



## Transtacheal oxygen catheters

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Reports of the percutaneous placement of intravenous catheters into the trachea began to emerge in 1960 [1–6]. The intended benefit of the catheters was to reduce postoperative pulmonary complications such as atelectasis and pneumonia. Catheters were inserted through the cricothyroid membrane and detergents were periodically instilled in efforts to stimulate cough and enhance clearance of tracheobronchial secretions. Experience with the “tickle tube” (Fig. 1) showed that the procedure was relatively safe [1–6]. Infrequent complications included subcutaneous emphysema [2,3], bronchospasm [4] and cephalad displacement of the catheter [1,3].

Over 20 years after the introduction of the tickle tube, Heimlich became the first to describe the use of a transtacheal catheter for the long-term administration of home oxygen. In 1982 he used a canine model [7] to demonstrate that, with supplemental oxygen administration, the partial pressure of arterial oxygen (PaO<sub>2</sub>) continued to increase as the catheter tip was placed progressively closer to the carina. Heimlich also reported a limited experience with 14 patients [7] who underwent percutaneous placement of a transtacheal catheter between the second and third tracheal rings. Administered transtacheal oxygen (TTO) flow rates ranged from 0.25 to 1.5 L/min. Compared with the nasal cannula, there was a 57% reduction in oxygen flow requirement. Heimlich first used a custom device consisting of a 16 gauge Teflon intravenous catheter externally secured by a reversed pediatric tracheostomy tube that was fastened about the neck with cloth ties (Fig. 2A). Later, a modified 16 gauge Teflon catheter was inserted through a companion needle (Micro-Trach, Erie Medical, Mil-

waukee, WI). The final version of the device (Micro-Trach, Ballard Medical Products, Drapper, UT) was commercially available from 1990 to 1993 (Fig. 2B).

While Heimlich and Carr continued their evaluation of the Micro-Trach [8], Banner and Govan [9,10] in the United Kingdom and both Hoffman [11] and Bloom [12] in the United States studied transtacheal oxygen delivery using Heimlich’s custom device.

In 1986 Leger and coworkers from Lyon, France described a TTO catheter that was inserted using a needle-wire guide, dilator-introducer technique [13]. The larger diameter catheter delivered mean flows of 2.9 L/min to achieve adequate oxygen saturations in patients that were refractory to nasal cannula administration. The catheter (Fig. 3) and companion introducer system (Oxycath, Laboratoire Smad, Labresle, France) were commercially available in Europe, but not in the United States.

One year after Leger and colleagues introduced the Oxycath technology, Johnson and Cary [14] described an implantation procedure involving subcutaneous tunneling of a silicone TTO catheter from the midanterior chest to extend approximately 2 cm into the lumen of the trachea (Fig. 4). The catheter (ITOC, Cook Critical Care, Bloomington, IN) was commercially available until the year 2000.

In the mid-1980s we developed a TTO catheter system using a needle-wire guide, dilator insertion technique and initially reported our experience in treating patients with severe hypoxemia that was refractory to nasal cannula therapy [15]. We then reported on the safety and efficacy of a comprehensive transtacheal oxygen therapy program in 1987 [16]. The acronym SCOOP (Spofford Christopher Oxygen Optimizing Program) was later coined and the program continues to be the most widely used method of TTO administration. The SCOOP transtacheal catheters and insertion trays (Transtacheal

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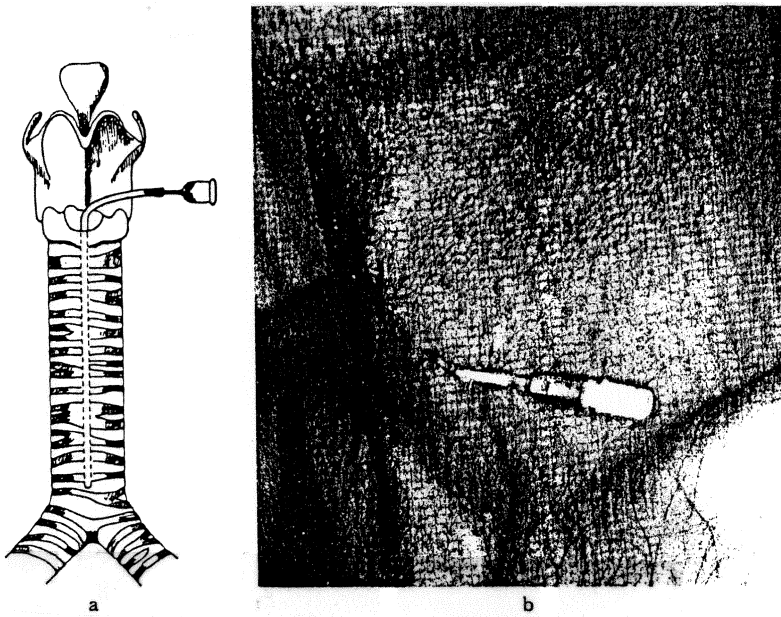


Fig. 1. The drawing (a) shows the level of insertion and position of the indwelling tracheal catheter. The photograph (b) demonstrates that fixation of the catheter to the skin is accomplished with skin suture. (From Sizer JS, Frederick PL, Osborne MP. The prevention of postoperative pulmonary complications by percutaneous endotracheal catheterization. *Surg Gynecol Obstet* 1966;123:336–40; with permission.)

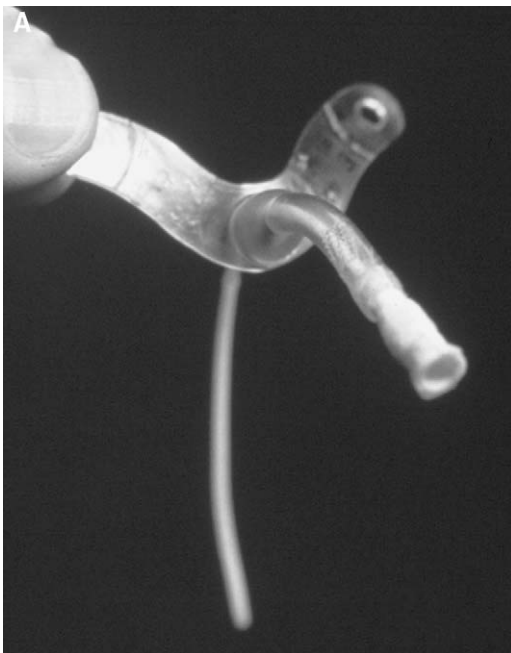


Fig. 2. Heimlich's custom transtracheal oxygen delivery device (A) consisted of a 16 gauge Teflon intravenous catheter that was stabilized by an externally placed pediatric tracheostomy tube. The Heimlich Micro-Trach (B) was commercially available (Ballard Medical Products, Drapper, UT) from 1990 to 1993.



Fig. 3. This transtracheal oxygen catheter (Oxycath, Laboratoire Smad, Labresle, France) was evaluated in Europe (Leger P, Gerard M, Robert D. Home use of transtracheal catheter for long term oxygen therapy of 30 chronic respiratory insufficiency patients [abstract]. *Chest* 1986; 89:486S).

Systems, Inc, Denver, CO) have been available for more than 15 years and approximately 15,000 to 20,000 patients have been treated worldwide. Because the majority of the research and clinical experience is based upon this technology, and because the only products that are now commercially available in the United States relate to this method of TTO administration, the remainder of this article will focus on SCOOP transtracheal oxygen therapy.

### Overview of the SCOOP

The SCOOP for developing the TTO catheter tract was initially constructed around a modified Seldinger technique (MST). The MST program has been extensively described elsewhere [17]. An alternative surgical method for tract creation was introduced [18] in 1996. Lipkin's surgical approach [18] presents some potential advantages over the MST, which in-

clude a reduction in potential complications and both streamlined education and shortened program duration. To date, there are supporters of both methods of TTO catheter insertion. Both methods of tract creation will be reviewed. Whether the MST or the surgical path is taken, the TTO program is comprised of four clinically defined phases. Phase I is focused on patient evaluation and preparation. The primary goal is to properly select patients, while identifying established indications, contraindications and precautions. The transtracheal tract is created in phase II, and the goals are to create a quality tract and to make certain that the patient remains clinically stable during either the MST or surgical intervention and associated postprocedure period. In phase III, the patient begins TTO therapy, but the tracheocutaneous tract has not fully matured. The major goals in this phase are to prevent inadvertent catheter removal and prevent symptoms from adherence of inspissated mucus to the outer surface of the catheter (mucus balls). To facilitate this, clinicians must periodically remove the catheter over a wire guide for cleaning. In phase IV, the tract is mature and patients can be trained to remove the catheter for cleaning on an individualized cleaning schedule. The goals in phase IV are to monitor and prevent complications such as chondritis, keloid formation, and lost tracts, and to facilitate the patient's realization of the benefits of TTO, including the maintenance of an acceptable level of activity and optimal quality of life.

