

The logo for SCOOP, featuring the word "SCOOP" in a stylized, white, sans-serif font with a registered trademark symbol (®) to the right. The letters are set against a black rectangular background.

SCOOP®

TRANSTRACHEAL
OXYGEN THERAPY

CLINICAL GUIDE
FOR THE
MODIFIED SELDINGER
INSERTION TECHNIQUE

The logo for TRANS TRACHEAL SYSTEMS. The word "TRANS" is in a blue, italicized font with a stylized 'X' over the 'A'. "TRACHEAL" is in a blue, bold, sans-serif font. "SYSTEMS" is in a smaller, blue, sans-serif font below "TRACHEAL".

TRANS TRACHEAL
SYSTEMS

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Transtracheal Oxygen

Introduction

Summary: Benefits of Transtracheal Oxygen

Physiologic benefits

- Reduced erythrocytosis
- Reduced pulmonary vascular resistance
- Improved cor pulmonale
- Improved A-a DO₂ while breathing room air
- Decreased physiologic dead space
- Reduced inspired minute ventilation
- Reduced work of breathing
- 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 cannula complications
- Improved self-image

Reduced hospital days and cost

Improved survival

The Nocturnal Oxygen Therapy Trial (NOTT)¹ concluded that more continuous oxygen therapy delivered to ambulatory patients improved survival and quality of life in hypoxemic patients. But the “continuous” group in that study only used oxygen for an average of 18 hours per day, and most clinicians recognize that few patients wear nasal prongs continuously. Nasal prongs are often removed because of discomfort, restricted mobility or cosmetic concerns. Prongs are also unstable and are frequently dislodged when the patient sleeps.

Patients most commonly seek transtracheal oxygen (TTO) as an alternative to nasal prongs because of discomfort and restricted mobility.² Greater convenience and oxygen conservation are of intermediate importance, and appearance is last when patients are asked to rank these issues as they enter a transtracheal program.

Transtracheal oxygen therapy offers many benefits which meet the therapeutic goals identified in the NOTT study in a cost effective way. True 24 hour per day compliance, a more active lifestyle and conservation of oxygen resources are feasible with this new technology. The average TTO patient has a 55% reduction of oxygen flow at rest and a 30% decrease with activity. Even allowing for increased compliance from an average of 18 hours per day to 24 hours per day, transtracheal patients average about 20% less bulk oxygen consumption than when on nasal prongs. TTO can be used in tandem with oxygen conservation devices, and in that way further reduce bulk oxygen consumption. Transtracheal oxygen therapy has also been shown to increase exercise tolerance and decrease the oxygen cost of breathing.^{7,8}

The safety and efficacy of the SCOOP program have been previously reported.^{3,4} A nationwide survey of physicians who received formal training in TTO showed similar low morbidity rates.⁵

TTO is best delivered by a knowledgeable team consisting of a physician, hospital- or office-based respiratory therapist (or R.N.), the patient, the significant other and the home care provider. The “ideal” setting is a transtracheal facil-

ity with dedicated space, phones, at least one full-time respiratory therapist (or R.N.) and after-hour support. The facility should offer training for health care professionals and provide open access to a community of patients, doctors and home care companies. A practical interim alternative to a dedicated facility is a bronchoscopy suite. Outpatient surgery or ER would be less suitable.

The following booklet summarizes tens of thousands of patient months of experience. The program consists of four clinically-defined phases which are married to transtracheal catheters and supplies specifically designed for the program.

Four Clinically Defined Phases	
Phase I	Orientation, Evaluation, Selection and Preparation
Phase II	Transtracheal Procedure and Stent Week
Phase III	Transtracheal Oxygen Therapy - <i>Immature Tract</i>
Phase IV	Transtracheal Oxygen Therapy - <i>Mature Tract</i>

The SCOOP system is designed to meet the physiologic and biomechanical needs of long-term transtracheal oxygen therapy. The system maximizes safety and efficacy while remaining compatible with the existing oxygen therapy base. The catheters and hoses permit flow rates up to 6 L/min at less than 2 p.s.i. back pressure and may be used with standard 2 p.s.i. pop-off humidifiers, fixed orifice flow meters and concentrators. Patients with flow rates greater than 6 L/min may require a humidifier with a 6 p.s.i. pop-off.

The SCOOP transtracheal procedure tray contains a custom wire guide, dilator and pre-SCOOP stent necessary to form a 9 French tract. The wire guide and dilator have reference marks to avoid over insertion and inadvertent withdrawal. The thick wall of the stent forms a superior tract by resisting deformation by the strong intercartilaginous ligaments of the trachea. The stent remains open during the week after the procedure and serves as a surgical drain for air, blood and bacteria.

Six L/min administered transtracheally has more oxygenation power than twice that rate by nasal prongs. This “therapeutic reserve” is desirable to meet the increased demands for normal activity, exacerbations of pulmonary disease and refractory hypoxemia. Concerns about the potential for excessive oxygen delivery with retained CO₂ have not been realized, and high flow rates may actually facilitate the wash-out of CO₂. Investigations to explore high transtracheal flow rates as a means to augment ventilation are in progress.⁶

The SCOOP catheters are made of high tech biopolymers which resist kinking and crushing. The internal tubing is radiopaque and is available for adults in 9cm, 11cm, and 13cm internal lengths. The thermoplastic tubing rapidly takes a set at body temperature to conform to individual patient anatomy. The catheter gently rests against the posterior membranous tracheal wall and is insensible with normal respiratory movements. The overall flexibility of the catheter is carefully controlled to balance stability (stiffness) with comfort (flexibility). The catheter tip is beveled and molded to facilitate easy insertion and is oriented to direct gas away from the tracheal mucosa. The SCOOP catheter has one distal port and is used by all patients in Phase III when the catheter is cleaned in place and in Phase IV when the tract is fully healed, permitting daily removal for cleaning.

