



Efficacy of external fixation of a straight silicone stent in the treatment of subglottic stenosis

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Background: The incidence of subglottic stenosis is rising year by year. For this difficult clinical problem, the efficacies of surgical and bronchoscopic intervention treatments vary. A simple and effective method to affix silicone stents is needed for the treatment of subglottic stenosis.

Methods: Eight patients suffering from subglottic stenosis underwent straight silicone stent placement with external fixation in the First Affiliated Hospital of Chengdu Medical College between January 2015 and August 2019. All patients received regular postoperative bronchoscopy. A retrospective analysis was conducted to analyze the efficacy and complications of the operation.

Results: Straight silicone stent placement was successful in seven patients and the external fixation of stents was completed. Symptoms of dyspnea were resolved in seven cases (87.5%), and the mean diameter of the upper trachea was significantly increased from 3.54 ± 0.59 to 12.71 ± 2.42 mm after the operation ($t=15.78$, $P=0.002$). The modified Medical Research Council dyspnea scale score significantly decreased from 3.4 (2.7, 3.8) to 0.8 (0.4, 1.4) after the operation ($Z=-6.63$, $P=0.001$). Postoperative complications were observed, including one case of mediastinal emphysema and pneumothorax, two cases of granulation tissue hyperplasia, four cases of intractable cough, six cases of postoperative infection at the external fixation site, one case of postoperative bleeding, and one case of sputum retention. All were promptly treated and quickly controlled. No stent displacement was observed during follow-up.

Conclusions: External fixation of straight silicon stents for the treatment of subglottic stenosis had good short-term outcomes and stable stent fixation. The proportion of postoperative infections was high. Therefore, the advantages and disadvantages of this operation need to be considered.

Keywords: Subglottic; stenosis; stent; external fixation

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Introduction

Subglottic stenosis is a common disease in interventional pulmonology. It can be divided into congenital and acquired disease, according to the cause of its occurrence. Acquired subglottic stenosis accounts for more than 90% of all

cases and is usually the result of endotracheal intubation, tracheotomy, or tracheal papillomatosis (1,2). Many patients suffer airway mucosal injury due to endotracheal intubation in clinical practice, after which excessive repair of damaged tissue and granulation tissue hyperplasia eventually cause scar formation. There are no exact preventive measures for

acquired subglottic stenosis. Genetic susceptibility factors and airway microenvironment may play important roles in airway scar (2). When the tracheal tube is removed, patients gradually experience dyspnea, wheezing, and ventilator dependence.

The anatomical location of subglottic stenosis is rather unique: located between the inferior margin of the vocal cords and the lower border of the cricoid cartilage. It is very difficult to completely resect the scar tissue during surgery and complete the end-to-end anastomosis of the trachea. Surgical trauma will cause bilateral recurrent laryngeal nerve paralysis, causing the patient to lose vocal function (3-5). New techniques, such as balloon dilation, freezing, and using a Montgomery T-tube as a silicone stent, have been widely used in the treatment of airway stenosis (6,7). However, the technical requirements for the placement of a Montgomery T-tube with subglottic stenosis are very high, and the placement of the stent must be extremely accurate to avoid affecting the vocal function of the patient; if a straight silicone stent is implanted, its position is difficult to fix due to the frequent activity of the glottis and the proneness of the stent to shifting (7,8). These can lead to silicone stent placement failure.

Here, external fixation of straight silicone stents was performed in eight patients with subglottic stenosis. The efficacy and safety of this treatment method is reported. We present the following article in accordance with the STROBE reporting checklist (available at <http://dx.doi.org/10.21037/apm-20-2475>).

Methods

Study subjects

Eight patients (four males and four females) suffering from subglottic stenosis who underwent straight silicone stent placement with external fixation in the First Affiliated Hospital of Chengdu Medical College between January 2015 and August 2019 were included in the study. The range of ages was 18–76 years, and the average age was 48.67 ± 15.61 years. This study was approved by the Ethics Committee of The First Affiliated Hospital of Chengdu Medical College (No. 2020CYFYIRB-BA-101). All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). Informed consent was taken from all the patients.