### Complications of a program using the MST for tract creation

The potential complications resulting from administration of the transtracheal oxygen program by the MST are shown in Table 1. The table presents the initial large experience in United States [16] and compares those results with a more recent study from the Netherlands [19]. The investigation of Kampelmacher and colleagues [19] adds additional value because the Netherlands experience with their initial 10 patients is contrasted with results obtained from their subsequent 65 patients. Complications were infrequent and minor in severity during the procedure and stent week. Both studies identified a variety of minor complications during tract maturation (phase III) and the more long-term delivery of TTO with a mature tract (phase IV). The Kampelmacher study demonstrated that the complication rate markedly improved after gaining experience with the initial 10 patients. Of note, only 4 (4%) of the patients in the initial United States study elected to discontinue

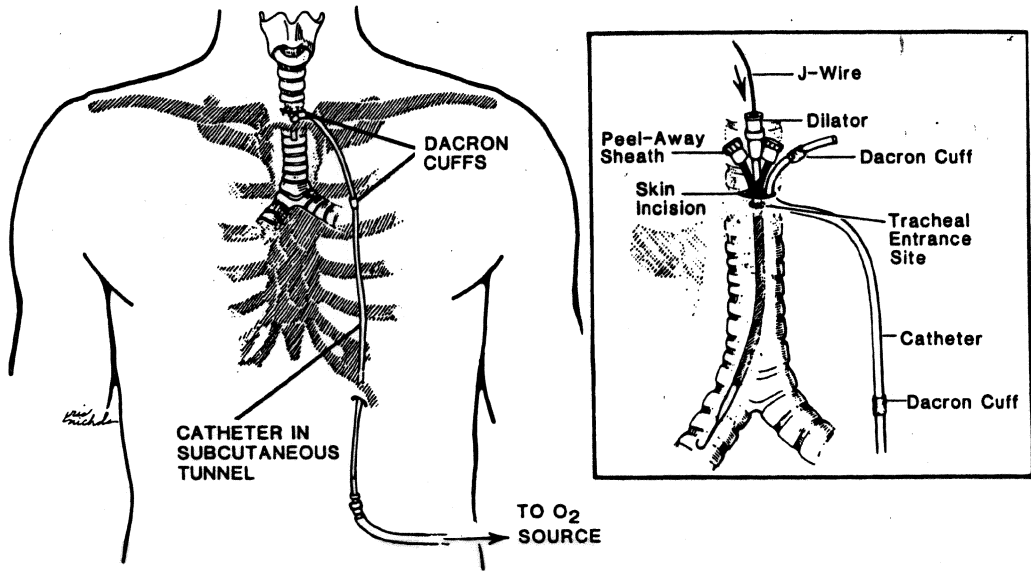


Fig. 4. A subcutaneously tunneled silicone transtracheal oxygen catheter (ITOC, Cook Critical Care, Bloomington, IN) was available until 2000. (From Johnson LP, Cary JM. The implanted intratracheal oxygen catheter. *Surg Gynecol Obstet* 1987; 165:75–6; with permission.)

TTO therapy and only 2 subjects (3%) in the Netherlands study elected to return to nasal oxygen.

Adamo and colleagues reported their initial experience with TTO in 21 patients over a 2-year period [20]. Serious complications using the MST were infrequent, and included respiratory failure, misplacement of catheters into the anterior and middle mediastinum, and moderate hemoptysis. Though most other complications were minor and resolved, 14% had mucus balls and 38% of patients had an episode of catheter dislodgement. After treatment of their subsequent 31 patients [21], review of their data only demonstrated a trend for reduction in technically related complications.

Hoffman and coworkers reported on 40 patients [22]. They encountered a higher incidence of symptomatic mucus balls (25%) as well as inadvertent catheter displacement in both the immature (22%) and mature tract phase (22%). The investigators were unable to reinsert the catheter (lost tract) with an incidence of 7% in phase III and 7% in phase IV. In a more recent report of 56 patients treated over 5 years, Orvidas and colleagues [23] found that severe complications such as pneumothorax and pneumomediastinum were rare, but 38% of patients had mucus balls.

Over 16 years have passed since the introduction of TTO using the MST. During that time there have

been rare case reports of one death [24] and seven life-threatening events due to airway obstruction from mucus balls [25–31]. In addition, there has been one case report of tracheal perforation [32] and one report of death due to catheter misplacement [33].

In summary, the literature and extensive clinical experience demonstrate that TTO using the MST for catheter insertion is safe. Severe or life-threatening complications are very rare. The most frequent minor complications encountered with the MST are symptomatic mucus balls, lost tracts or catheter displacement, keloids, and chondritis. Minor complications do not seem to be a significant deterrent to use. Patient acceptance rate is generally on the order of 96%.

### Potential benefits of transtracheal oxygen therapy

The potential benefits of transtracheal oxygen therapy compared with nasal oxygen delivery are shown in **Box 1**. A number of physiologic benefits have been described in the literature. We noted a marked reduction in erythrocytosis in the treatment of hypoxemia that was refractory to nasal oxygen therapy [15]. Significant reductions in hematocrit were also seen in patients thought to be adequately treated with nasal cannula therapy [16]. Domingo and associates reported reduced pulmonary vascular re-

Table 1  
TTO SCOOP complications utilizing MST insertion technique

Complication	Christopher KL, et al [16]		Kampelmacher MJ, et al [19]			
	Patients (n = 100)	Frequency (%)	Initial experience		Subsequent experience	
			Patients (n = 10)	Frequency (%)	Patients (n = 65)	Frequency (%)
Procedure and stent week (phase II)			Procedure and stent week (phase II)			
Subcutaneous emphysema	3	(3)	-	-	2	(3)
Bronchospasm	2	(2)	-	-	-	-
Immature (phase III) and mature (phase IV) tract periods			Immature (phase III) and mature (phase IV) tract periods			
Symptomatic mucus balls	10	(10)	1	(10)	-	-
Lost tracts	7	(7)	6	(60)	1	(2)
Cricothyroid puncture	3	(3)	-	-	1	(2)
Cephalad-displaced catheter	3	(3)	7	(70)	-	-
Bacterial cellulitis	1	(1)	1	(10)	-	-
Hemoptysis (>10 to 25 ml)	2	(2)	-	-	-	-
Keloid	4	(4)	4	(40)	8	(11)
Candidal dermatitis	2	(2)	-	-	-	-
Contact dermatitis	3	(3)	-	-	-	-
Subcutaneous emphysema & pneumomediastinum	1	(1)	-	-	-	-
Chondritis	-	-	3	(30)	2	(3)
Inadvertent dislodgement of catheter	-	-	5	(50)	7	(9)
Fractured catheter <sup>a</sup>	-	-	1	(10)	-	-
Tracheobronchitis	-	-	-	-	1	(2)
Tracheitis	-	-	-	-	1	(2)

Abbreviation: MST, modified Seldinger technique for catheter insertion.

<sup>a</sup> Occurred in one of the initial five patients using the Oxycath (Laboratoire Smad, Labresle, France), before switching to the SCOOP catheter (Transtrachel Systems, Denver, CO).

Data from [16] Christopher KL, Spofford BT, Petrun MD, McCarty DC, Goodman JR, Petty TL. A program for transtheal oxygen delivery: assessment of safety and efficacy. *Ann Intern Med* 1987;107:802–8; [19] Kampelmacher MJ, Deenstra M, van Kesteren RG, Melissant CF, Douze JMC, Lammers J-WJ. Transtracheal oxygen therapy: an effective and safe alternative to nasal oxygen administration. *Eur Resp J* 1997;10:828–33.

sistance upon initial study [34] and follow-up [35] in patients requiring supplemental oxygen. Another investigation by Domingo's group [36] suggested improved oxygenation during sleep. Reduced cor pulmonale was particularly notable in patients with severe refractory hypoxemia [15].

O'Donohue and colleagues [37] evaluated room-air arterial blood gases in patients that received nasal oxygen therapy during a control period and following administration of TTO. The room air alveolar-to-arterial oxygen tension gradient was significantly less after receiving transtracheal oxygen delivery. In addition, Hoffman and coworkers [38] demonstrated that exercise capacity was significantly increased with TTO. Couser and Make [39] showed that TTO decreases the inspired minute ventilation as a result of a reduction in tidal volume, and Bergofsky and Hurewitz [40,41] documented reduced physiologic dead space with transtracheal gas delivery. Finally, Celli's group [42] reported reduced oxygen

cost of breathing and shortened respiratory duty cycle with TTO.

Improved mobility usually results from TTO delivery. Oxygen flow requirements are reduced by over 50% at rest and approximately 30% during exercise [16]. Consequently, portable oxygen delivery systems last longer and patients can take advantage of smaller and lighter units. Mobility is facilitated by improved exercise tolerance, and patients often experience reduced dyspnea. Improvement in dyspnea may result from the previously described reduced physiologic dead space, decreased inspired minute ventilatory requirements, and reduced oxygen cost of breathing.

True 24-hour per day compliance can be achieved with TTO therapy. Most patients conclude that TTO is more comfortable than the nasal cannula. Consequently, they are more likely to use TTO continuously. In one study, the most common reason for patients to seek TTO was the need for improved

**Box 1. Potential benefits of transtracheal oxygen therapy compared with nasal oxygen delivery**

*Physiologic benefits*

- Reduced erythrocytosis
- Reduced pulmonary vascular resistance
- Improved cor pulmonale
- Improved room-air alveolar-to-arterial oxygen tension gradient
- Decreased physiologic dead space
- Reduced inspired minute ventilation
- Reduced work of breathing
- Shortened respiratory duty cycle
- Improved exercise capacity
- Improved oxygenation during sleep

*Improved mobility*

- Greater exercise tolerance
- Longer lasting, lightweight portable oxygen sources
- Reduced dyspnea

*True 24-hour per day compliance*

- Greater comfort
- Elimination of nasal prongs (cannula) complications
- Improved self-image

*Reduced medical cost*

- Decreased hospital days
- Decreased cost per hospitalization

comfort [43]. Patients on nasal oxygen may have suboptimal compliance due to discomfort from chronic irritation around the nose and ears or from more significant complications such as contact dermatitis, chondritis, or skin ulceration. Though cosmesis is not a significant concern for many patients [43], some individuals may be more compliant with TTO, due to improved self-image resulting from the fact that the delivery device is entirely off the face and can easily be hidden from view.

