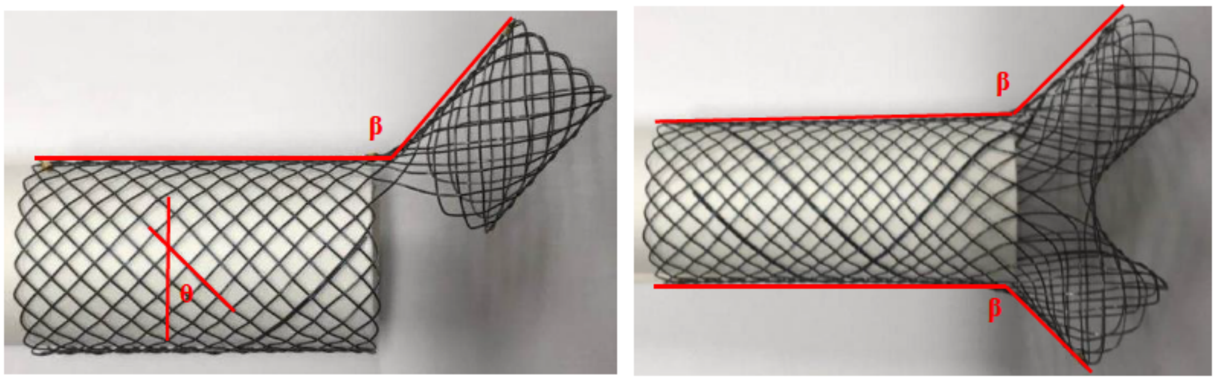


Figure 1: The angle between the branches and stem in (a) J-shaped stent and (b) Y-shaped stent.

tion of the self-expandable metallic stents, either J-shaped or Y-shaped, was nonexistent, but it is essential for optimal clinical outcomes. For example, a larger bending resistance of the branches might cause abnormal stresses in the lesion subjected to the change in the tracheobronchial angle during inspiration and expiration [16]. This might be associated with long-term complications.

In this work, the mechanical behavior of eight self-expandable metallic tracheobronchial stents in three types (*i.e.*, straight, J-shaped, and Y-shaped), with or without cover, was characterized. The influence of the branches on the compression resistance of the stem in J-shaped and Y-shaped stents was investigated using the compression test and indentation test. The bending resistance of the branches in the J-shaped and Y-shaped stents was investigated through a specially designed bending test device. The impact of the cover on the compression resistance and the bending resistance was also investigated.

2 Materials and methods

Stent information

Eight self-expandable metallic tracheobronchial stents are summarized in Table 1. Two straight stents, with and without cover, were denoted as SC and S, respectively. Three J-shaped stents with one branch (*i.e.*, uncovered J-shaped stent, covered J-shaped stent, and covered J-shaped stent with one blocked-end branch) were denoted as J, JC, and JC&B, respectively. Three Y-shaped stents with two branches, (*i.e.*, uncovered Y-shaped stent, covered Y-shaped stent, and covered Y-shaped stent with one blocked-end branch) were denoted as Y, YC, and YC&B, respectively.

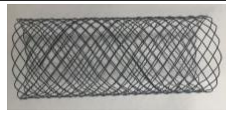
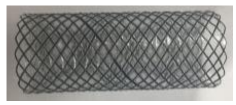
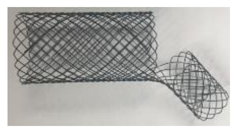
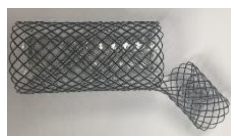
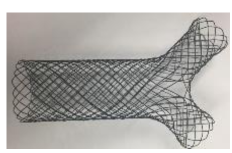
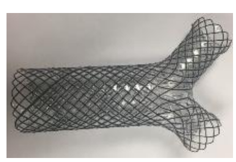
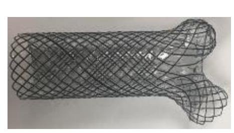
The nominal diameter of the straight stent and the stem in the J-shaped and Y-shaped stents was 20 mm. The nominal diameter of the branches in the J-shaped and Y-shaped stents was 12mm. The length of the straight stent and the stem in the J-shaped and Y-shaped stents was 50 mm, 40 mm, and 45 mm, respectively. The length of the branch in all the J-shaped stents was 20 mm except the JC&B, which was 25mm. The length of the two branches in the Y-shaped stents was 20 mm and 15 mm except the YC&B, which was 5mm. The branch angle, denoted as β, was 130° for the J-shaped stent, and 135° for both branches in all the Y-shaped stents (Figure 1). The angle between both of the two branches in the Y-shaped stents was 90°. The vertex of the angle separated the branches from the stem zone for J-shaped or Y-shaped stents.