Indications and contraindications

- (I) Indications: (i) tracheal stenosis exceeded 2/3 of the tracheal diameter and was less than 2 cm from the glottis. There was one case of posttraumatic stenosis, four cases of postintubation or post-tracheotomy tracheal stenosis, and three cases of tracheal tuberculosis. The efficacy of general interventional treatment, such as balloon dilatation and freezing, was difficult to maintain. (ii) The area of tracheal stenosis exceeded 1/2 of the entire tracheal cross-sectional area, and the patient had obvious dyspnea and chest tightness after exercise. These symptoms severely affected the quality of life. (iii) Tracheal softening events occurred, and lung function was severely reduced. (iv) Scar tissue in stenotic lesions tended to be stable, with no exudate, and bronchoscopy showed scar stenosis or accompaniment by tracheal softening. If one of the above items (i-iii) was met along with item (iv), straight silicone stent placement and external fixation was considered.
- (II) Contraindications: (i) severely impaired coagulation function and poor cardiopulmonary function that precluded surgery; (ii) respiratory-associated infections or purulent secretions and ulcers in the stenosis.

Proper selection, placement, and external fixation of silicone stents

- (I) Silicone stent selection: three-dimensional reconstruction of the respiratory computed tomography (CT) was used to process images to understand the anatomical structure around the stenosis. The nature, location, length, and degree of stenosis and the condition of the granulation tissue surface were determined by fully considering the findings of flexible bronchoscopy. For subglottic stenosis, a straight silicone stent was used. CT images were measured using the Neusoft Medical System. The size of the normal airway anteroposterior and mediolateral diameters was measured at 0.2 cm above the starting position of the stenosis in the cross-sectional image. According to the authors' experience and previous literature (9), the diameter of the stent was 90% of the average of the normal airway internal diameters at the upper and lower ends of the stenotic segment. The stent was 0.5–1.0 cm longer than the stenosis.

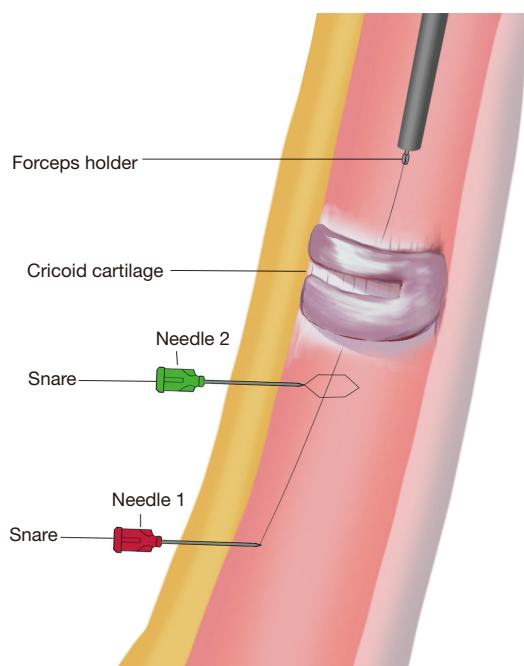


Figure 1 Schematic illustration of the external fixation of a straight silicone stent.

- (II) Stent placement and fixation: before inserting the endoscope, the patient had to be in a good anesthetic state. Freezing and balloon dilation were used to dilate the stenosis site. If the scar was too thick and difficult to dilate, a needle-shaped electric knife or holmium laser was used to make a transverse incision, and then balloon dilation was done by using a pressure of 1 atm. The front end of a rigid bronchoscope (14 mm in diameter) was then inserted into the distal end of the stenosis lesion, and the stent was slowly placed using a stent introducer. After the stent was released from the rigid bronchoscope, according to the circumstances, the balloon dilation could be performed again, or forceps could be used to adjust the position of the stent to fully deploy it.
- (III) External fixation of the stent: the neck was disinfected and covered with drapes, and then (i) a 50-mL empty green needle penetrated the midline of the trachea 3 cm below the cricoid cartilage under direct vision through the bronchoscope. The needle penetrated the silicone stent and the trachea and was perpendicular to the midline of the airway. A suture with a diameter of 0.30 mm was inserted into the core of the empty needle, and the suture was fed into the trachea through

the core of the needle. The forceps was sent into the airway through the bronchoscope to clamp the suture, and the 50-mL empty needle was pulled out of the skin. (ii) A 50-mL empty red needle penetrated the midline of the trachea 2 cm below the cricoid cartilage (Figure 1). The needle penetrated the silicone stent and the trachea and was perpendicular to the midline of the airway. The snare wire at the front end of the snare was inserted into the empty needle and fed through the needle into the trachea. The snare was unfolded to form a ring, and the suture in the trachea was clamped with a forceps and passed through the loop of the snare. The snare was fixed, folded, and pulled out from the 50-mL empty needle. At this point, the suture came out from the green needle (ii) 2 cm below the cricoid cartilage. The green needle (ii) was pulled out, and the two sutures were knotted and fixed to buttons on the body surface. The distance between the two needle holes was approximately 1 cm (Figure 2).