The Nocturnal Oxygen Therapy Trial (NOTT) [44] and Medical Research Council (MRC) [45] data document that survival in hypoxemic chronic obstructive pulmonary disease (COPD) is directly related to

hours of oxygen use. In the “continuous group” of the NOTT study, patients only used the nasal cannula approximately 19 hours per day. It is likely that 24-hour per day TTO therapy has the potential to further improve survival. The study by Clifford suggests that this may be the case [46].

Recent years have brought increasing concern for cost-containment. Prolonged hospitalizations are much more costly than long-term oxygen therapy. Compared with a nasal cannula control period, Hoffman [38] showed that hospital days were significantly reduced with TTO. Bloom [12] also demonstrated that hospital days for patients on TTO were significantly fewer than the hospital days during a period when they had received nasal oxygen. Likewise, the TTO group’s hospital days were lower than seen in a separate nasal cannula control population. Clifford [46] also showed reduced cost per hospitalization with TTO.

**Highlights of the SCOOP with the MST for tract creation**

This section is a discussion of the overall program, but is not intended as a comprehensive educational manual for patient care. The entire SCOOP using MST has been more fully described elsewhere [17]. Comprehensive video, electronic, and printed educational materials are available through the manufacturer (Transtracheal Systems Inc, Denver CO)

*Phase I: patient orientation, evaluation, selection, and preparation*

As noted previously, a primary goal in this phase is to select the right patient. The specific indications, contraindications, and precautions for TTO are shown in Box 2. These recommendations have evolved through data drawn from scientific publications and extensive day-to-day clinical experience. Patients considering TTO should first meet well-established reimbursement criteria for continuous long-term oxygen therapy. TTO is specifically indicated if the individual experiences complications or discomfort from nasal prongs that result in suboptimal compliance. Patients may remove the cannula due to chronic pain or discomfort over the ears or under the nose resulting from abrasion, maceration, ulceration, chondritis, or contact dermatitis.

Hypoxemia that is refractory to maximal nasal cannula therapy is a specific indication for TTO. In addition to refractory patients that have inadequate oxygen saturations both day and night, there are

**Box 2. Transtracheal oxygen therapy: specific indications, contraindications, and precautions**

*Specific Indications*

Complications of nasal prongs  
 Hypoxemia refractory to maximum nasal prong therapy  
 Cor pulmonale or erythrocythemia on nasal prongs  
 Nocturnal hypoxemia on nasal prongs  
 Need for improved mobility  
 Noncompliance related to nasal prongs  
 Patient preference

*Contraindications*

Severe anxiety neurosis  
 Poor compliance with medical therapy  
 Mental or physical incompetence  
 Upper airway obstruction  
 Pleura herniated over puncture site

*Precautions*

Poor mechanical reserve  
 Profound hypoxemia  
 Hypercarbia without acidemia  
 Obese neck or other anatomic abnormality  
 Mild to moderate anxiety neurosis  
 Bronchial hyperreactivity  
 Copious or viscous sputum  
 Serious cardiac arrhythmia  
 Bleeding disorder

individuals on continuous oxygen therapy who selectively experience nocturnal hypoxemia on nasal prongs. A more subtle subset of patients on long-term oxygen therapy demonstrate adequate oxygen saturations on spot checks during periodic brief medical examinations, but continue to experience cor pulmonale or erythrocytosis on nasal oxygen. These individuals may benefit from TTO as an alternative delivery system. As noted previously, patients requiring improved mobility frequently benefit from TTO. Patient preference is extremely important; TTO should be considered when nasal prongs promote noncompliance due to cosmetic, discomfort, or impaired mobility issues.

Contraindications for TTO have been well-established. Individuals with severe anxiety neurosis tend to

become more anxious when faced with the responsibility of catheter self-care. Patients with generalized poor compliance with medical therapy should not be considered. Those with severe mental or physical incompetence may not be able to adequately care for the catheter. The presence of a severe upper airway obstruction is also a contraindication. Barotrauma could potentially result because oxygen delivered into the distal trachea at a point below the obstruction may not be able to escape. Finally, the finding on a chest radiograph of herniation of pleura over the planned procedure site constitutes a contraindication because the MST will likely result in complications such as pneumothorax or pneumomediastinum.

There are a number of patients that do very well with TTO, but one or more precautions are identified during their initial evaluation. It is not uncommon for patients to have a poor mechanical reserve, profound hypoxemia, or hypercarbia without acidemia. Care must be taken to have these patients on maximal medical therapy and in stable condition before the procedure. Individuals with a serious cardiac arrhythmia, bleeding disorder, or anticoagulant therapy must be adequately prepared for the procedure and monitored carefully. In patients with an obese neck or other anatomic abnormality, it may be wise to either have an experienced interventional pulmonologist perform the MST or consider the Lipkin surgical approach for tract creation.

Some individuals have an element of bronchial hyperreactivity associated with their COPD. Preprocedure pharmacologic control of airway reactivity is important. The presence of copious or viscous sputum in patients with diseases such as cystic fibrosis and bronchiectasis should not necessarily preclude TTO as a treatment option. Optimal control of bronchial infection and maintenance of adequate bronchial hygiene are essential in this preprocedure phase, however, and throughout the entire program. Individuals with very copious or viscous sputum and those with uncontrolled bronchial hyperactivity are particularly prone to encountering difficulty in phase III, due to the development of symptomatic mucous balls. Unrelenting cough may also predispose marginally compensated patients to respiratory muscle fatigue. The presence of mild to moderate anxiety is not uncommon in patients struggling with severe chronic lung disease. Aggressive education and reassurance often help these individuals overcome their fears and they usually do well with TTO. Increased confidence often comes with improved mobility and activity.

Patients should be fully informed about the potential benefits and risks of TTO therapy before making a commitment to proceed with MST for creation of the

catheter tract. In addition to a question-and-answer session with a knowledgeable health care professional, an ideal orientation includes an opportunity for the candidate to talk or meet with a transtracheal patient. A targeted history should not only include historical pulmonary information, but details about prior oxygen therapy and compliance with the nasal cannula.

The physical examination should also include careful inspection of the nose, including nostrils, septum, and mucosa. The ears are examined for helical chondritis or irritation and other problems such as serous otitis media. Observations in the neck should include length, thickness, deviation of the trachea, position of the larynx, and position of anterior neck veins. The neck anatomy is inspected and palpated with the transtracheal procedure in mind.

Arterial blood gases on nasal prongs are helpful to assess the adequacy of alveolar ventilation and degree of compensation for respiratory acidosis. The partial pressure of arterial carbon dioxide ( $\text{PaCO}_2$ ) and respective liter flow give the patient and physician an estimate of reduced oxygen flow on transtracheal oxygen. The hematocrit is a simple test which reflects on the overall adequacy of oxygen therapy. A follow-up hematocrit on transtracheal oxygen demonstrating a shift from a high normal hematocrit to a mid or low normal hematocrit is common and suggests better 24-hour per day oxygenation. Pre- and postbronchodilator spirometry is helpful to estimate mechanical reserve and airway hyperreactivity. Posteroanterior and lateral chest radiographs with a properly fitted bead chain necklace are helpful in excluding rare individuals with pleura over the anterior neck and identifying unusual variants of anatomy before the transtracheal procedure. Additional laboratory data may be beneficial in individual cases. Special tests may include exercise oximetry, a 1.0 fraction of inspired oxygen ( $\text{FiO}_2$ ) study (to determine the degree of refractoriness to oxygenation), lung volumes, diffusion capacity, coagulation studies (anticoagulant therapy), or an electrocardiogram (arrhythmias).

Patients determined to be good candidates for TTO are scheduled for an outpatient procedure. They are instructed to take nothing by mouth after midnight (except for medications with a sip of water) and arrive one hour before the procedure. A significant other should provide transportation and stay with the patient throughout the procedure visit.

#### *Phase II: the transtracheal MST procedure and stent week*

The primary goals in phase I are to create a quality tract and to make certain that the patient remains

clinically stable during the MST and associated 1-week stent period. The MST procedure is generally performed on an outpatient basis. Most patients with  $\text{PaCO}_2 < 50$  mm Hg may be given one oxycodone capsule 1 hour before the procedure for antitussive, analgesic, and sedative effects. Patients with  $\text{PaCO}_2 > 50$  mm Hg may be given diphenhydramine 25 mg to 50 mg as an alternative. Cephalexin 500 mg or another antibiotic effective against *Staphylococcus aureus* is given for infection prophylaxis. Patients at risk for bronchospasm receive nebulized bronchodilator about 30 minutes before the procedure.

The procedure should be performed with the patient sitting upright, and ideal positioning is achieved with an otolaryngology examination chair with a headrest. The back of the chair is angled backward about  $10^\circ$ , and the headrest is adjusted to slightly extend the patient's neck. The ideal neck position is the same as when the patient is looking in a mirror at his or her own anterior neck. Nasal prongs are repositioned to arrive from behind; this leaves the anterior neck unobstructed for the procedure. The most recent posteroanterior and lateral chest radiographs are displayed in the procedure room on a view box. A spotlight is focused on the anterior neck.