The external tubing extension removes the connectors away from the flange at the collar line for improved comfort and ease of manipulation. The flange and external tubing are made of clear plastics to minimize visibility. The flange is small and when used with a properly fitted SCOOP bead chain necklace allows air to get to the skin around the tract opening and avoid maceration by secretions. When the flange is upright and readable, the internal portion of the catheter is oriented for comfort and efficiency. The standard Luer taper connector fits Dey Vials, Blairex saline canisters, standard Luer taper syringes and the SCOOP oxygen hose.

The SCOOP cleaning rods are made for both cleaning in place and removal for cleaning. The tip of the rod is atraumatic, and the length extends slightly past the tip of the catheter. The adult cleaning rods fit 9cm, 11cm, and 13cm catheters, because the overall length remains a constant 20cm.

The SCOOP oxygen hose is available in nine size combinations to fit various patient sizes and upper body to lower body proportions. These hoses are made of clear plastic to minimize visibility. The supple small caliber upper body tubing is worn beneath the clothing. The larger caliber kink and crush resistant lower body segment connects to the upper body segment at a security clip, which attaches to the top of the lower body clothing on the right side.

Security, reliability and comfort have been considered along every segment of the system from the tip of the catheter to the oxygen source. The procedures and protocols which make best use of the SCOOP system are the subject of this guide.

References

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Phase I

Patient Orientation, Evaluation, Selection and Preparation

Phase I Goals

- Inform the patient
- Identify contraindications and precautions
- Select the right patient
 - identify good starting candidates (>10%)
 - observe precautions with majority (80%)
 - exclude poor candidates (<10%)
- Stabilize the patient before the procedure

General indications for transtracheal oxygen therapy are the same as for oxygen delivered by nasal prongs. Continuous oxygen is indicated for patients with chronic hypoxemia which persists in spite of optimal medical therapy. Arterial blood gases obtained on room air should show $\text{PaO}_2 \leq 55$ mm Hg. Transtracheal oxygen is also indicated for patients with a PaO_2 of 56-59 mm Hg if they also have: 1) dependent edema caused by congestive heart failure, 2) "P" pulmonale on EKG (P wave greater than 3mm in standard leads II, III, or AVF), or 3) erythrocythemia with a hematocrit > 55%. Room air oximetry may also be used to document the need for oxygen if the $\text{SaO}_2 < 85\%$ or if, 1, 2 or 3 is present with an SaO_2 of 86-89%.

General Indications

Long-Term Oxygen Therapy

- $\text{PaO}_2 \leq 55$ mm Hg
- $\text{PaO}_2 = 56-59$ mm Hg with
 - dependent edema
 - p wave > 3mm in II, III or AVF
 - hematocrit > 55%
- $\text{SaO}_2 \leq 85\%$
- $\text{SaO}_2 = 86-89\%$ with
 - dependent edema
 - p wave > 3mm in II, III or AVF
 - hematocrit > 55%

Specific indications for transtracheal oxygen therapy include: 1) a need for improved mobility, 2) noncompliance related to nasal prongs, 3) complications of nasal prongs, 4) cor pulmonale or erythrocythemia on nasal oxygen, 5) refractory hypoxemia, 6) nocturnal desaturation corrected by TTO, and 7) patient preference. Mobility may be improved by the extension of portable oxygen sources and better exercise tolerance. Complications of nasal prongs are common and include ear sores, serous otitis media, nasal sores, nasal crusting, nose bleeds, diminished sense of smell and taste, tear duct blockage, chronic dry sore throats, hoarseness, and burns caused by ignition of the nasal prongs. Cor pulmonale or erythrocythemia with an adequate PaO_2 suggest noncompliance with nasal prongs.

Specific Indications

Transtracheal Oxygen Therapy

- Need for improved mobility
- Noncompliance related to nasal prongs
- Complications of nasal prongs
- Cor pulmonale or erythrocythemia on prongs
- Refractory hypoxemia
- Nocturnal desaturation corrected by TTO
- Patient preference

Phase I

Patient Orientation, Evaluation, Selection and Preparation

Contraindications

Contraindications include mental or physical incompetence which would interfere with use of a transtracheal catheter. Transtracheal oxygen should not be used in patients with a severe anxiety neurosis. Transtracheal oxygen at typical flow rates < 2L/min. is usually insensible, and severely anxious patients often worry that they are not getting their oxygen. Moreover, these anxious patients may also perceive transtracheal oxygen as more complex and intimidating. Because of the risk of pneumothorax, the procedure should not be performed if a pre-procedure chest x-ray shows pleura herniated over the proposed procedure site. Transtracheal oxygen also should not be used if subglottic stenosis, bilateral vocal cord paralysis or any other cause of a significant upper airway obstruction is present. The transtracheal catheter and possible formation of mucus balls could seriously aggravate the upper airway obstruction.

Absolute Contraindications *Transtracheal Oxygen Therapy*

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

Orientation

Patients are fully informed about the potential benefits and risks of transtracheal oxygen therapy before making a commitment to proceed with the procedure. An ideal orientation includes viewing the orientation segment in the SCOOP Oxygen Program for Patients training video, a question and answer session with a knowledgeable health care professional and an opportunity to talk or meet with a transtracheal patient. Interested patients should then receive a SCOOP Patient Workbook and Guide and have a basic minimum of evaluations to identify precautions and possible contraindications.

Evaluation

All patients have a targeted history, physical examination, and basic laboratory evaluations. Selected patients may require additional tests. The *SCOOP Patient Chart* is an especially useful record keeping tool which prompts the clinician to seek specific information relevant to the success of the transtracheal program. For example, the *history* would normally inquire about bed clothing. This is important information because catheter security routines require that the upper segment of the hose remain under upper body clothing and that the security clip be attached to the lower body clothing (or a belt) at all times.