All of the stents were braided with one single Nitinol wire, while the number of the mesh along the circumferential and longitudinal direction varied in different types of the stents. The pitch angle (*i.e.*, the angle between the wires and the circumferential direction of the stem or branch (Figure 1a) can be estimated based on the two diagonal lengths of the rectangular mesh as:

$$\theta = tan^{-1}\left(\frac{L/n_1}{\pi D/n_2}\right) \quad (1)$$

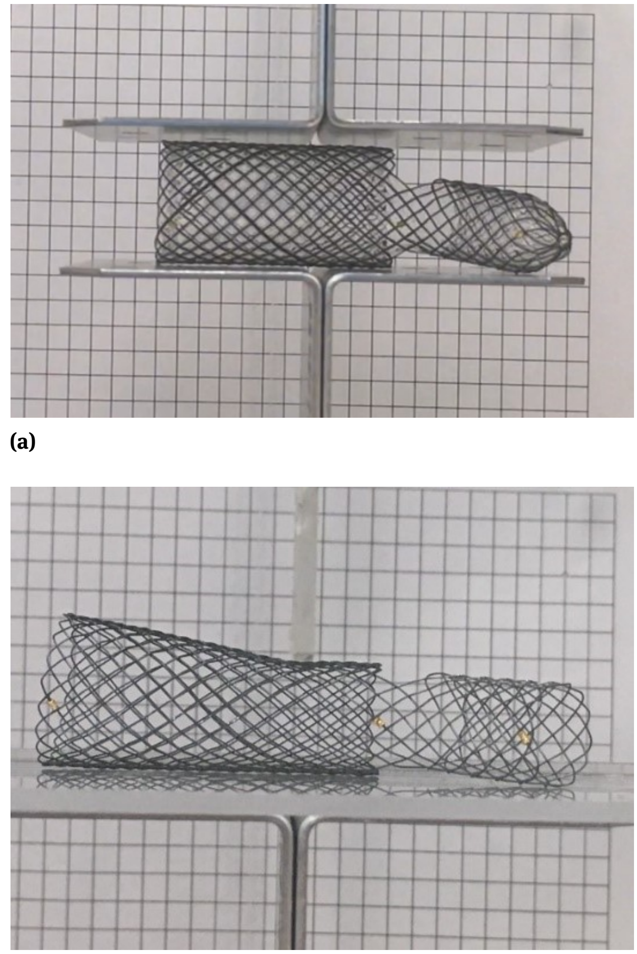
where L is the length of the stem, n_1 is the number of the mesh along the longitudinal direction, D is the diameter of the stem, and n_2 is the number of the mesh along the circumferential direction. The pitch angles of the straight, J-shaped, and Y-shaped stent were 35.27°, 46.70°, and 44.40°, respectively. All of these stents were braided with a single Nitinol wire with a diameter of 0.23 mm (Micro-Tech, Nanjing, China).

Table 1: Stent specifications

Symbol	Structural information	Photos
S	Straight, uncovered 20×50mm	
SC	Straight, covered 20×50mm	
J	J-shaped, uncovered Stem: 20×40mm Branch: 12×20mm	
JC	J-shaped, covered Stem: 20×40mm Branch: 12×20mm	
JC&B	J-shaped, covered Stem: 20×40mm Blocked branch: 12×25mm	
Y	Y-shaped, uncovered. Stem: 20×40mm Branch: 12×20mm; 12×15mm	
YC	Y-shaped, covered. Stem: 20×40mm Branch: 12×20mm; 12×15mm	
YC&B	Y-shaped, one side of branches blocked Stem: 20×40mm Branch: 12×15mm Blocked branch: 12×5mm	