Procedure site selection and preparation are accomplished using the upper tier (Fig. 5) of the procedure tray (T-9 Procedure Tray, Transtracheal Systems, Inc, Denver, CO). The superficial anatomy of the anterior neck is palpated and special attention is paid to anterior neck veins and position of the trachea. The notch of the thyroid cartilage is marked using a surgical marking pen with a "V," the



Fig. 5. The preparatory tier (*bottom*) of the procedure tray (T-9 Procedure Tray, Transtracheal Systems, Inc., Denver, CO) is used to select the proper position for the catheter and prepare the procedure site. The second tier (*top*) contains the stent and necessary instruments and supplies to perform the modified Seldinger procedure.



cricothyroid membrane is marked with a horizontal “—,” and the notch of the manubrium is marked with a gentle “U.” The cervical trachea rests between the “—” and the “U” and creates a vertical axis. The most stable position for the catheter is at the crossing of the security necklace and the trachea. A bead chain necklace is passed around the neck and adjusted with wire cutters to accomplish a proper fit, which usually accommodates two fingers snugly but should not be excessively tight with neck hyperextension or heavy cough. The crossing point may be marked using the surgical pen with two dashes laterally over the sternocleidomastoid muscles. In about 85% of patients, the necklace will cross at the first or second interspace. In about 10%, it will cross lower, and in 5%, it will cross the cricothyroid membrane. In this case, the chain is loosened to permit it to dip to the first tracheal interspace. A tract should not be created through the cricothyroid membrane because it predictably results in hoarseness, difficulty with catheter insertion, keloids, and chondritis.

Skin anesthesia is performed using a 27 GA needle with 2% lidocaine with epinephrine 1:100,000 at the level where the necklace crosses the cervical trachea. First, initial intradermal injection spans the medial aspects of both sternocleidomastoid muscles. Next, the trachea is transfixed with the thumb and forefinger of the nondominant hand and 1 mL of local anesthetic is injected from the skin down to the trachea. The 27 GA needle is removed and the 20 GA needle is attached to the syringe. With the trachea transfixed, the needle is inserted into the trachea at the puncture site, air is aspirated into the syringe, and the remaining 2 cc of local anesthetic is quickly injected. The needle is immediately removed to avoid lacerating the mucosa with coughing, and the patient is permitted to cough. The anterior neck is then prepped with the chlorhexidine scrub.

The lower tier (see Fig. 5) contains the stent and other necessary supplies for creation of the trans-tracheal tract and is used with sterile technique. A sterile drape is applied straight across the chest at the level of the clavicles. A No. 15 scalpel is used to make a vertical 1 cm incision at the selected puncture site. Attempts should be made to place the incision to the side of any visible anterior neck vein to avoid bleeding and bruising. Two passes of the blade are usually required and sequentially expose dermis and then fat.

The 7 cm, 18 GA, thin-wall needle attached to a syringe containing 2 mL of sterile saline is passed through the small incision down to the trachea. The cartilages are gently palpated with the needle, which is then popped through the intercartilaginous ligament.

The maneuver resembles a thoracentesis when the rib is palpated with a needle that is passed over the rib and into the pleural cavity. A common misconception is that the trachea is parallel to the anterior neck and chest. In most patients, the trachea falls away from the anterior chest wall at about a 45° angle. With the patient sitting 10° back, the trachea is usually vertical. Passing the needle horizontal to the floor will usually cause the needle to enter the trachea perpendicularly. Air is aspirated back, and the syringe is detached from the needle. The needle is rotated to bring the notch on the hub to the inferior rim; this directs the bevel of the needle downward. The hub is then elevated to angle the needle downward toward the carina.

The atraumatic end of the wire guide is inserted through the needle to the 11 cm reference mark. Insertion should feel like passing the wire guide through the needle into air. If any resistance is met, the needle may be misplaced outside the trachea. When doubt exists, the wire guide is removed and the procedure is repeated. After proper positioning of the wire guide, the needle is removed. A gloved assistant should hold the black reference mark on the wire guide at the level of the skin to free the physician for the dilation step.

The dilator is passed over the wire guide with a firm and steady push. Twirling the dilator is not necessary. To avoid traumatizing the posterior tracheal wall, the dilator is angled downward toward the carina. When the dilation of the intercartilaginous ligament reaches the full diameter of the dilator, less resistance is encountered. Insert the dilator an additional 2 cm into the trachea but do not go beyond the black reference mark at 8 cm. The dilator is left in place for 1 minute to fatigue the elastin fibers of the ligament.

The dilator is removed, taking special care to leave the wire guide in place. (Note: This is different from insertion of a central venous catheter because of the absence of an introducer sheath.) Again, a gloved assistant holds the black reference mark on the wire guide at the level of the skin. The previously lubricated stent is immediately inserted over the wire guide. As the tip passes through the neck tissues, it is twirled a full 360° until the flange comes to rest against the skin. The exchange from the dilator to the stent is made quickly, because venous oozing is most likely to occur at this point and the stent tamponades the bleeding.

The stent is stabilized with 1 cm sutures passed vertically through full thickness skin. The small eyelets of the stent are intended to discourage the use of the necklace, which could become excessively tight with normal swelling or subcutaneous emphysema. As the stent is being sutured in place, the patient is

asked to cough gently. This should result in air regurgitating out of the lumen of the stent. If it does not, a syringe is used to aspirate air out and confirm that the tip of the stent is in the airway. The 1 cm vertical incision is not closed with sutures and should be intentionally left open to permit the stent to function as a surgical drain. A nonocclusive dressing is lightly taped over the flange of the stent, and the procedure is terminated.

At the conclusion of the transtracheal procedure, the patient is taken to the radiology suite for a posterior-anterior and lateral chest radiograph. This should document the absence of extravasated air (subcutaneous emphysema, pneumomediastinum, and pneumothorax) and confirm the intratracheal location of the radio-opaque stent. The relationship of the tip of the stent to the carina is noted. The internal length of the stent is identical to that of the functioning transtracheal catheter with an internal length of 11 cm. If the tip of the stent is closer than 1 cm to the carina, a shorter 9 cm catheter should be obtained before transtracheal oxygen is started 1 week later. In contrast, if the tip of the catheter is 3 cm or more above the carina, the 13 cm catheter may be more appropriate. Placement of the stent with an open incision and nonocclusive dressing minimizes the potential for subcutaneous emphysema or barotrauma. The absence of gas flow minimizes coughing, because the trachea rapidly accommodates to the presence of just the foreign body. Systemic antitussives and topical lidocaine further suppress coughing.

All patients are observed for a minimum of 1 hour following the procedure. Patients with impaired mechanical reserve, refractory toxemia, or chronic hypercarbia may be admitted to an observation unit overnight. The physician should also admit to observation unit other patients who would be a concern at home.

Antibiotic prophylaxis with cephalexin 250 mg TID (or another antibiotic effective against *Staphylococcus aureus*) 1 or 2 weeks following the procedure is recommended. Exposure of cartilage is sometimes unavoidable because of fused tracheal rings. These unusually long periods of prophylaxis appear to be required because of the avascular nature of cartilage and the presence of a foreign body. Substantial clinical experience suggests that failure to administer antibiotic for these longer periods may result in tracheal chondritis 2 or 3 weeks later.

As the topical anesthesia wears off during the 1-hour postprocedure observation time, most patients develop some degree of cough. The severity of cough is assessed 1 hour after the procedure, and a cough suppression plan is designed. Patients are instructed

to resist any urge to cough, because it can result in respiratory fatigue or subcutaneous emphysema. Nonnarcotic cough suppressants are dispensed for use as needed. For individuals with the more severe cough, 4 mL of 1/4% lidocaine may be instilled through the stent every hour as needed. Patients regularly report that the procedure is less painful than an arterial blood gas. Patients usually require only acetaminophen for pain. Aspirin and ibuprofen products are avoided because their antiplatelet effect could cause increase bruising. During the first hour after the procedure, patients review cough suppression, tract care, and circumstances that should result in a call to the physician for help. A follow-up appointment is set for 1 week later. A phone call the afternoon of the procedure and another the day after the procedure are recommended to confirm that the patient is not experiencing problems.

During the week following the transtracheal procedure, patients continue to receive supplemental oxygen via nasal prongs. Patients are specifically instructed not to connect oxygen to the stent. Once the open lumen of the stent is lost due to the use of the channel for oxygen delivery, experience demonstrates that air cannot adequately leak between the outer lumen of the stent and the tissues. Consequently, development of subcutaneous emphysema or other barotrauma complications is possible. The non-occlusive dressing may be removed after the first day, but the tract is kept clean and dry. The tract is cleaned twice daily with a cotton-tipped applicator and 3% hydrogen peroxide. Regurgitation of air through the stent usually stops after 2 or 3 days when the lumen becomes blocked by inspissated secretions.

### *Phase III: transtracheal oxygen with an immature tract*

In phase III, the patient begins TTO therapy, but the tracheocutaneous tract has not fully healed or matured. A major goal in this phase is to teach the patient proper care in cleaning of the catheter. Other goals in phase III are to prevent inadvertent catheter removal, prevent tract problems, and avoid symptoms from adherence of inspissated mucus to the outer surface of the catheter (mucus balls). To facilitate this, clinicians must periodically evaluate the patient and remove the catheter over a wire guide for cleaning.

