

**Peer Review File**

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**Reviewer A**

Can you elaborate on the elemental composition of the metal stents and their compatibility with MRI?

Reply : We added the data of elemental composition of Y metal stents (see Page 4, line 70; Page 12, line 241). This metal stent is made of nickel titanium alloy and is compatibility with MRI.

Changes in the text: Micro-Tech stents (Micro-Tech Corporation, Nanjing, China) are self-expanding metal (nickel titanium alloy) stents available in different shapes that are individually customizable.

**Reviewer B**

The article entitled “Customized self-expanding bare metal Y stents in the treatment of malignant carinal stenosis: A retrospective analysis” describes the efficacy of customized Y-shaped self-expandable metallic stents (SEMSs) on the management of malignant carinal involvement.

It is interesting in that the customized SEMSs were useful in the palliative care for the airway obstruction, whose effect was accompanied by proved airway patency. However, there are some concerns to be solved.

Major;

1) The assessment of the current SEMSs placement should be more specific (Line 115). Especially, the definition of “clinical success” should be clearer, such as the improvement in mMRC by 1 point, etc. The respiratory support classification is too obscure, with only 3 grades ranging from in room air to invasive ventilation.

Reply 1 .we have modified our text as advised (see Page 8, line 144-147). The definition of “clinical success” was modified as advised. The respiratory support classification was increased into 4 grades.

Changes in the text: Respiratory support was classified into 4 grades: breathing room air, low concentration oxygen therapy by cannula ( $FiO_2 \leq 33\%$ ), high concentration oxygen therapy by mask ( $FiO_2 \geq 35\%$ ), and invasive ventilation. Clinical success was

defined as symptomatic improvement (at least 1 grade in the respiratory support) and improvement of the modified Medical Research Council (mMRC) dyspnea scale (at least 1 grade) after stent placement.

2) The authors assessed the clinical success amongst the technically succeeded population (n=35). I think the clinical success should be assessed in the full analysis set (n=36).

Reply 2 : We have modified our text as advised (see Page 3, line 50; Page 10, line 190)

Changes in the text: The clinical success rate was 97.2% (35/36).

3) The case failing to achieve technical success should be fully described in the Result section. I think the relevant patient had to undergo additional intervention to remove the stent left behind. Since airway stenting is an invasive procedure, this procedure should have been harmful to the relevant patient. Therefore, the outcome of the patient should be described.

Reply 3 : We added some data about this case (see Page9, line 172-180)

Changes in the text: The customized Y stent was removed immediately by an alligator biopsy forceps and a spare uncovered metallic cone-shaped stent was inserted instead. The patient was a 75-year-old male who was diagnosed as squamous cell carcinoma of right lung and underwent surgical resection of the entire right lower lobe and right middle lobe. Tumor recurrence was found in the lower part of trachea and carina. The proximal end (18mm) of cone-shaped stent was positioned in the trachea while the distal end (10mm) was positioned in the left main-stem bronchus. The meshes on the cone-shaped stent near the opening of right main-stem bronchus was enlarged by laser cutting, which allowed the airflow and sputum could pass through.

4) The advantage of SEMSs lies in the easy adoptability under topical anesthesia, even when the patient's performance status is not good enough for general anesthesia. Since the silicon Y-stent placement is a standard treatment for the malignant carinal involvement, the author should put an emphasis on this point when discussing the advantage of the current Y-shaped SEMSs.

Reply 4 : We have modified our text as advised (see Page 12, line 230-232).

Changes in the text: Compared with silicone Y-stent, the self-expandable metallic Y-stent has easier adoptability under topical anesthesia, even when the patient's performance status is not good enough for general anesthesia.

5) And also, the authors stated in the Methods section that these procedures were conducted under general anesthesia after 2013, while early 12 cases were performed under fiber-optic bronchoscopy. I cannot understand the reason why the authors changed the anesthesia during SEMSs placement. Was it decided for a safety measure? The author should refer to this point as well.

Reply 5 : We have modified our text as advised (see Page 6-7, line 120-122)