Observation index

- (I) Exudation, hematoma, and necrosis on punctured skin: Bronchoscopy was performed on postoperative days 1, 3, and 7 to see if the stent completely covered the stenotic area, if there was any distortion, and if there was any displacement. The modified Medical Research Council (mMRC) dyspnea scale was assessed on the patients. This scale is based on the American Thoracic Society dyspnea scale (10). It is graded from 0 to 4 (0: normal breathing; 1: shortness of breath during quick walking; 2: shortness of breath when walking at normal speed; 3: shortness of breath during walking at normal speed and needing to stop walking; 4: shortness of breath during mild activity).
- (II) Postoperative observation: (i) mMRC score was assessed at 1 week and 3 months after stent placement. (ii) The stent displacement was evaluated by bronchoscopy at 2 weeks, 1 month, 3 months, 6 months, and 1 year after operation. (iii) Granulation tissue hyperplasia was recorded and scored (11): 1 point meant the lumen diameter was narrowed by <25% by granulation tissue, 2 points meant narrowing by 25% to 50%, 3 points meant narrowing by 50% to 75%, and 4 points meant narrowing by greater than 75%. (iv) Sputum retention and irritating cough, sputum, hemoptysis, or other discomfort were monitored, as was the improvement in the mMRC score. If granulation tissue growth or

sputum retention was observed during follow-up, the follow-up interval was shortened appropriately.

Statistical analysis

SPSS 20.0 software was used for statistical analysis, and all parameters were tested for normality. The data with a normal distribution are represented as $\bar{x} \pm s$. Differences

between two groups of continuous variables were compared by the paired *t*-test. Data not conforming to a normal distribution are presented as median (P_{25} , P_{75}) and compared by the Mann-Whitney U test. $P < 0.05$ was considered statistically significant.

Results

Clinical data and treatment status (Table 1)

Subglottic stenosis in the patients: six cases of scar stenosis, two cases of laryngotracheal amyloidosis.

Stent placement: seven straight stents were successfully placed in seven patients, and the stent fixation was completed. The placement of one stent failed due to concurrent pneumothorax and mediastinal emphysema. The shortest follow-up time was 100 days, and the longest was 1 year.

Evaluation the efficacy of stent placement and external fixation

Alleviation of clinical symptoms: seven straight silicone stents covered the stenotic segments after placement, with good fixation and good positioning. Small amounts

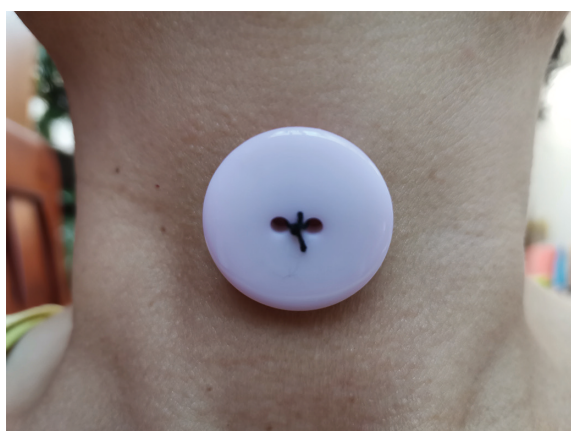


Figure 2 Postoperative images of external fixation of a straight silicone stent.

Table 1 General information and treatment status of all eight patients

Case No.	Gender	Age (years)	Expansion method	Cause of stenosis	Type of stenosis	Stent type	Stent size (mm) ^a	Follow-up time (days)
1	Male	18	Balloon dilation	Trauma	Scar stenosis	Straight silicone stent	50/14	100
2	Male	34	Balloon dilation and freezing	Endotracheal intubation	Scar stenosis	Straight silicone stent	40/13	Placement failure
3	Male	64	High frequency electric knife, balloon dilation	Tracheotomy	Scar stenosis	Straight silicone stent	50/15	150
4	Male	57	Balloon dilatation, metal stent	Trachea tuberculosis	Scar stenosis	Straight silicone stent	40/13	110
5	Female	41	Balloon dilation	Tracheotomy	laryngotracheal amyloidosis	Straight silicone stent	40/14	120
6	Female	34	Balloon dilation and holmium laser	Trachea tuberculosis	Scar stenosis	Straight silicone stent	50/14	150
7	Female	45	Balloon dilation and freezing	Trachea tuberculosis	laryngotracheal amyloidosis	Straight silicone stent	40/13	100
8	Female	53	Balloon dilation	Endotracheal intubation	Scar stenosis	Straight silicone stent	40/13	120

^a, the specifications for straight stents are given as length/outer diameter.

of exudate and swelling of the skin wound at the external fixation site were observed, and symptoms such as severe cough and shortness of breath before the operation were significantly relieved. The placement effect was satisfactory.