Phase III begins one week after the transtracheal procedure. During the first visit, the stent is exchanged for a functioning SCOOP catheter. The exchange is accomplished with the patient seated in the procedure chair with a headrest. Nasal prongs are rearranged to arrive from behind so as to free anterior

neck. A SCOOP catheter is selected based on the position of the stent relative to the carina on the postprocedure radiograph. A catheter with an 11-cm internal length is usually the proper size (SCOOP Catheter, Transtracheal Systems, Inc, Denver, CO). As shown in Fig. 6, a shorter catheter (9 cm internal length) and a longer version (13 cm internal length) are also available to accommodate variations in body habitus. A small amount of sterile water-soluble jelly is placed on the tip of the catheter. The customized necklace saved from the initial procedure is passed through the eyelets of the catheter. The atraumatic end of the wire guide is passed through the stent up to the black reference mark to clear dried secretions. About 2 cc of 1% plain lidocaine is drawn into a luer taper syringe, then quickly injected through the stent. The crusts about the stent are cleaned with cotton-tipped applicators dipped in 3% hydrogen peroxide. The sutures are then cut with the scissors saved from the prior week. The SCOOP wire guide is inserted to the black reference mark, and the stent is withdrawn. An assistant holds the black reference mark at the level of the skin to prevent inadvertent removal of the wire. The SCOOP catheter with the prethreaded necklace is then passed over the wire guide and twirled 360° into the tract. When the flange comes to rest against the skin, the wire guide is removed and the necklace clasp connected. Inadvertent dislodgement during phase III is likely to result in lost of tract, as the tract is immature and not lined by epithelium. Placing a 2 inch piece of

clear plastic tape over the necklace immediately right and left of the flange is a simple and effective way to help prevent early dislodgements.

The patient is fitted with a SCOOP oxygen hose, and catheter cleaning supplies are dispensed. Pulse oximetry is used to titrate transtracheal flow rates at rest and with exertion. The patient is instructed in cleaning the catheter in place using instilled saline and a cleaning rod. The individual should also be observed through a cleaning cycle to confirm proper technique. The significant other should be encouraged to sit through the entire session. The patient is educated about security routines to avoid losing the tract and symptoms that suggest the presence of a mucus ball.

A mucus ball is an accumulation of inspissated mucus that adheres to the anterior and lateral surfaces of the catheter, just above the tip. As noted earlier, symptomatic mucus balls occur in approximately 10% to 30% of patients in phase III when the catheter is cleaned in place. They generally disappear in phase IV, when daily removal strips the mucus off the catheter, allowing it to be expectorated. In many patients, the trachea adapts, and mucus balls spontaneously diminish in frequency during phase III. Although mucus balls can cause a tickle cough, dyspnea, or wheezing, they rarely result in airway obstruction. The pathogenesis of their formation is related to the volume of dry gas introduced into the lower airway and baseline secretions. Patients with low forced expired volume in one second (FEV<sub>1</sub>) and weak cough are less able to generate the glottic blast to dislodge mucus balls and are at relatively greater risk. Ineffective cleaning, inadequate humidification, failure to periodically strip the catheter during phase III, and insufficient systemic hydration are iatrogenic factors that predispose a patient to mucus ball formation. The use of a mucocoevacuant such as Guaifenesin may be helpful. Clinicians should maintain a high index of suspicion during phase III. Mucus balls, which may form in spite of adequate cleaning and humidification, should be immediately recognized and treated.

All patients should return for a clinical evaluation and catheter stripping within the first week of initiating TTO. The catheter stripping technique is very similar to the procedure for exchanging the stent for a functioning catheter. In brief, the patient uses nasal prongs and 1% lidocaine is instilled into the catheter. The atraumatic end wire guide is inserted to the 11 cm mark. With the bead chain disconnected, the soiled catheter is removed and cleaned while the wire guide remains in place with the black reference mark held at the level of the skin. Water soluble jelly is applied to the tip of the catheter, which is then reinserted over the wire guide. Once the bead chain necklace is at-

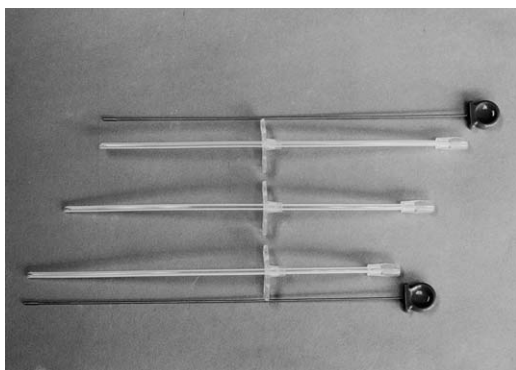


Fig. 6. Most commonly, a catheter with an 11 cm internal length (*middle*) is adequate to place the tip a few cm above the carina. Depending upon patient stature, a shorter 9 cm, (*top*) or longer 13 cm (*bottom*) internal length radiopaque catheter may be appropriate (SCOOP Catheter, Transtracheal Systems, Inc, Denver, CO). The single cleaning rod accommodates the constant internal plus external length of 20 cm for each catheter.

tached and secured with tape, transtracheal oxygen is resumed.

Time required for tract maturation, or the duration of phase III, is generally 6 to 8 weeks. The number of visits required during this phase is determined by the need for reinforced education and the patient's propensity to develop mucus balls that require stripping. Detailed customizable protocols for humidification, cleaning regimes, and scheduled catheter stripping are available from the manufacturer.

Dislodgment of the catheter during phase III can result in closure of the tract in a matter of minutes. Awareness of this potential problem is of utmost importance. The physician should have a sterile catheter and wire guide available for possible emergent use. In the event of dislodgment, the patient must be seen immediately, and the physician should attempt to reinsert the SCOOP catheter using a small amount of sterile water soluble jelly on the catheter tip. If after a few minutes this is not successful, an attempt to pass a SCOOP wire guide should be made. Local anesthetic is not injected, as it tends to distort tissues. Often the tract will be open through soft tissues but closed at the intercartilagnous space of the trachea. Prolonged attempts at recovering the tract are not advised, as the wire guide may make numerous false tracts. If the tract cannot be recovered, the patient goes home on nasal prongs, and an elective procedure may be scheduled for a later date. The physician should resist the temptation to do an unscheduled procedure without preparation and support available with a planned procedure.

A variety of tract problems may be seen during phase III. Erythema may be caused by maceration, abrasion, granulation tissue, contact hypersensitivity, *Candida albicans*, and bacterial cellulitis. All that is red is not infected. Maceration and abrasion may result from a necklace that is too tight or a patient who buttons a shirt collar. A cuff of granulation tissue is a normal part of healing for most patients. Granulation tissue is a bright red and friable mass of capillaries, fibroblasts, and inflammatory cells. If the granulation tissue is exuberant and is associated with minor bleeding, simple cautery will correct the problem. *Candida* is usually an iatrogenic complication from use of broad spectrum antibiotic ointments. Other factors which predispose to *Candida* include oral steroids, oral antibiotics, and diabetes mellitus. The best protection against *Candida* is a clean, dry tract. Contact hypersensitivity can occur with chlorhexidine residues on the catheter and other substances that the patient may be applying to the tract. Patients should only clean with true soap (eg, Ivory bar soap). Bacterial cellulitis is uncommon but would

be treated with antibiotics. Tracheal chondritis is a special issue that deserves discussion.

Cartilage is a unique tissue, because it is avascular and has a tendency to become colonized by bacteria and behave like a foreign body. Refer to the earlier discussion justifying the prolonged use of antibiotic prophylaxis around the time of the procedure. Clinically, about 10% of patients develop a deep indurated lump around the tract several weeks after the procedure. The lump is often tender; unlike an abscess, it is not fluctuant. The bacteriology is unclear, but the knot appears to be a regional inflammatory response to colonization of exposed tracheal cartilage. Treatment with oral antibiotics effective against *Staphylococcus aureus* for an additional 3 weeks is usually effective.

#### *Phase IV: transtracheal oxygen with a mature tract*

As noted previously, the goals in phase IV are to monitor and prevent complications such as chondritis, keloid formation, and lost tracts, and to facilitate the patient's realization of the benefits of TTO, including the maintenance of an acceptable level of activity and optimal quality of life. Phase IV usually begins about 6 weeks after the transtracheal procedure in patients with slim and medium necks and 8 or more weeks after the procedure in patients with obese necks or no cervical trachea. A customized cleaning protocol for each patient is desirable, because it takes into consideration liter flow, mucus production, underlying lung disease, the patient's level of comfort with catheter removal and insertion, and the ability to generate an effective cough. A cleaning routine should include cleaning in place at least twice a day. Cleaning in place is the foundation of care. The frequency may easily be increased or decreased based on the patient's needs. Removal for cleaning can be done as often as twice a day or as little as once a week. Daily or twice daily catheter removal reduces risk of mucus ball formation and is recommended. Patients who do not experience mucus balls may prefer to remove the catheter for cleaning less frequently. A customized cleaning protocol is essential for each patient to maximize safety and efficiency.

A mature tract is fully lined by squamous epithelium that grows outward from the trachea. When the patient arrives on the first visit of phase IV, tract maturity is assessed. The patient is seated in the procedure chair with a headrest, and oxygen is delivered by nasal cannula. Topical lidocaine is optional during this visit. A new catheter is made ready, threading the patient's necklace through the flange and lubricating the tip with water soluble jelly. A wire

guide is immediately available, but the catheter is removed without inserting the wire guide. If the clinician has difficulty inserting the catheter, the tract is judged immature. The SCOOP catheter is reinserted, and cleaning in place is continued for 2 more weeks. If the physician can easily insert the catheter, the patient is asked to demonstrate the removal for cleaning sequence using a second catheter.