The physical exam should also include careful examination 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.

TTO Candidate Evaluation

- Arterial blood gases (room air)
- Arterial blood gases (on nasal oxygen)
- Hematocrit
- Spirometry (pre and post bronchodilator)
- Chest x-ray (PA and lateral) with properly fitted bead chain necklace

Phase I

Patient Orientation, Evaluation, Selection and Preparation

Basic laboratory data is gathered on all individuals. Arterial blood gases on room air and on nasal prongs are obtained to document the need for oxygen therapy, to identify any risk factors for transtracheal oxygen therapy and to give the patient an estimate of reduced oxygen flow on transtracheal oxygen. For example, a patient with an inadequate PaO₂ of 47 mm Hg on 2 L/min. by nasal prongs may be disappointed to only go down to 1.5 L/min. on SCOOP, even though the PaO₂ goes up to 65 mm Hg. The hematocrit is an easy test which reflects on the overall adequacy of oxygen therapy. A shift on transtracheal oxygen from a high normal hematocrit to a mid or low normal hematocrit is common and suggests better 24 hour per day oxygenation. Spirometry (both pre and post bronchodilator) is used to estimate the risk for bronchospasm during transtracheal procedure. Posteroanterior and lateral chest x-rays 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 helpful in individual cases. Special tests may include exercise oximetry, a 100% F_iO₂ study, lung volumes, diffusion capacity, or an electrocardiogram. The 100% F_iO₂ study warrants special discussion. Although SCOOP transtracheal oxygen is efficacious in many patients with refractory hypoxemia, it cannot be expected to oxygenate all patients. Two patients with refractory hypoxemia and inadequate oxygenation on maximal nasal prong therapy may have PaO₂ results of 50 mm Hg and 150 mm Hg with an F_iO₂ of 100%. Only the second patient is a good candidate for SCOOP.

<u>Additional Laboratory Data</u>
<ul style="list-style-type: none"> • Exercise oximetry • 100% F_iO₂ study (refractory hypoxemia) • Lung volumes and diffusion capacity • Coagulation studies • Electrocardiogram • CBC • SMA 22 • UA

After completing these evaluations, **MOC** (**M**echanical reserve, **O**xygenation, **C**O₂ retention) and **SAL** (**S**core for **A**ctivity **L**evel) scores are determined. These are easily determined from the history, spirometry and blood gas results (on oxygen). The MOC score is useful for identifying especially fragile patients who must be observed more closely during the procedure, the night after the procedure and during Phase III. The SAL score is useful in identifying more active patients who are the best starting candidates. The SAL is a simple score which also permits charting of changes in activity level related to changes in treatment.

<u>MOC Score</u>			
<i>Risk Assessment</i>			
	<u>0</u>	<u>1</u>	<u>2</u>
<u>M</u> echanical reserve (FEV ₁)	M ₀ :>1.0	M ₁ :.50-.99	M ₂ :<.50
<u>O</u> xygenation (PaO ₂ on O ₂)	O ₀ :>55	O ₁ :50-55	O ₂ :<50
<u>C</u> O ₂ (PaCO ₂ on O ₂)	C ₀ :<40	C ₁ :41-50	C ₂ :>50

Phase I
Patient Orientation, Evaluation, Selection and Preparation

<p><u>Score for Activity Level (SAL)</u> <i>Risk Assessment</i></p> <p>1 = Bedridden 2 = Housebound except for doctor visits; out of bed < 12 hours/day 3 = Housebound except for doctor visits; out of bed > 12 hours/day 4 = Leaves home for shopping and other needs of daily living 5 = Routinely leaves home for socializing, recreation or work</p>

Selection

The physician now has the information needed to complete the pre-procedure review. It requires that the physician review the findings of the evaluations and consider indications, contraindications and precautions. Candidacy and special considerations are discussed with the patient. If the physician recommends transtracheal oxygen and the patient requests it, informed consent is obtained. Thereafter, the patient is medically and psychologically prepared for the procedure.

The transtracheal procedure and program should be undertaken by a team in a graduated fashion starting with easier patients and progressing to more difficult patients after experience has been gained. The transtracheal team includes the pulmonologist, referring physician, respiratory therapist or nurse, patient, significant other, and home care provider. The first ten procedures should be relatively easy patients who fit the criteria listed below. An active individual who is early in the natural history of his or her lung disease will be around for a long time to help counsel subsequent patients. The first six months should be considered a learning period. During this start-up phase, the team should expect to see a slightly higher morbidity rate. With experience, transtracheal oxygen therapy will become progressively more routine and morbidity will steadily decline.

<p><u>Transtracheal Team</u></p> <ul style="list-style-type: none">· Pulmonologist· Respiratory Therapist or Nurse· Patient and Significant Other· Home Care Provider

<p><u>Initial Patient Selection</u> <i>First 10 Patients</i></p> <ul style="list-style-type: none">· Not refractory (no individual MOC = 2)· Active (SAL = 4 or 5)· Lives nearby and has reliable transportation· Slim or medium neck· No severe disabling anxiety· Motivated and cooperative

More challenging patients with obese necks, copious sputum, reactive airways, coagulation disorders, or moderate anxiety as well as patients who live more than one hour away can be considered after the team has acquired experience with the first ten relatively easier patients. The majority of patients, can be successfully treated by a team with enough experience to anticipate and avoid most potential problems. When minor morbidity occurs, the team is able to recognize and intervene definitively.