Change in luminal diameter: After stent placement, the average diameter of the upper trachea significantly increased from 3.54 ± 0.59 to 12.71 ± 2.42 mm ($t=15.78$, $P=0.002$).

Improvement of mMRC score: the mMRC score significantly decreased from 3.4 (2.7, 3.8) points before the operation to 0.8 (0.4, 1.4) points after the operation ($Z=-6.63$, $P=0.001$).

Complications and their treatment

Postoperative complications

Pneumothorax and mediastinal emphysema occurred in the process of stent placement in one case. The patient suddenly experienced severe cough and dyspnea, and oxygen saturation continued to decline to 85% during the operation. Stent placement immediately stopped, and bedside chest X-ray examination was performed. The results suggested that the right pneumothorax was compressed by approximately 50%, and there was a small amount of mediastinal emphysema, which was immediately managed by closed thoracic drainage. Lung recruitment was good one week later.

One patient showed a large amount of sputum retention around the stent one day after the operation, which was difficult to cough up. A repeat bronchoscopic aspiration was performed, and symptoms were relieved after the application of nebulized saline.

One patient experienced a small amount of exudation at the puncture site 1 day after the operation. Carbazochrome sodium sulfonate and sodium chloride (80 mg) were intravenously injected, and the bleeding stopped.

Six patients had infection at the puncture site of the external fixation within 3 days after the operation, with small amounts of exudate, redness, and swelling, accompanied by severe coughing. Skin disinfection and dressing change were performed twice a day, and antibiotic infusion was given. The wound recovered well after 1 week.

The rest of the patients had symptoms such as foreign-body sensation in the throat, cough, sputum, and blood in sputum to varying degrees after the operation, which were quickly alleviated by symptomatic treatment.

Postoperative follow-up

(I) Stent displacement: during the follow-up visits, all the stents were fixed well, with no stent displacement.

(II) Hyperplastic granulation tissue: among the seven patients in whom placement was successful, bronchoscopy 1 week after the operation revealed a small amount of hyperplastic granulation tissue at the two ends of the stent in four patients. Two of them showed granulation tissue covering approximately 50% of the lumen (2 points) under bronchoscopy. Treatments such as lyophilization and removal of granulation tissue using forceps were performed. No new granulation tissue was observed during the 6-month follow-up. The other two showed granulation tissue covering the luminal tissue below 25%, and at 6 months the granulation tissues were removed using forceps. No granulation tissue was observed during continued follow-up.

(III) Intractable cough: four patients had intractable cough during follow-up for 1 week; coughing was relieved after symptomatic treatments such as cough suppressants and removal of granulation tissue.

(IV) Wound infection at the external fixation site: during the first month of follow-up, five patients experienced secondary infection at the external fixation site. Local skin was red and swollen, accompanied by a small amount of exudate and severe coughing. The patients were admitted and given disinfection and dressing changes twice a day along with transfusion of antibiotics. The wound infection was alleviated after that.

Discussion

Subglottic stenosis after tracheotomy and endotracheal intubation has always been a problem for clinical physicians. Most patients require metal stent placement for a long-term after tracheotomy to resolve dyspnea. The procedure causes complications that seriously affect the quality of life of the patients. Scholars (10-12) have recommended the placement of a Montgomery T-tube under a rigid bronchoscope; however, some parts of the T-tube silicone stent are exposed outside of the body, so the maintenance inside the stent is difficult afterwards.

In this study, all eight patients had significant subglottic stenosis. Except for one failed case, the stenosis of other seven patients alleviated quickly after stent placement. The lumen diameter of the stenosis was widened, the effective airway ventilation was restored, and dyspnea was alleviated, for a total effective rate of 87.5%.