During the remainder of the first visit in phase IV, the patient's necklace fitting is evaluated, the appearance of the tract is noted, oximetry is used to adjust flow rates, and education is emphasized. The security routines, tract care, and cleaning are carefully reviewed. The majority of patients in phase IV will remove the SCOOP catheter daily or twice daily.

Patients should not immediately go from cleaning in place in phase III to twice daily removal for cleaning in phase IV. The first week of phase IV is considered a trial period. During the first week all patients who remove the catheter for cleaning do so only at 8 AM. The regular second cleaning should be done at 4 PM using the in-place technique. Patients who are unable to reinsert the catheter within 5 minutes should put on nasal prongs and see the physician immediately for help. If the individual needs help, the physician inserts a SCOOP catheter with or without the aid of a wire guide. The tract is declared immature, and the patient returns to cleaning in place for 2 more weeks. Thereafter, virtually all patients are able to progress to catheter removal for cleaning. This trial period concept has dramatically lowered the lost tract rate in phase IV.

Individuals who successfully remove and reinsert the catheter for 1 week may advance to twice per day (BID) removal for cleaning. BID removal for cleaning is preferably done at 8 AM and 4 PM so that any difficulty that may arise would occur during regular working hours when help is more easily obtained. Cleanings in excess of BID should always be done using an in-place method; excessive removal and reinsertion may traumatize the tract and result in tenderness or chondritis.

Late tract problems may appear months or years following the procedure. Abrasion, maceration, contact hyper-sensitivity, and *Candida albicans* are uncommon, because the patient has usually learned proper tract care by this time. Problematic scar tissue develops in about 5% of patients and causes problems inserting the catheter or visible keloids. Visible keloids differ from granulation tissue because of their late appearance (pink rather than red color, and keratinized surface). Factors that appear to result in excessive scar tissue include cricothyroid membrane punctures, exposure of cartilage during the procedure, excessive catheter removal for cleaning (>BID), and patient

predisposition. Keloids and chronic tract problems at the level of the cricothyroid membrane are managed by revising the procedure at a lower site. Small keloids at lower puncture sites sometimes respond to repeated injection of small amounts of depo-steroid (eg, Kenalog, depomedrol) directly into the keloid. Large keloids and chronic tract problems that do not respond to simpler methods require a Lipkin's surgical method for tract creation. Problematic patients who continue to experience chronic tract problems can be successfully treated using the surgical procedure.

### **The Lipkin surgical procedure and modified SCOOP**

Alan Lipkin, an otolaryngologist, developed a surgical procedure for revision of previous MST tracts that resulted in recurrent problems such as chondritis, lost tracts, and keloids. Our further investigation suggested that the surgical approach has a number of advantages over the MST as a primary method of tract creation [18]. We have modified the

#### **Box 3. The Lipkin surgical procedure compared with the modified Seldinger technique**

##### *Reduced complications*

- Symptomatic mucus balls
- Lost tracts
- Chondritis
- Keloids

##### *Earlier initiation of transtracheal oxygen therapy*

After 24 hours

##### *Streamlined transtracheal oxygen therapy program*

- Shorter program duration
- Procedure well-suited for otolaryngologists
- Clinician training simplified
- Simplified patient education
- Reduced demands on clinician time and resources
- Facilitates referral center treatment of out-of-town patients

SCOOP to be used in conjunction with the Lipkin surgical procedure for TTO tract creation [18]. The program is an alternative to the SCOOP for the MST. The potential advantages of the Lipkin surgical procedure are shown in Box 3. As noted in the above review of the literature, the most frequently encountered complications with the MST are symptomatic mucus balls, lost tracts, chondritis, and keloids. The Lipkin surgical approach has been shown to markedly reduce the frequency of these complications [18]. With the MST technique, tracheal cartilage can be inadvertently exposed and injured. Lost tracts, chondritis, and keloids largely result from injury to cartilage. With the Lipkin surgical procedure, a window of cartilage is removed, eliminating cartilage as a potential source of complications.

The MST procedure requires 42 to 56 days (6 to 8 weeks) for the tract to mature. Consequently, the patient is unable to remove the catheter for cleaning during this time. Inability to remove the catheter for cleaning predisposes to mucus balls. In contrast, the Lipkin surgical approach facilitates more rapid tract healing by incorporating a lipectomy and creation of skin flaps. The surgically created tract is generally mature in 10 to 14 days, thus limiting the period of time in which mucus balls are problematic [18]. Using the MST, oxygen cannot be administered transtracheally for a period of 1 week because of the risk of subcutaneous emphysema, pneumomediastinum, and pneumothorax. Due to the surgically created leak between the stent and the stoma that persists for a few days following the procedure, TTO may be initiated the day following the surgical procedure without risk of barotrauma.

Another major advantage of the Lipkin surgical procedure is that the SCOOP can be significantly shortened due to a reduction in phase II (from 8 to 2 days) and a shortening of the duration of phase III (from 42 to 56 days to 10 to 14 days). Phase III is the most labor intense and educationally intense portion of the program. Training of clinicians can be streamlined and patient education can be markedly simplified. The combination of the decrease in unscheduled or emergent visits due to complications and the streamlined, shortened program results in reduced demands on clinician time and resources. Finally, the shortened and streamlined program facilitates referral center treatment of out-of-town patients who otherwise might not have access to TTO.

The following is a brief summary of the program modifications for use with the Lipkin surgical procedure. The surgical technique and results have been more fully described elsewhere [18]. Comprehensive video, electronic, and printed educational materials

are available through the manufacturer (FastTract, Transtracheal Systems Inc, Denver CO).

*Phase I: patient orientation, evaluation, selection, and preparation*

The pulmonologist and a clinician, such as a respiratory therapist or nurse, continue to actively participate in the same orientation, evaluation, selection, and preparation process for TTO. In addition, the patient meets with a qualified surgeon who will discuss the surgical procedure, order any additional preoperative studies, and obtain informed consent.

*Phase II: the transtracheal MST procedure and stent week*

The bead chain necklace is fitted in the usual fashion to identify the proper site for the transtracheal tract. The procedure is performed in the operating room, with the patient under local anesthesia and intravenous sedation and continuous monitoring by an anesthesiologist. Nasal O<sub>2</sub> is provided throughout the procedure. Although it is rarely necessary, a patient may be converted to general anesthesia on an emergency basis.

The patient is positioned supine on the operating table with the neck gently extended and a roll is placed under the shoulders. The head of the bed may be elevated slightly for patient comfort. The area between the cricoid and sternal notch is infiltrated with lidocaine 1% with epinephrine 1:100,000. The neck is prepped and draped. Using cutting cautery, a vertical incision of approximately 1.5 cm to 2 cm is centered selected site. Flaps of full-thickness skin are elevated laterally 2 cm in each direction. The cutting cautery is then used to perform a cervical lipectomy, removing all the fat down to the level of the strap muscles. The strap muscles are separated at the midline, exposing the anterior wall of the trachea (Fig. 7A). Occasionally, division of the thyroid isthmus is necessary.

The previously elevated skin flaps are then used to fashion an epithelialized tract down to the anterior wall of the trachea. This is performed by suturing the flaps to the undersides of the previously exposed sternothyroid muscles with a running suture of 3-0 Vicryl (polyglactin 910, Ethicon, Sommerville, NJ) or similar absorbable material (Fig. 7B). It may be reinforced with additional interrupted sutures as necessary. Before entering the trachea, the entire surgical field is inspected and complete hemostasis is obtained. Additional local anesthetic (lidocaine 1% without epinephrine) is injected into the tracheal wall

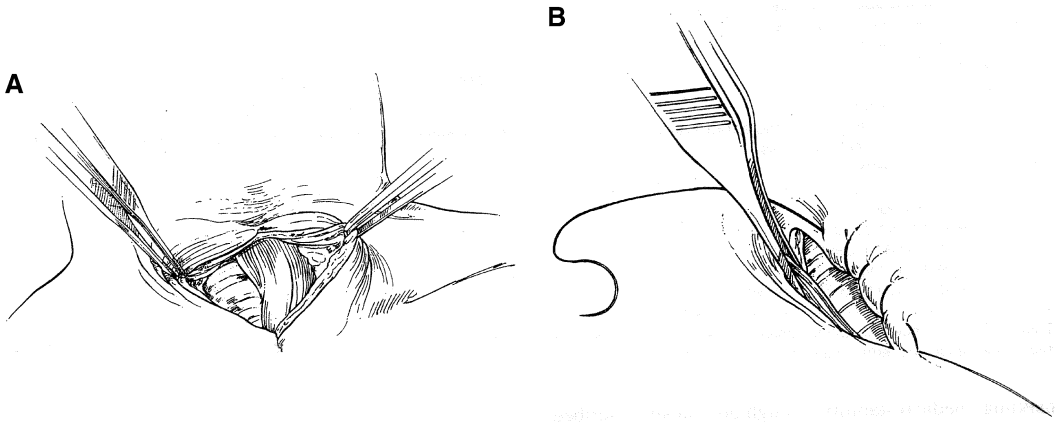


Fig. 7. After a vertical incision (A), skin flaps have been elevated and cervical lipectomy has been performed. Strap muscles are separated at the midline, exposing the cervical trachea. The skin flaps are then approximated (B) to the deeper strap muscles with a running suture. (From Lipkin AF, Christopher KL, Yaeger ES, Diehl S, Jorgenson S. Otolaryngologist's role in transtracheal oxygen therapy. *Otol Head Neck Surg* 1996;115:447–53; with permission.)

and lumen, particularly at the point of entry into the trachea. This will help prevent movement and coughing when the trachea is entered. Because oxygen in high concentration is flowing into the trachea, the electrocautery cutting blade should never be used to enter the trachea.