Phase I

Patient Orientation, Evaluation, Selection and Preparation

Precautions

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

The efficacy of TTO in refractory hypoxemia has unfortunately suggested to some that TTO is most appropriate for end-stage patients. Many physicians feel pressured to “do something” when patients begin a rapid preterminal phase. These patients are most challenging, and the inexperienced team will experience high morbidity and mortality. Transtracheal oxygen can become stigmatized with the image of reckless heroics. This is unfortunate because TTO is best used early in the natural history of COPD and other disorders resulting in chronic hypoxemia. Transtracheal oxygen is the first practical means of delivering true 24 hour per day ambulatory oxygen and is a superior means of preventing sequelae of hypoxemia for the typical oxygen dependent patient. ***The message is clear - don't start with refractory patients!***

Preparation

Patients should be under optimal medical treatment and stable at the time of the transtracheal procedure. In some circumstances, this may require the administration of antibiotics or steroids. In others it may call for interruption of anticoagulation therapy. No fixed interval should be set between the pre-procedure review and the procedure when patients are unstable. It may take several weeks to get an unstable patient in shape for the procedure.

Normal Sequelae

Informed Consent

- Transient tenderness at puncture site
- Transient increase in coughing
- Transient changes in sputum
 - increased volume
 - blood streaking
- Closure of tract (if catheter removed)

Potential Complications

Informed Consent

- Extravasated air
 - subcutaneous emphysema (1%)
 - pneumothorax (rare)
- Infection
 - tracheal chondritis (10%)
 - cellulitis (1%)
 - abscess (rare)
- Bleeding > 10ml (rare)
- Acute respiratory failure (1%)
- Keloid formation (5%)
- Symptomatic mucus balls (10-20%)

Informed consent is obtained at the time of the pre-procedure review. The SCOOP Patient Education and Training Video includes a segment about potential benefits and risks. Sequelae are differentiated from complications, because they are normal for most patients to experience.

When the patient leaves the pre-procedure review session, he/she should know exactly what the procedure involves, where and when it will be done, how long it will take and whether or not he/she will spend the night following in an observation unit. The patient is 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. A methodical program, intense education and visits with other transtracheal patients are reassuring. A patient who is adequately prepared will arrive composed and mentally ready for the procedure.

Phase II

Transtracheal Procedure and Stent Week

Phase II Goals

- Create a quality tract
 - proper level for stability
 - not through cricothyroid membrane
 - in the midline of the trachea
 - not through cartilage
- Do not destabilize the fragile patient
 - on day of procedure
 - during week after procedure

The best time to do the procedure is early in the day and early in the week. This allows the patient to be monitored in the hospital for the remainder of the day, the next morning, and then at home throughout the week. Patients should arrive in optimal medical condition and be psychologically prepared for the transtracheal procedure.

As mentioned earlier, a dedicated facility or bronchoscopy suite are suitable places to do the outpatient procedure. A day surgery may also be used, but patients should not be recumbent on a surgical table for the procedure. Emergency rooms tend to be claustrophobic and are generally less acceptable. The procedure should only rarely be done in the intensive care unit or on a hospital ward since, by definition, these patients are not stable.

Preprocedure Routine

The patient arrives about 1 hour before the procedure and should not have taken anything by mouth after midnight (other than medications with a sip of water). A brief interim history and physical are obtained to identify any new symptoms such as increased cough, purulent sputum or wheezing. If the patient is unstable because of an acute exacerbation, the procedure is postponed. If the patient is stable, then the previously-ordered preprocedure medications are administered. Most patients with $\text{PaCO}_2 \leq 50$ mm Hg may be given one Tylox or Percocet capsule 1 hour before the procedure for anti-tussive, analgesic and sedative effects. Most patients with $\text{PaCO}_2 > 50$ mm Hg are given Benadryl 25-50 mg one hour before the procedure. 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. Routine atropine is not recommended but may be indicated if a patient has a history of syncope. Nebulized lidocaine for topical anesthesia is not recommended.

During the subsequent hour, the patient changes into a hospital gown. Patients remove upper body clothing, but ladies do not need to remove their bras. The patient is seated in a ENT examination chair with a headrest. The back of the chair is angled backward about 10 degrees, 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. Patients who are using a non-rebreather face mask should have the device inverted and taped to the forehead.

The most recent posteroanterior and lateral chest x-rays are displayed in the procedure room on a view box. The patient's chart is in the room and opened to the transtracheal procedure worksheet. The SCOOP transtracheal procedure tray is placed on a small Mayo stand in front of the chair. The complementary supplies listed on the front of the tray are brought into the room.

Patients are psychologically most comfortable in an open room, preferably with a window. A confident and organized transtracheal team is reassuring to patients. Background music also tends to create a relaxed atmosphere, but classical music isn't necessarily relaxing for a patient who prefers country western music.

The patient is encouraged to sit erect and straight in the chair and with the head square on the shoulders. This position should help avoid rotational distortions of neck anatomy. A spotlight is focused on the anterior neck.

Phase II

Transtracheal Procedure and Stent Week

The sitting position is recommended for three reasons. First, the patient's respiratory mechanics are better than when supine. Second, the venous pressure in anterior neck veins and the thyroid isthmus is lower than when supine. Third, the procedure is less intimidating than when supine. The usual tracheotomy position with the patient supine, a roll under the shoulders and surgical drapes covering the face is uncomfortable and unnecessary.

The tray is properly oriented if placed on the Mayo stand with the label readable by the physician. The tray is removed from the plastic bag, and the paper drape is opened, taking care not to touch the inside of the drape. The upper preparatory tier is used clean while the lower procedure tier is used sterile.