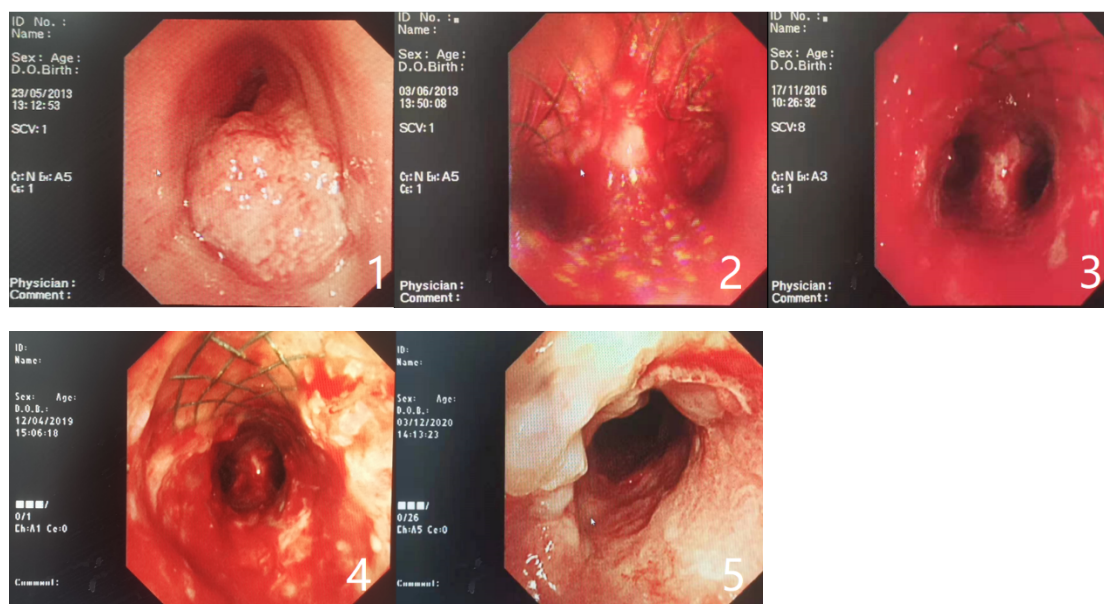
Changes in the text: After 2013, the placement of Y stents in our center was performed during a rigid bronchoscopy under general anesthesia with high-frequency jet ventilation in order to obtain a better tolerance and safety in patients.

6) The authors raised the removal and replacement of Dumon Y-stents as one of disadvantageous point (Line 188). I think this is rather an advantage of silicon stent to metallic stents, since SEMSs cannot be removed even when they become unnecessary.

Reply 6 : We have deleted this sentence. (see Page 12, line 227-228)

The longest follow-up period in the current study was 2130 days (Line 176). I think the removal of SEMSs should be considered in the relevant patient, especially when the response to the treatment was complete response.

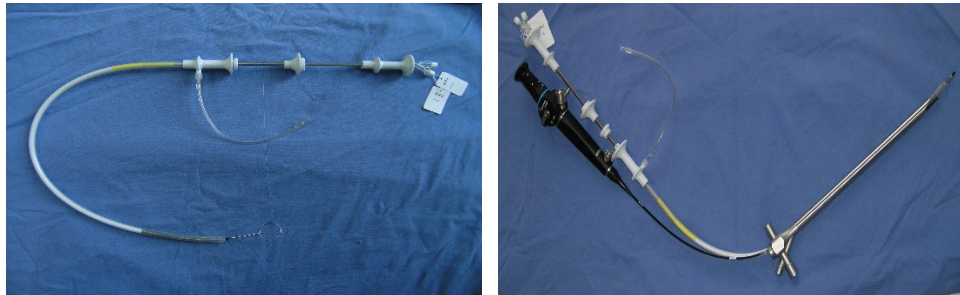
Reply 6: This is a 58-year-old male patient diagnosed as trachea and carina squamous cell carcinoma (well differentiated) (Figure 1). He received customized self-expanding bare metallic Y stent insertion in June,2013 (Figure 2), then received 5 cycles of postoperative chemotherapy and 1cycle of radiotherapy. However, re-stenosis of the stent due to tumor growth still needed to be treated by interventional bronchoscopy intermittently (Figure 3), and the interval between two interventional bronchoscopy examinations was getting shorter. No other stent-related complications occurred. Therefore, the customized Y stent was not removed. The last follow-up date in this article was April, 2019 (Figure 4). He is still being followed up, and the last contact date was December, 2020 (Figure 5).



7) The authors insisted that difficult placement and sputum retention are the disadvantage in the silicon Y-stents placement in the Introduction and Discussion sections. I think the technical problems are almost the same as the silicon stents when SEMSs are placed under general anesthesia. The sputum retention is rather difficult to

remove in SEMSs compared to silicon stents.

Reply 7: Compared with silicon Y-stent, the delivery catheter of SEMS is much thinner (As shown in the figure below). Therefore, it is easier to pass through the stenosis segment which lead relatively easier placement process especially for severe tracheal stenosis patients. Moreover, due to their thin walls, SEMSs have a larger internal luminal diameter than silicone stents, which allow for better clearance of secretions.



8) There are several mistakes in English terminology as well as grammar. And the colloquial expression such as “pass away” is not suitable in the scientific manuscript. The manuscript should be revised by native English scientists.