The trachea is then entered with a small horizontal incision in the interspace between two upper tracheal rings previously marked by the necklace. The blunt end of the tracheal punch (shown on the top of Fig. 8) is passed through the incision, the punch is engaged, and a small window of cartilage is resected. Using the available stylet, the stent (shown on the bottom of

Fig. 8) is inserted into the tracheal window. A trach dressing is placed over the procedure site, and ties or straps are then used to secure the stent in proper position. A trach collar is applied to the stent to provide humidity for the patient's comfort. Oxygen is supplied by nasal prongs or mask to achieve an oxygen saturation of >90% via pulse oximetry. The postprocedure routine is similar to the MST program; however, the patient remains in the hospital until the next day.

#### *Phase III: transtracheal oxygen with an immature tract*

Approximately 24 hours after the procedure most patients are able to advance to phase III. As with the MST, the stent is replaced by the functioning TTO catheter. Gauze is placed between the flange of the catheter and the surgical site, oxygen flow is titrated for rest and exertion, and the patient receives education on the care and cleaning of the catheter. The patient is advised that a noise may occur due to air coming out of the tract, and voice may be impaired for a few days. The patient is scheduled for a return visit within seven days. Tract maturation and progression into phase IV occurs in approximately 10 to 14 days.

#### *Phase IV: transtracheal oxygen with a mature tract*

There are no significant changes in phase IV except that fewer complications are expected with this method of tract creation.

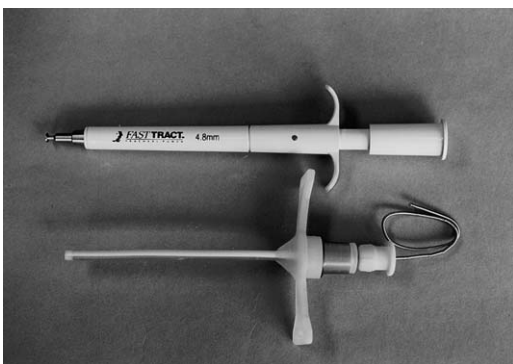


Fig. 8. Following approximation of the skin flaps to the deeper strap muscles (see Fig. 7B), a tracheal punch (Fast Tract Tracheal Punch, Transtracheal Systems, Inc., Denver, CO) is used to resect a small window of cartilage (top). A stent (bottom) with companion stylet (Fast Tract Stent, Transtracheal Systems, Inc, Denver, CO) is then inserted into the tracheal window.

### Combination of TTO and demand oxygen delivery systems

TTO has been classified as an oxygen conserving device. Though TTO certainly provides other benefits, flow requirements are significantly reduced during rest and exercise [16]. Because demand oxygen delivery systems (DODS) have also been shown to conserve oxygen, we conducted in initial evaluation to see if the two technologies could be combined [47]. Results showed that oxygen saturations were adequate and that the devices reliably triggered via the transtracheal catheter. In a collaborative study with Tiep [48], a modified DODS with settable trigger delays (Oxymatic, Chad Therapeutics Inc, Chatsworth, CA) was used to evaluate patients on nasal oxygen and TTO. Though delays in triggering adversely affected nasal oxygen saturation, triggering delay had no significant impact upon saturations with TTO. This is probably because the position of the TTO catheter within the trachea already allows for maximally efficient early delivery of oxygen. Results, however, showed that DODS combined with TTO was more efficient than continuous flow TTO.

In a comprehensive study [49], we compared DODS to a continuous flow control with both nasal cannula and TTO delivery. Patients could be adequately oxygenated during rest, sleep, and exercise with DODS TTO. Though patients had adequate oxygen saturations during sleep and rest with DODS by nasal cannula, a subgroup of these patients could not achieved adequate oxygen saturations with exercise. Compared with the standard continuous flow nasal cannula therapy, the daily bulk liquid oxygen use was decreased by 29.4% with continuous flow TTO, by 48.2% with DODS via nasal cannula, and by 49.9% with DODS combined with TTO. Thus, use of a DODS with TTO maximized the efficiency of TTO as an oxygen conserving device.

Experience today shows that TTO is safe and effective when combined with DODS, but systems requiring a double-lumen have not been compatible with a single-lumen transtracheal catheter. As with the use of any oxygen-conserving device or potential combinations of those devices, it is prudent to specifically evaluate each patient using the device or combination of devices for intended use.

### Transtracheal augmented ventilation (TTAV)

Our early anecdotal experience with refractory hypoxemia [15] showed that patients requiring transtracheal flow rates of 4 to 6 L/minute appeared to

have less labored breathing compared with periods when the same patients were receiving nasal oxygen at equal or greater flow rates. As noted earlier, TTO studies have demonstrated reductions in inspired minute ventilation [39], physiologic dead space [40,41], oxygen cost of breathing, and the respiratory duty cycle [42]. Reductions in each of those physiologic parameters were inversely proportional to delivered transtracheal flows up to approximately 6 L/minute. Under these evaluations, the reduced minute ventilation was secondary to reduction in tidal volume [39]. The medically stable patients evaluated in these studies showed no significant acute change in PaCO<sub>2</sub>. We wondered whether higher transtracheal flow rates might augment ventilation in patients with hypoxemia due to severe lung disease.

Using a canine model [50], we found that inspired minute ventilation was significantly reduced with the transtracheal administration of an air/oxygen mixture at 10 L/minute. We then evaluated two TTO patients [51] with severe hypercarbia associated with chronic respiratory failure. As with our previous experience, the transtracheal high flow ( $\geq 10$  L/minute) of a humidified air/oxygen blend resulted in a marked reduction in tidal volume. Respiratory rate remained approximately the same, and minute ventilation was substantially reduced. The patients were in a stable state and PaCO<sub>2</sub> was unchanged. The two patients then received high-flow transtracheal administration of the humidified air/oxygen blend, or transtracheal augmented ventilation (TTAV) nocturnally on a long-term basis. One of the patients was later hospitalized for superimposed acute respiratory failure. He declined intubation, but consented to maximal medical therapy and continuous TTAV. In contrast to prior experience with stable patients, the elevation in PaCO<sub>2</sub> resolved in the acutely ill patient treated with TTAV.

### TTAV for nocturnal support in the home

We then evaluated the potential safety and efficacy of TTAV for the nocturnal home management of a larger number of hypoxemic patients with chronic severe respiratory disease [52]. The first portion of the study evaluated patients before and after a 3-month intervention with nocturnal (Noc) administration of TTAV at 10 L/minute. Resting physiologic studies were conducted on standard low flow transtracheal oxygen (LFTTO), TTAV, and breathing oxygen enriched gas without transtracheal flow via a mouth-piece (MP). Nocturnal polysomnography, bronchoscopy, ventilatory drive and treadmill exercise were also studied. Results of the first part of the investiga-



tion showed that pleural pressure-time index and respiratory duty cycle were significantly lower when comparing MP with TTAV. In this group of stable patients, arterial blood gases and the total volume delivered to the lung (volume delivered by the catheter plus volume inspired via the upper airway) were not significantly changed with MP, LFTTO, or TTAV. The percentage of the total volume delivered to the lung via TTAV (45%), however, was significantly greater than that delivered by LFTTO (20%). Sleep quality and nocturnal oxygenation with TTAV were similar to LFTTO. Three months of Noc TTAV had no effect on ventilatory drive. No evidence of clinically significant mucosal injury was noted on bronchoscopy. Treadmill exercise tests demonstrated significantly longer exercise time and increased total work following Noc TTAV. The changes in the slope for heart rate and acid-base balance (pH) with exercise were significantly less steep following Noc TTAV, suggesting improved fitness. The 3-month follow-up in the first portion of the investigation and the long-term evaluation ( $29 \pm 18$  months, range 6.8 to 60 months) in the second portion of the study showed that Noc TTAV was well-tolerated and safe, with reported high compliance. A patient receiving TTAV in the home is shown in Fig. 9.

### TTAV for weaning from prolonged mechanical ventilation

We speculated that the physiologic benefits of TTAV with respect to reductions in inspired minute ventilation, respiratory duty cycle, and oxygen cost of breathing might facilitate the weaning process [53] in patients requiring prolonged mechanical ventilation. In the setting of long-term acute care, we assessed medically stable patients who consistently failed to wean from mechanical ventilation in spite of tracheostomy and weaning efforts using a variety of ventilatory modes. Before treatment, endoscopic examination showed the absence of glottic or subglottic obstruction. The existing tracheostomy tube was exchanged for a 6 mm cuffed tube. The cuff of the tracheostomy tube was fully deflated and a transtracheal catheter (Transtracheal Systems, Inc, Denver, CO) with a customized 15 mm cap was inserted into the tracheostomy tube, creating an airtight seal. An adjustable blend of air and oxygen was passed through a servo temperature control humidifier. Flows of at least 10 L/minute were delivered through the catheter during spontaneous breathing trials. The frequency and duration of spontaneous breathing trials with TTAV were adjusted according to patient tolerance.