Procedure Highlights

Upper Preparatory Tier:

- Puncture site selection
 - crossing of necklace and tracheal midline
 - below cricothyroid membrane
 - not through cricothyroid membrane
- Local anesthesia (3 steps)
 - skin 1 1/4" wide
 - midline subcutaneous pretracheal tissues
 - transtracheal with 20 GA needle
- Skin prep (chlorhexidine scrub)

Lower Procedure Tier:

- Draping
- Incision (vertical 1 cm through dermis)
- Needle insertion
 - midline of trachea
 - enter perpendicular to trachea
 - through interspace (not through cartilage)
- Wire guide insertion
 - should pass into trachea easily
 - keep black reference mark at skin level
- Dilation
 - 2 cm past "give" but not more than 8 cm
 - leave in place 1 minute
 - don't remove wire guide with dilator
- Stent insertion
 - insert immediately to tamponade tract
 - twirl stent 360° up to flange
 - secure with good bites of skin & good knots

The upper tier contains supplies for site selection, local anesthesia and skin disinfection. *The upper tier is fully prepared before starting, and all components are returned to their original location to encourage use in proper sequence.* This requires removing tapes which hold some of the components in place during shipping, opening the alcohol swabs, drawing 5 cc 2% lidocaine with epinephrine 1:100,000 into the syringe with the 20 GA needle, changing the needle to the 27 GA X 1 1/4" needle, adding 5 cc of 4% chlorhexidine soap to the prep well and diluting the soap with 10 cc of sterile water. The patient storage envelope is located, labeled with the patient's name and set aside.

With the neck slightly elevated and square on the shoulders, the superficial anatomy of the anterior neck is palpated. Special attention is paid to anterior neck veins and position of the trachea. The notch of the thyroid cartilage is

Phase II

Transtracheal Procedure and Stent Week

marked using a surgical marking pen with a “V”, the cricothyroid membrane is marker 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. One of the 2 bead chain necklaces provided is passed around the neck and adjusted with wire cutters to accomplish a proper fit. A proper fit will usually accommodate 2 fingers snugly but 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.

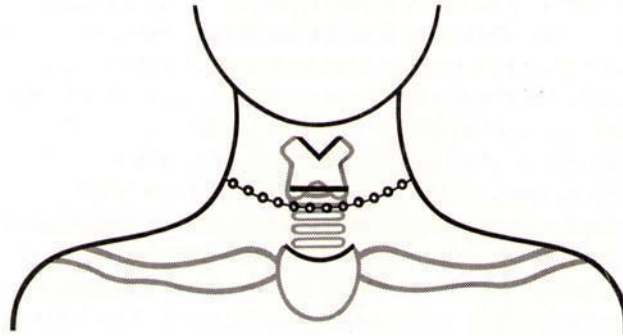


Figure 1. Puncture site selection.

A tract should not be created through the cricothyroid membrane because it predictably results in hoarseness. This appears to be related to the presence of the cricovocal ligament passing from the cricoid up to the vocal cords. More importantly, experience with the procedure has demonstrated that tracts through the cricothyroid membrane often become indurated and tender. Keloids may form and make catheter insertion difficult. Many tracts created at this level subsequently require revision.

Skin anesthesia is accomplished in 3 steps. An alcohol wipe is used to prep the skin over the procedure site. The 27 GA needle is inserted at the anterior margin of the sternocleidomastoid muscle and a wheal is created by injecting across the midline of the contralateral sternocleidomastoid muscle. This uses 2 cc of the local anesthetic. Intradermal injection causes blanching and is too superficial while failure to create wheal indicates the injection is too deep. The full length of the 1 1/4" needle is used and is necessary to give anesthesia for sutures placed through eyelets of the stent. The trachea is transfixied with the thumb and forefinger of the nondominant hand. The wrist is flexed and the elbow is kept down at the side to avoid touching the patient's face and blocking illumination. The fingers are about 1 1/2" apart and inside the anterior margins of the sternocleidomastoid muscles. Proper transfixion of the trachea is important, because it is critical for identification of the midline of the trachea. With the trachea transfixied, 1 cc of local anesthetic is injected from the skin down to the trachea but not into the trachea. The 27 GA needle is removed and the 20 GA needle is attached to the syringe. The patient is forewarned about an incipient cough, bad taste and globus sensation which is caused by transtracheal injection of local anesthetic. It is helpful to indicate that "the illusion of being short of breath is sometimes experienced." Facial tissue is given to the patient who is encouraged to resist the urge to cough for a few seconds. With the trachea transfixied and an alcohol swab in the palm of the same hand, 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, the alcohol swab is placed over the puncture site, and the patient is permitted to cough.

After the brief paroxysm of coughing, the *anterior neck is prepped* with the chlorhexidine scrub. Chlorhexidine soap is ideal for an outpatient procedure, because it does not stain the skin or clothing. The prepping usually takes 5-10 minutes and should extend from the jaw superiorly to the upper chest inferiorly and beyond the sternocleidomastoid muscles laterally. Systematic scrubbing begins at the puncture site and extends radially outward without coming back to the center. The second sponge is used in a similar way. Adequate scrubbing should remove most of the orientation marks, but the selected puncture site will remain visible because of the central 20 GA needle puncture mark and blanching of the sur-

Phase II

Transtracheal Procedure and Stent Week

rounding skin from the epinephrine in the local anesthetic. A single pass with several 4" X 4" gauze sponges across the chest at the level of the clavicles will permit the Steri Drape to stick to the skin.

The upper tier is removed from the Mayo stand by inserting fingers into the wells. The lower tier should not be contaminated with ungloved hands, since it will be used sterile. An assistant places the necklace and wire cutters in the patient's storage envelope. Sterile gloves are put on, and a sterile technique is hereafter followed. A cap, face mask and sterile gown are not required. The *Steri Drape* is applied straight across the chest at the level of the clavicles. The physician is reminded that sterile technique is necessary, and the unprepped skin of the shoulders, chest or neck should not be touched as they often are during bronchoscopy. The patient should also be reminded not to touch the drape or neck during the remainder of the procedure.