The materials selected for all patients were straight

silicone stents. Silicone stents have the advantages of better tissue tolerance, softer texture, and less residual secretion than metal stents. Compared with metal stents, silicone stents are easier to remove, replace, and relocate. Their disadvantage is that the wall of the silicone stent is relatively thick, and the rigidity and tension are relatively small. The fixation of a straight silicone stent relies on the pressure and friction between the nail-shaped protrusions on the outer wall of the silicone stent and the inner wall of the trachea. The stent is not easy to fix firmly in the stenosis of the subglottis due to the large mobility of the glottis, so the stent is prone to move. Therefore, we adopted the external fixation method for subcutaneous fixation of the straight silicone stent and the trachea through a suture.

No stent displacement was observed during the 1-year follow-up. Because silicone stent placement did not have obvious complications, it was generally not taken out quickly. The follow-up time in this study was short, at only 1 year. No cases of suture removal or stent removal due to stenosis cure were reported. Among the eight patients, only one had pneumothorax associated with mediastinal emphysema, and the others did not have serious complications. All complications were treated promptly. These findings indicate that the external fixation of straight silicone stent for the treatment of subglottic stenosis is a safe and effective treatment, with fewer postoperative complications, better patient tolerance, and better short-term effects.

Silicon stents have better histocompatibility than metal stents, cause less tissue irritation after placement and less granulation tissue growth than metal stents, and can be left in place for a long time. The main complications of silicone stent implantation are injury and hemorrhage to scar tissue of airway caused by rigid bronchoscope (12-14). After external fixation, the silicone stent can be firmly fixed in the upper tracheal segment. However, long-term silicone stent placement and external fixation still lead to some adverse reactions: (I) Granulation tissue growth: The incidence of granulation tissue growth in this group was 57%, which is consistent to the data reported in other studies (15,16). After silicone stent placement and external fixation, granulation tissue will form at both ends of the stent and around the suture, and a small amount of granulation tissue is conducive to stent fixation, but excessive granulation tissue hyperplasia may lead to clogging of the lumen. (II) Sputum retention: Prolonged placement of silicone stents can affect the ciliary movement of the airway surface and cause retention of secretions. If nebulization is not used

for a long time to moisturize the airway, the sputum on the inner wall of the stent is easy to scab and difficult to cough up, and even cause asphyxia in severe cases. Therefore, after external fixation of stent placement, the nebulizer therapy should be strengthened to dilute the sputum. Bronchoscopy should be performed regularly to remove secretions in the stent promptly. (III) Wound infections at the external fixation sites: There were six cases of postoperative skin infections in this study. Because the long-term retention of sutures in the skin may lead to infection around the suture, the skin surrounding the suture should be observed after external fixation of straight silicone stents. The surrounding skin was regularly disinfected and changed of dressing. In five cases, infection was also observed during the first month of follow-up, and the patients were hospitalized again for active treatment. This may be because sutures were foreign bodies that stayed between the skin and that airway secretions can penetrate the interstitial space and leak out of the wound. Disinfection of external fixation sites and the administration of antibiotics after operation can prevent infection. (IV) Severe complications: In this study, only one patient had pneumothorax with mediastinal emphysema, in whom the right lung compression was approximately 50%, which may be due to pleural tearing and lung bullae at the right side that caused by the severe coughing during the application of balloon dilation before stent placement. The symptoms were relieved after application of closed chest drainage.

Mediastinal emphysema is a relatively serious complication that can affect cardiopulmonary circulation in severe cases, leading to apnea and cardiac arrest. During the operation, to avoid the occurrence of mediastinal emphysema, the patients should be carefully evaluated before surgery. If the stenosis site is thick, temporary placement of a covered metal stent for expansion may be attempted first. The intraoperative operation should be gentle. When using a balloon, the pressure should be increased gradually, and the bleeding and tissue in the dilatation site should be closely observed.

Straight silicone stent placement and external fixation must be chosen only after weighing its pros and cons. Patients should be comprehensively evaluated to determine their indications, and timely treatment should be given if adverse reactions or complications are found, to ensure the safety of this operation. Overall, the external fixation of straight silicon stents for the treatment of subglottic stenosis has good efficacy, high safety, and acceptable complications.

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Footnote

Reporting Checklist: The authors have completed the STROBR reporting checklist. Available at <http://dx.doi.org/10.21037/apm-20-2475>

Data Sharing Statement: Available at <http://dx.doi.org/10.21037/apm-20-2475>

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/apm-20-2475>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was approved by the Ethics Committee of The First Affiliated Hospital of Chengdu Medical College (No. 2020CYFYIRB-BA-101). All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). Informed consent was taken from all the patients.

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