Reply 8 : We have modified our text as advised (see Page 10, line 185-186). The manuscript had been revised by native English speakers. The certificate of English editing has been upload as an attachment.

Changes in the text: They died of the fatal evolution of their malignant disease.

Minor;

1) The follow-up period started from zero. Does this mean the patient died on the day of stent placement which ended in a technical error? The authors stated that one patient died within 48 hours after the procedure (Line 168). If so, the follow-up period should be 1-2 days.

Reply 1 : We have modified our text as advised (see Page 10, line 182)

Changes in the text: Duration of follow-up ranged between 1 and 2130 days.

2) The authors listed “balloon dilatation” as one of interventional bronchoscopy. The balloon dilatation is not useful in the malignant central airway obstruction.

Reply 2 : We have modified our text as advised (see Page 6, line 114; Page 14, Line 277)

Changes in the text: “balloon dilatation” has been deleted.

3) There are several expressions indicating central airway obstruction (CAO) caused by lung cancer such as “malignant carinal stenosis”, “malignant central airway obstruction”, and “malignant disease involving the main carina”. The CAO includes malignant carinal involvement which is the most severe scenario. The terminology should be consistent.

Reply 3 : We have modified our text as advised (see Page 4, line 61-62; Page 12, Line 223)

Changes in the text: Malignant central airway obstruction is a life-threatening disease, in which malignant carinal stenosis is the most severe scenario.

Dumon Y-stent that was useful and was well-tolerated in the management of malignant carina stenosis

- 4) If a rigid bronchoscopy is abbreviated to RB, fiber-optic bronchoscopy should be FOB.

Reply 4 : We have modified our text as advised (see Page 7, line 124)

Changes in the text: “RB” was amended as “rigid bronchoscopy”.

- 5) The authors used “main bronchus”, which should be “mainstem bronchus”.

Reply 5 : We have modified our text as advised (see Page 3, line 56; Page 6, line 107; Page 7, line 126; Page 7, line 131; Page 9, line 172; Page 15, line 286)

Changes in the text: “main bronchus” was amended as “main-stem bronchus”.

- 6) Line 95: The expression of “in a 27-F introducer sheath” should be “on a 27-F delivery catheter”.

Reply 6 : We have modified our text as advised (see Page 6, line 116)

Changes in the text: The customized self-expanding bare metal Y stent was loaded on a 27-F delivery catheter.

- 7) Line 181: “Slastic stent” seems typographical error, which could be “Plastic stent”.

Reply 7: It’s not a typographical error. Please refer to Reference 6: Neville WE, Hamouda F, Andersen J, Dwan FM. Replacement of the intrathoracic trachea and both stem bronchi with a molded Silastic prosthesis. J Thorac Cardiovasc Surg. 1972 Apr;63(4):569-76.

- 8) Line 217: Does “MSCT” mean multi-planner reconstruction (MPR) or thin-slice CT (TSCT)?

Multi-slice computed tomography

Reply 6 : We added some data about MSCT (see Page 5, line 92; Page 13, line 260).

Changes in the text: Multi-slice spiral computed tomography (MSCT) scans of the chest with 1.25 mm collimation, including coronal and sagittal reconstruction

**Reviewer C**

The authors present a retrospective single center review of patients who received customized self-expanding bare metallic Y stents for malignant CAO. The authors review the technical and procedural success and the technique employed. Some minor comments would be helpful to further clarify the main point of the paper that this technique palliates symptoms.

Table 1: Follow up days, should be Median, not Media

Reply: We have modified our text as advised (see Table 1)

Changes in the text: Follow up days, Median

Line 116-118, 156, and Table 3: Respiratory support before and after Y stent placement in 35 patients

There is a statement that "The respiratory difficulty instantly improved after treatment." How was this assessed for ventilated patients? Were all 4 patients extubated immediately post-procedure? Please clarify how long it took, in hours/days, for patients to go from level 1 or 2 respiratory support to level 0, room air, post procedure. Please include a time range, ie hours, days, etc to go from level 1 1/2 to level 0. It looks like this was assessed by day 3, but please clarify.

Reply: We have modified our text as advised (see Page 10, line190-196)

Changes in the text: The respiratory difficulty instantly improved after treatment and all of the patients experienced an improvement of at least 1 grade post-procedure. The 4 patients who received invasive ventilation before Y stent placement were extubated immediately post-procedure. The respiratory support grades of all patients were classified into Grade 1 (breathing room air) when they left anesthesia recovery room (P<0.0001, Table 3). The average dyspnea index decreased from 3.14±0.73 to 1.71±0.62 before and 3 days post-procedure.