Compression test

The radial strength of the straight stent and the stem in the J-shaped and Y-shaped stents were evaluated with a parallel plates compression test. A universal testing machine (TestResources, Shakopee, MN, USA) with a load cell of 5 lbs was used. Two horizontally parallel plates with a vertical handle were firmly clamped between gripping jaws to compress the stems of the stents (Figure 2a). The displacement control mode with a compression distance of 5 mm was adopted. The compression displacement rate was 0.1mm/s, warranting a quasi-static state. The compression process was monitored to make sure there was no slip between the stent and the plates. The resistance force was recorded during the compression. The radial strength was defined as the resistance force at the compression displacement of 5 mm. The normalized radial strength was calculated as the radial strength divided by the stem length.



(a)

(b)

Figure 2: (a) Compression test, and (b) Indentation test of the stents.

Indentation test

A rectangular vertical polycarbonate plate with a thickness of 2.2 mm was firmly clamped between gripping jaws to indent the stems of stents at three locations (*i.e.*, the center and 10 mm away from each end of the stem (Figure 2b). The vertex of the branch angle (Figure 1) served as the end

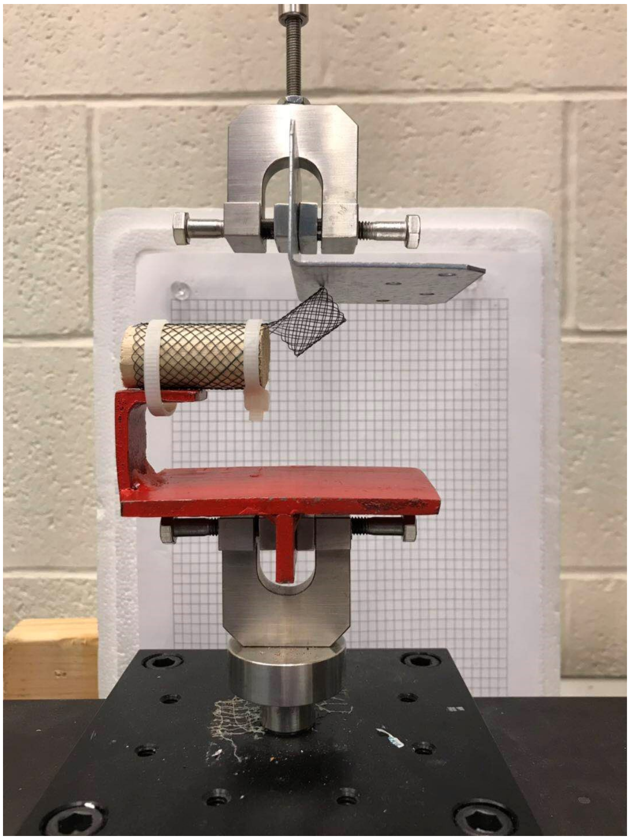


Figure 3: Bending test of the branches for both J-shaped and Y-shaped stents.

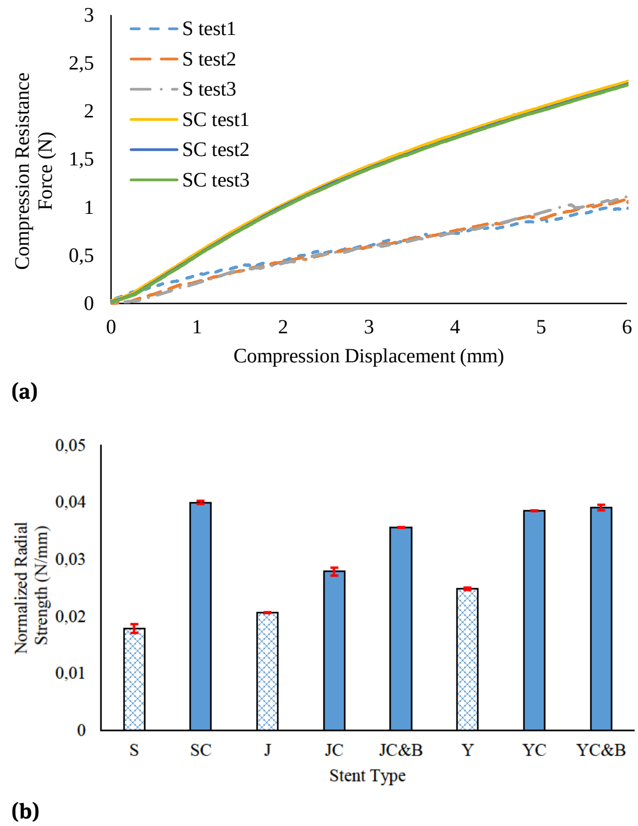


Figure 4: (a) Representative compression behavior, and (b) Normalized radial strength of the stems.