The lower procedure tier contains supplies for creation of the transtracheal tract. *The lower tier is fully prepared before starting, and all components are returned to their original location to encourage use in proper sequence.* An assistant pours sterile saline into the fluid well at the top of the tray. The scabbard is removed from the No. 15 scalpel and set aside in a gutter on the perimeter of the tray. The syringe is filled with about 2 cc of saline from the fluid well, and the 7 cm 18 GA thin wall needle is attached. The guard from the 7 cm needle is removed and set aside in a gutter. The needle and syringe are returned to the original location. The wire guide is inspected, and the atraumatic end is palpated. The water soluble jelly packet is opened, and a small dab is applied to the tip of the pre-SCOOP stent. The suture pack is opened, the needle is grasped with the needle holder, and the needle holder is returned to its original location with the needle tip pointed down. The plastic bag around the 4" X 4" gauze sponges is discarded. The tier is now ready for use. The 10 minutes used prepping the skin and making the procedure tier ready permits a local anesthetic to take full effect.

A 4" X 4" gauze sponge is held in the palm, and the trachea is transfixied with the nondominant hand. Please review the notes on transfixion of the trachea (above), since creation of the tract midline of the trachea is essential. The belly of the No. 15 scalpel is used to make a *vertical 1 cm incision* at the selected puncture site. Try 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, which is white, then fat, which is yellow. Often a pea size amount of fat herniates through the incision.

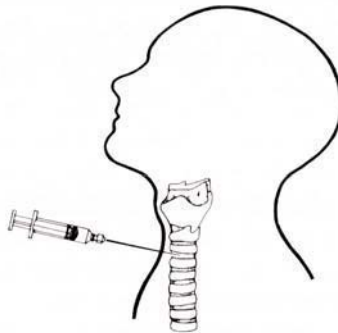


Figure 2. Insertion of needle.

The syringe and 7 cm needle are grasped like a dart, and the needle 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 which 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 degree angle. With the patient sitting 10 degrees 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.

Phase II

Transtracheal Procedure and Stent Week



Figure 3. Insertion of wire guide.

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, it may be because the needle is in the mediastinum rather than 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.



Figure 4. Dilation of tract.

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. During this minute, the physician can talk to the patient and indicate that the procedure is almost over.



Figure 5. Insertion of stent.

With a gauze in the nondominant hand, 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,

Phase II

Transtracheal Procedure and Stent Week

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 degrees 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.

Postprocedure Routine

At the conclusion of the transtracheal procedure, the patient is taken to the radiology suite for a *posteroanterior and lateral chest x-ray*. This should document the absence of extravasated air (subcutaneous emphysema, pneumomediastinum and pneumothorax) and confirm the intratracheal location of the radiopaque stent. The relationship of the tip of the stent to the carina is noted. If the tip of the stent is closer than 1 cm to the carina, a shorter catheter should be obtained before transtracheal oxygen is started one week later.

Confirmation of Tract Placement

1. Air draws back through 18 GA needle
2. Wire guide passes freely (as into air)
3. Air regurgitates through stent
4. PA & lateral CXR confirm stent position

Four serial errors would have to be made to get the stent outside the trachea. First, air would not be aspirated as the needle is inserted. Second, the wire guide would not fall freely into the trachea. Third, air would not be regurgitated out through the lumen of the stent. And fourth, the postprocedure chest x-rays would show the radiopaque stent outside the trachea. No injury would result if during any of these steps the stent is recognized to be outside the trachea and is removed.

Avoidance of Extravasated Air *(Subcutaneous Emphysema)*

- Stent Design
 - open lumen
 - open incision
 - nonocclusive dressing
- Reduced Coughing
 - foreign body without gas
 - systemic antitussives
 - topical lidocaine

A *low rate extravasated air* (subcutaneous emphysema, pneumomediastinum and pneumothorax) results from several factors. The highest rate has been observed with other systems when a functioning catheter is inserted at the time of the procedure and immediately connected to oxygen. The additive tickle of the foreign body and flow of oxygen cause brisk coughing. Coughing without a skin incision and with the lumen of the catheter obstructed allows gas to pass around the catheter into the tissues. The stent encourages gas to pass through the lumen or around the stent to the surface via

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Transtracheal Procedure and Stent Week

an open incision and nonocclusive dressing. 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.

Procedure notes are entered on the procedure worksheet in the SCOOP Patient Chart. The tip of the dilator is inspected for splitting or etching, which would suggest exposure of tracheal cartilage. The suture scissors and wire guide are washed with chlorhexidine solution, placed in the patient's storage envelope and set aside for use the following week.

All patients are observed for a minimum of 1 hour following the procedure. Patients with a single MOC score of 2 (e.g. $FEV_1 < 0.5$, $PaO_2 < 50$ mm Hg on oxygen, or $PaCO_2 > 50$ mm Hg on oxygen) are admitted to an observation unit over night. The physician should also admit to *observation unit* other patients who would be a concern at home. The observation unit should be used liberally when patients live further than 1 hour away and as the transtracheal team is developing experience with the new procedure (e.g. first ten patients).