Fig. 9. A patient receives transtracheal augmented ventilation in the home using a servo temperature controlled device (SCT 3000, Vital Signs, Denver, CO) that humidifies the 10 L/minute of an air/oxygen blend delivered by custom device (Transtracheal Systems, Inc, Denver, CO).

Once patients demonstrated that they could be on TTAV for 24 hours or more, they were progressively weaned with TTO to a low flow that achieved adequate oxygen saturations by pulse oximetry. At that point, a variety of choices for planned discharge were considered. Removal of the catheter was one option. Supplemental oxygen could be discontinued or the patient could receive oxygen by nasal cannula. Patients could also be discharged on 24-hour TTO therapy, or receive a combination of nocturnal TTAV with daytime TTO.

It was observed that patients on TTAV weans were able to phonate normally and markedly increased their communication with medical staff and significant others. Ability to use the glottis in a normal fashion also improved the effectiveness of cough. Patients, particularly those with COPD, were able to regain normal glottic function as a variable regulator of expiratory flow.

We recently reported [54] our experience with TTAV as compared with conventional weaning methods (CWM) in the treatment of patients requiring prolonged mechanical ventilation (PMV) in the setting of a long-term acute care (LTAC) hospital. A 2-year retrospective chart review of PMV admissions was conducted. Progressive neuromuscular disease pa-

tients were excluded. Therapist-driven protocols were not used. CWM included pressure support, intermittent mandatory ventilation, flow-by, continuous positive airway pressure, T-piece trials, or some combination. TTAV was nonrandomly ordered when selected patients had repeatedly failed CWM in LTAC, but full ventilatory support was not required. Liberation success was defined as 72 consecutive hours off the ventilator.

Result showed that TTAV weaning success rate (73.1%) was greater than CWM (51.8%); results approached significance ( $P = 0.056$ ). The study was statistically biased against TTAV because a significantly higher portion of patients had COPD with TTAV than with CWM. There was no age difference in wean failures, but successfully weaned TTAV patients were significantly older than successfully weaned CWM patients. Comparing successful TTAV with CWM, and comparing failed TTAV with CWM, there were no significant differences on admission in gender, severity of illness scores, admission transfer and gait scores, required  $FIO_2$ , arterial blood gases on PMV, or spontaneous ventilatory parameters, except that minute ventilation was significantly lower in those successfully weaned with TTAV as compared



Fig. 10. A patient requiring prolonged mechanical ventilation in long-term acute care facility (Kindred Hospital, Denver, CO) undergoes a spontaneous breathing trial using transtracheal augmented ventilation. A customized catheter with a cap (Transtracheal Systems, Denver, CO) is attached to a 6 mm tracheostomy tube (Portex DIC, SIMS Portex, Inc, Keene, NH) with the cuff deflated. The patient receives a heated and humidified (SCT 2000, Vital Signs, Denver, CO) mixture of oxygen and compressed air (Timeter PCS 414, Allied Health Care Products, St. Louis, MO).

with CWM. No complications with TTAV weans were encountered. From a clinical standpoint, in spite of the fact that there was a statistical bias against TT AV due to a higher portion of patients that were older and had COPD, a greater weaning success rate was achieved with TT AV than with CWM. A patient undergoing a spontaneous breathing trial is shown in Fig. 10.

The potential benefits of TTAV are summarized in Box 4. Physiologic studies of TTO in the flow range of approximately 1 to 6 L/minute have demonstrated that reductions in physiologic dead space, minute inspired ventilation, respiratory duty cycle, and oxygen cost of breathing are inversely related to flow. In other words, as flow increases, patients benefit from reductions in these physiologic parameters. Further physiologic improvement occurs with the high flows of  $\geq 10$  L/minute with TTAV. In addition, patients receiving nocturnal TTAV in the home have been shown to have the ability to perform more work during daytime exercise, and exercise for longer periods. Improved fitness has also been described.

**Box 4. Potential benefits of transtracheal augmented ventilation (TTAV)**

*Flow-dependent physiologic improvements*

- Reduced inspired minute ventilation
- Reduced work of breathing
- Shortened respiratory duty cycle
- Decreased physiologic dead space

*Potential benefits of nocturnal TTAV in the home*

- Improved duration of daytime exercise
- Improved work capacity during exercise
- Improved physiologic fitness during exercise

*Potential benefits of TTAV in weaning from prolonged mechanical ventilation*

- Normal phonation with improved communication
- Improved cough effectiveness
- Use of glottis as a variable regulator of expiratory flow
- Improved mobility

Patients requiring prolonged mechanical ventilation are difficult to liberate from the ventilator. TTAV appears to facilitate the weaning process. In addition to the physiologic benefits described above, the TTAV wean modality allows the glottis to function more normally. Patients have improved ability to cough effectively. The glottis can function as a variable regulator of expiratory flow. As with pursed lips breathing, the ability to finely control glottic aperture is beneficial to patients with obstructive lung disease. TTAV also frees the patient from the ventilator while still delivering augmentation of ventilation. This improves the mobility, which is markedly impaired when patients are tethered to a ventilator. Finally, individuals on prolonged mechanical ventilation are unable to speak while connected to a ventilator by a tracheostomy tube. During TTAV, individuals are able to phonate without difficulty. This has a markedly positive impact on will to live and the individual's ability to communicate with caregivers and significant others. TTAV appears to be a promising method for liberation from PMV.

**Treatment of sleep apnea**

In 1985 we encountered a patient with severe hypoxemia, obesity-hypoventilation syndrome, and associated severe obstructive sleep apnea [55]. The patient did not receive benefit from nasal continuous positive airway pressure (CPAP) and refused tracheotomy. He was placed on TTO for long-term oxygen therapy and sleep polysomnography was done to evaluate his response to nocturnal TTO. Results on 3 L/minute TTO showed that his apneas and hypopneas resolved and oxygen saturation was adequate. Video fluoroscopy during sleep demonstrated that his hypopharyngeal obstruction was relieved by TTO. One year later we reported our experience with four patients [56]. Median apnea plus hypopnea index fell 61%, but the duration of apneas is increased. Though nocturnal desaturation occurred with nasal cannula therapy in this small group, oxygen saturation was greater than 90% throughout the night with administration of 3 L/minute of TTO, even in the presence of prolonged apneas. Sleep efficiency improved with TTO delivery.

In 1990 Chauncey and Aldrich [57] compared nasal cannula oxygen to TTO in four patients with obstructive sleep apnea that were unable to tolerate nasal CPAP. At TTO flow rates of 2 to 3 L/minute, there were improvements in mean respiratory disturbance index, overall nocturnal oxygen saturation, and sleep disturbance. In this study, the mean apnea

duration was not increased by TTO and the duration of the longest apneic spells was decreased by 33% to 85%. Daytime sleepiness improved and therapy was well-tolerated.

Farney and coworkers have published two studies evaluating TTO for the treatment of obstructive sleep apnea [58,59]. In the first study [58], five patients were selected that were either noncompliant with nasal CPAP or also required continuous long-term oxygen therapy. Each had been previously documented to have severe obstructive sleep apnea that could be corrected with nasal CPAP therapy. The authors concluded that the most significant observation from the study was that TTO corrected hypoxemia related to sleep disordered breathing, even if some types of respiratory events such as hypopnea were not completely eliminated. Because TTO was effective and well-tolerated, they decided that tracheotomy was not necessary in the patients that were studied.

In the second study [59] Farney's group evaluated five patients with severe obstructive sleep apnea that were either noncompliant with nasal CPAP or also required continuous long-term oxygen therapy. Results showed that, compared with baseline room air polysomnography studies, TTO significantly reduced apnea/hypopnea frequency from 65 to 26 per hour of sleep and maintained improved nocturnal oxygen saturations compared with nasal oxygen.

In the prior studies of TTO for obstructive sleep apnea, the evaluated flow rates were in the range of 2 to 6 L/minute, and flow was titrated primarily for oxygen saturation rather than for correction of obstructive events. More recently, Schneider's group [60] found that even higher flow rates have the potential to be efficacious in the treatment of obstructive sleep apnea. This treatment concept is more consistent with the concept of TTAV because the titration flow may be for a physiologic effect (resolution of obstruction) rather than a titration for correcting hypoxemia. We are currently faced with a clinical dilemma in the management of patients that are noncompliant with CPAP or refuse tracheotomy. Further studies need to be done to evaluate the potential role of TTO and TTAV in the treatment of sleep apnea.

## Summary

Over the past 20 years a variety of transtracheal catheters have been developed for long-term oxygen therapy. A modified Seldinger technique has been the standard in the past, but a more recent procedure for surgical creation of the tracheocutaneous tract presents a number of potential advantages. TTO should be

administered as a program of care, and recent advances with a streamlined and shortened program have simplified and improved the delivery of a technology that has a number of potential benefits and established safety. TTO may further increase the oxygen conservation efficiency of demand oxygen controller devices, and studies have shown TTO to be a potential alternative to nasal oxygen, continuous positive airway pressure, and tracheotomy for severe obstructive sleep apnea. Very high flows (>10 L/minute) of a humidified air/oxygen blend, termed transtracheal augmented ventilation, extend the physiologic benefits of TTO and have promise in both the outpatient nocturnal ventilatory support of patients with severe respiratory disease and in liberation of patients from prolonged mechanical ventilation.

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