of the stem in the J-shaped and Y-shaped stents. The resistance force was recorded through the indentation process, and the indentation strength was defined as the resistance force at the indentation depth of 5 mm.

2.1 Bending test

The stem portion of the stents was filled with a solid rod of 20 mm in diameter, and then fixed to a custom-designed fixture, which was clamped between lower jaws (Figure 3). An L-shaped plate was firmly clamped between upper gripping jaws to compress and bend the branches of the J-shaped and Y-shaped stents. Both the bending resistance force and the deformation of the branches were recorded in synchronization during the bending procedure. The bending angle, defined as the change in the branch angle, was measured using ImageJ [17]. The linear regression between the bending angle and the bending resistance force was performed. The coefficients and constants were obtained using the minimal least square method. The Pearson correlation coefficient was calculated as:

$$r = \frac{\sum(x-\mu x)(y-\mu y)}{\sqrt{\sum(x-\mu x)^2}\sqrt{\sum(y-\mu y)^2}} \quad (2)$$

where x is denoted as the bending angle, y is denoted as the bending resistance force, and μx and μy are the means of the x and y variables. There is a strong linear dependence between x and y if r is closer to 1 or −1.

3 Results

The representative compression behavior of the straight stent, with or without cover, is demonstrated in Figure 4a. The experiment showed a good repeatability for both stents. The covered stents exhibited a higher radial resistance than the uncovered ones. The normalized radial strength for all the stents is shown in Figure 4b. As expected, the uncovered stents (S, J, and Y) had less radial strength than the covered ones. The normalized radial strength was less than 0.025 N/mm for all the uncovered stents, while it ranged from 0.027 N/mm to 0.043 N/mm

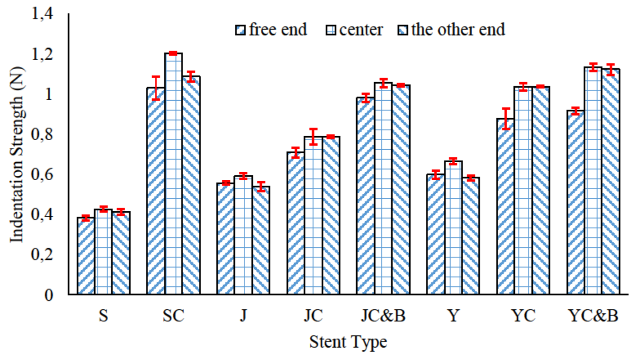


Figure 5: Indentation tests of all stems.