Antibiotic prophylaxis with cephalexin 250 mg TID (or another antibiotic effective against *Staphylococcus aureus*) 1 week following the procedure is recommended. Two weeks of antibiotics is recommended when clinical circumstances suggest exposure of cartilage. Exposure of cartilage is suggested if during the procedure a gritty sensation is noted on passing the needle, wire guide or dilator. It is also suggested if the tip of the dilator is split or etched. 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. The existing body of literature about antibiotic prophylaxis does not address the special considerations of cartilage. 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 with a low FEV_1 or elevated $PaCO_2$ generally cough very little. Conversely, patients with a high FEV_1 or interstitial lung disease seem more likely to cough. Brisk coughing is rare during the stent week when patients are permitted to accommodate the foreign body before oxygen is started. Patients are instructed to resist any urge to cough, because it can result in respiratory fatigue or subcutaneous emphysema. *Tessalon Perles*, one by mouth every 4 hours (or another non-narcotic cough suppressant), is dispensed for use as needed.

Topical lidocaine may also be dispensed to augment the oral cough suppressant. A simple method for making topical lidocaine is as follows. Draw 10 cc of 1% lidocaine into a syringe, add 1 cc to each of 10 saline vials containing 3 cc saline, recap and place in a Ziplock bag. The patient may instill one 4 cc vial of 1/4% lidocaine every hour as needed. Only a rare patient will require oral narcotics to suppress coughing, but fortunately those individuals who cough briskly usually do not have a severe low FEV_1 or elevated $PaCO_2$.

Topical Lidocaine Recipe

1. Draw 10 cc of 1% lidocaine into a syringe
2. Uncap 10 saline vial 3 cc saline ampules
3. Add 1 cc of lidocaine to each ampule
4. Recap and place in Ziplock bag
5. *Sig: 1 vial via stent q 1 hr prn cough*

Patients regularly report that the procedure is less painful than an arterial blood gas. Patients usually require only *acetaminophen* (Tylenol) for pain. Aspirin and ibuprofen products are avoided because their anti-platelet effect could cause increase bruising.

During the first hour after the procedure, patients review cough suppression, tract care and circumstances which should result in a call to the physician for help. Postprocedure instructions are printed in the *Patient Workbook and Guide*.

Phase II

Transtracheal Procedure and Stent Week

Stent Week

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. The nonocclusive 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.

The Stent Week allows the patient to adapt to the foreign body before the additional tickle of gas is introduced. The Stent Week is typically smooth, but a phone call the afternoon of the procedure and the day after the procedure is made to confirm that the patient is not experiencing problems.

Phase III

Transtracheal Oxygen with an Immature Tract

Phase III Goals

- Customize cleaning protocol
- Avoid/treat mucus balls
- Avoid lost tracts
- Treat tract problems
- Encourage the patient

Phase III begins one week after the transtracheal procedure when coughing has subsided. During the first visit the stent is exchanged for a functioning SCOOP catheter. The patient is fit with a SCOOP oxygen hose, and catheter cleaning supplies are dispensed. Transtracheal flow rates are titrated at rest and exercise, and an arterial blood gas is obtained at rest. The patient is instructed about cleaning in place and is observed through a cleaning cycle to confirm proper technique. The patient is also educated about security routines to avoid losing the tract and symptoms which suggest the presence of a mucus ball.

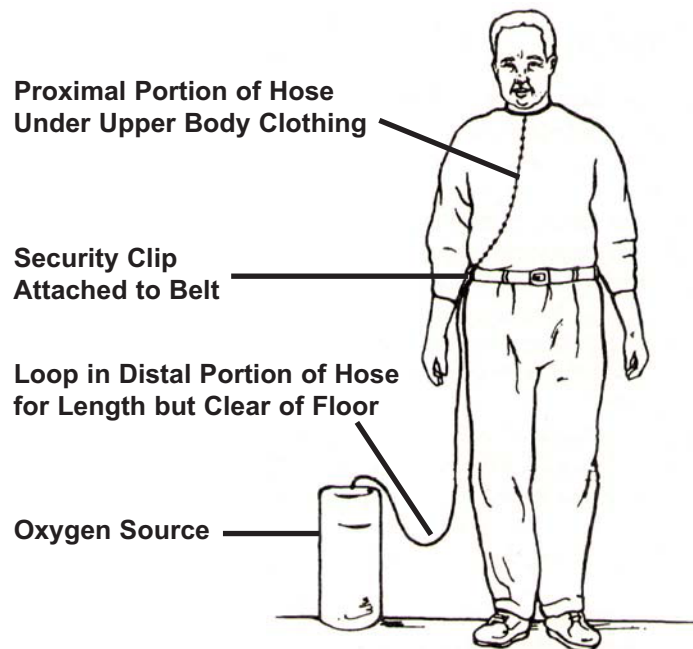


Figure 6. SCOOP oxygen hose fitting.

Before the patient is seated in the procedure chair, a *SCOOP oxygen hose* is measured. A cloth measuring tape is used to measure the gentle arc from the notch of the manubrium to the hip in inches. This is the upper length. A second measurement is taken from the hip to the tank as the patient stands next to the portable source. A short loop in the lower length is desirable to permit walking a few steps away from the portable source, but it should not touch the floor and create a tripping hazard. Hoses are available in 12, 15, 20 and 25 inch upper lengths and 40, 50 and 60 inch lower lengths. The H-2050 (20" upper + 50" lower) is the most common size. A hose is selected, the security clip is attached to the top of the lower body clothing, at the right hip, and the supple upper hose segment is passed under the upper body clothing up toward the base of the neck.

The *exchange of the stent for a functioning SCOOP catheter* 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. The supplies saved in the patient's storage envelope are set out on a sterile towel on a small Mayo stand. A SCOOP catheter is opened, and a small amount of sterile water soluble jelly is placed on the tip of the catheter. The previously-customized necklace 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. Facial tissue is given to the patient who is forewarned about the incipient

Phase III

Transtracheal Oxygen with an Immature Tract

cough, bad taste and globus sensation which is caused by transtracheal injection of local anesthetic. 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 degrees into the tract. When the flange comes to rest against the skin, the wire guide is removed and the necklace clasp connected.