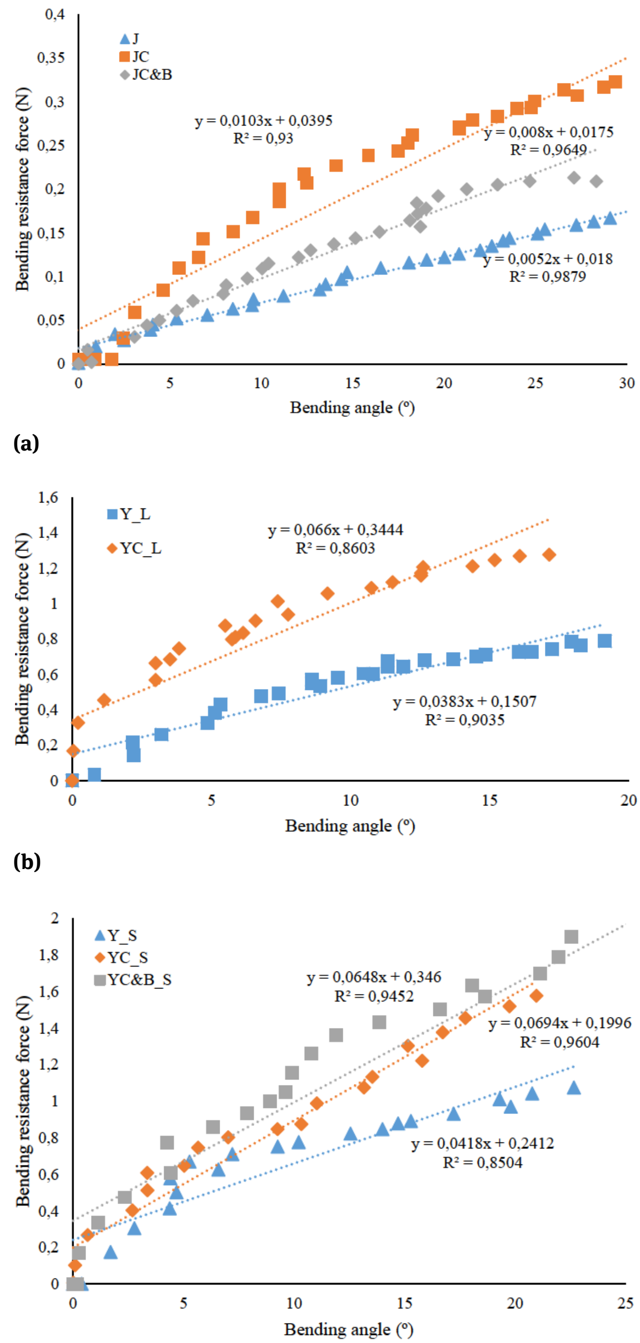


Figure 6: Bending test of (a) three J-shaped stents, (b) long branches of two Y-shaped stents; and (c) short branches of three Y-shaped stents.

for those covered ones. It is interesting to observe that the normalized radial strength of the stem in the uncovered J-shaped and Y-shaped stents was higher than the straight ones, while this trend was reversed for the covered counterparts. In addition, the blocked-end configuration of the J-shaped stent (JC&B) led to an increase in the normalized radial strength by 27.80%, compared with the JC stent. The normalized radial strength for both the YC stent and YC&B stent exhibited minimal differences (1.5%), which is also similar to the normalized radial strength of the SC stent.

The indentation strength of each stent at three locations, free end, center, and the other end of the stem (*i.e.*, the end adjacent to the branches) is shown Figure 5. The indentation strength was slightly larger at the center location than that at both ends. The indentation strength at the end adjacent to the branches was higher than the free end for the types JC, JC&B, YC, and YC&B. Moreover, the indentation strength showed a similar trend as the normalized radial strength among stent types. The cover induced higher indentation strength in stents.

The bending behavior of the branch in all the J-shaped stents is shown in Figure 6a. Among the three J-shaped stents: J, JC, and JC&B, the covered stents showed a higher bending resistance than the uncovered one. The blocked end (JC&B) exhibited a less bending resistance force compared with JC. This might be due to the 5mm longer branch in the JC&B compared with the JC. The regression coefficient of the bending, also referred to as bending stiffness, was approximately doubled in the JC stent, compared with that of the J stent. A positive regression intercept indicates a local deformation at the contact region between bending plate and the branch end during the initial bending. The regression intercept for the JC and J stents were 0.0395 N and 0.018 N, respectively. The bending of the JC branch exhibited more local deformation than that of the J-shaped stent.

The bending behavior of both branches in all the Y-shaped stents is shown in Figures 6b&c. The 20mm-long branch was denoted as "_L", and the 15mm-long branch was denoted as "_S". No 20mm-length branch existed in the YC&B stent. Again, the covered stents showed a higher bending resistance than the uncovered one. Both the re-

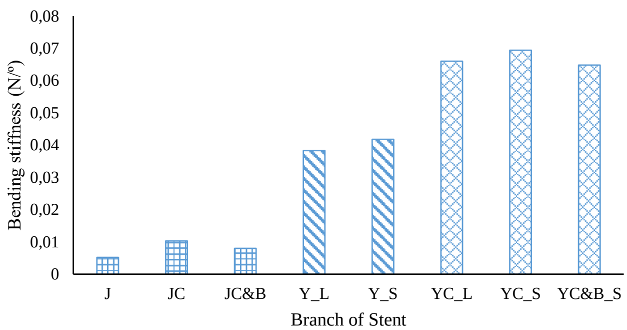


Figure 7: Bending stiffness of branches in both J–shaped and Y-shaped stents.

gression coefficient and interception of the YC stent were larger than the Y stent. The bending behavior of the 15mm-long branch in both YC and YC&B exhibited a minimal difference even though the other branch was distinctly different. This indicated that the bending behavior of branches in Y-shaped stents was independent from each other.

The bending stiffness of all eight branches is also summarized in Figure 7. It is obvious that the bending stiffness of J-shaped stents was less than that of Y-shaped ones. The bending stiffness ranged from 0.0052 N/° to 0.0103 N/° for J-shaped stents, and from 0.0383 N/° to 0.0694 N/° for Y-shaped stents. This could be attributed to the configurations of the branch-stem junction. The J-shaped stent has many fewer wire connections between its branch and stem. Again, the covered stents showed a higher bending resistance than the uncovered ones. It is interesting to see that the bending resistance is more sensitive to the junction configuration, rather than the cover. In addition, the 15mm-long branch had a slightly larger bending stiffness than the 20mm-long one.

4 Discussions

The mechanical performance of the tracheobronchial stents is essential for serving as a scaffold to restore the airflow. There is limited testing data available for the tracheobronchial stents. Moreover, the characterization of J-shaped or Y-shaped self-expandable metallic stents does not exist in the literature. In this work, the compression, indentation, and bending behaviors of eight commonly used self-expandable metallic tracheobronchial stents, including the J-shaped and Y-shaped stents, were characterized and compared. The radial strength of the main stems of the stents was accessed using both compression and indentation tests. The bending resistance of side branches in the J-shaped and Y-shaped stents was assessed.

The radial strength (*i.e.*, the scaffold capacity to open the blocked lumen) is a major consideration for stent design [8, 18]. It is clear that various configurations of side branches had minimal impact on the radial strength of the main stem of the stents. However, the covered stent could improve the radial strength, compared with the uncovered counterpart [19]. This could be explained by the load sharing capacity of the cover as well as the cover-induced extra constraints on the relative movement of wires. It has been reported that the relative sliding between wires could mitigate the radial strength of the braided stents [20].

Following the stent deployment, the mismatch between stent design and the anatomic dimensions could induce the bending of stents, especially on the side branches. To our best knowledge, this work is the first quantification on the mechanical behaviors of stents with side branches. We have observed that J-shaped stents have a much lower bending resistance than that of Y-shaped stents, regardless the cover. This was attributed to their junction configurations. Moreover, a larger bending resistance in the Y-shaped stents implied a larger wall stress on the lesion, and thus a higher risk of complications [8, 21]. Besides, the covered stent exhibited more bending resistance than its uncovered counterparts. It is interesting to see that the junction configuration, rather than the cover, has more impact on the bending resistance. In addition, a shorter branch could lead to a slightly larger bending resistance. Specifically, the partial connection from the stem to branch of the J-shaped stent along the circumferential direction is flexible than the fully connected one for the Y-shape stent.

Migration behaviors observed in clinical practices [22, 23] were not considered in this work. It has been shown that a larger radial/bending strength, correlated with higher contact force between stent and the lesion, could mitigate the migration of a straight stent [24]. The concern of migration was much relieved for both the J- and Y-shaped stents, because each junction configuration, itself, constrained the migration of the stent in a bifurcated lesion [25]. The fatigue behavior of the J-shaped and Y-shaped stents might be essential due to inspiration and expiration following stenting [26]. A sophisticated devise will be considered for the fatigue test in further work.

5 Conclusion

In this work, mechanical behaviors of the self-expandable metallic tracheobronchial stents, especially the J-shaped and Y-shaped stents, were characterized using a compression test, indentation test, and bending test. The radial strength of the stem was significantly enhanced by the cover but not affected substantially by the side branches. The bending resistance of side branches was sensitive to the junction configurations, as well as the cover. The mechanical evaluation of the stent-trachea interaction with experimental and computational methods may further validate the results from this work, help establish the standard of the test, and help the stent design.

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