A pulse oximeter is placed on the patient's finger, and the hose is connected to the catheter via the Luer taper connector. The oxygen flow rate is initially turned down to half of the nasal prong flow rate, and the SCOOP oxygen hose is connected to the source. The nasal prongs are then removed. The *patient is titrated on transtracheal oxygen* to an $\text{SaO}_2 > 90\%$ (usually 91-92%), and adequacy of oxygenation and ventilation are confirmed with an arterial blood gas per physician order. The patient is then walked with his/her own portable source, and an activity flow rate is prescribed. All TTO patients should have three flow rates documented: 1) a resting TTO rate, 2) an activity TTO rate, and 3) a nasal prong flow rate.

The patient is instructed about cleaning the catheter in place, and a cleaning kit containing Blairex saline (or Dey Vials) is dispensed. The catheter is packaged with "Cleaning in Place" and "Removal for Cleaning" patient instructions. The "Cleaning in Place" instructions are dispensed and the latter are discarded. The patient should also watch the appropriate segment in The SCOOP Oxygen Program for Patients Training Video. Instruction is not enough; proper technique must be demonstrated before the patient is discharged from the first visit in Phase III. The significant other should be encouraged to sit through the entire session.

Inadvertent dislodgement during Phase III is likely to result in lost of tract, since the tract is immature and not lined by epithelium. Keeping a 2" piece of clear plastic tape (OpSite or Tegaderm) taped over the necklace immediately right and left of the flange is a simple, but effective, way to avoid early dislodgements. This measure prevents hypermobility of the catheter both outward and laterally. Taping is not necessary in Phase IV, because the mature tract permits reinsertion of the catheter by the patient.

Before the patient departs from the first visit, he/she should review security routines necessary for avoidance of a lost tract, signs and symptoms of a mucus ball and The Ten SCOOP Rules. Normal *security routines* include a properly fitted SCOOP bead chain necklace. The length should not be modified by the patient, and the patient should not make substitutions at this time. The upper segment of the SCOOP oxygen hose must be worn under upper body clothing - especially when in bed. Women who wear nightgowns should fashion a cloth belt to which the security clip can be attached beneath the gown. Awareness of the potential for losing the tract if the catheter becomes dislodged is especially important.

Mucus Balls

A mucus ball is an accumulation of inspissated mucus which adheres to the anterior and lateral surfaces of the catheter, just above the tip. Symptomatic mucus balls occur in 10-20% 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 FEV_1 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 which predispose a patient to mucus ball formation. The use of a mucosolvent is often indicated. Guaifenesin, (Trade name Humibid L.A.), 1200 mg. BID increases respiratory tract fluid secretions, helps to loosen mucus viscosity and may reduce the incidence and severity of mucus balls. The transtracheal team should maintain a high index of suspicion during the first week of Phase III, and mucus balls, which form in spite of adequate cleaning and humidification, should be immediately recognized and treated.

Phase III

Transtracheal Oxygen with an Immature Tract

Mucus Ball Clinical Presentations

- Cough, increasing or severe
- Dyspnea, increasing or severe
- Wheezing, increasing or severe

The risk of forming mucus balls can be assessed when transtracheal oxygen therapy is initiated in Phase III. *Cleaning frequency, humidification and catheter stripping over a wire guide can be customized to prevent or minimize the formation of mucus balls in virtually all patients.* Patients at **low risk** are those who use less than 1 L/min at rest, have no baseline secretion problems and have no individual MOC score of 2. A small amount of dry gas, a small amount of normal mucus and a good cough equate to low risk. These patients start with catheter cleaning in place twice daily. A routine visit is scheduled one week after initiating transtracheal oxygen, and the catheter is stripped over a wire guide. Adjustments in the cleaning and humidification protocols are based on the clinical course between visits. Subsequent visits for catheter stripping are on an as-needed basis.

Initial Risk Assessment for Mucus Balls in Phase III

- Low Risk
 - < 1 L/min. at rest
 - and no baseline mucus problem
 - and no individual MOC = 2
- Moderate Risk
 - 1-4 L/min. at rest
 - or some baseline mucus problem
 - and no individual MOC = 2
- High Risk
 - 5-8 L/min. at rest
 - or cystic fibrosis or bronchiectasis
 - or any individual MOC = 2

Patients at **moderate risk** are those who use 1 to 4 L/min at rest or have a moderate secretion problem and have no individual MOC score of 2. A moderate amount of dry gas, a moderate amount of abnormal mucus and a normal cough equate to moderate risk. These patients start catheter cleaning in place twice daily and use a 2 p.s.i. pop-off Hudson nondisposable humidifier or a 6 p.s.i. pop-off black top Salter disposable humidifier (PN 7600) on the stationary oxygen source. Routine visits for catheter stripping are scheduled both one week and two weeks after initiating transtracheal oxygen. Adjustments in the cleaning and humidification protocols are based on the clinical course between visits. Subsequent visits for catheter stripping are on an as-needed basis.

Patients at **high risk** are those who use 5 L/min or more transtracheal oxygen at rest, have a major secretion problem (e.g. cystic fibrosis or bronchiectasis) or have any individual MOC score of 2. A large amount of dry gas, a major secretion problem or weak cough equals high risk. These patients need vigilant care to prevent mucus ball formation. Patients start catheter cleaning in place four times daily and initially use a 2 p.s.i. pop-off Hudson nondisposable humidifier or a 6 p.s.i. pop-off black top Salter disposable humidifier (PN 7600) on the stationary oxygen source. A servo-controlled heated humidifier should be immediately available to provide 100% humidity at body temperature. Routine visits for catheter stripping are scheduled at three days and one week after initiating transtracheal oxygen. Thereafter, similar visits are scheduled every week for the remainder of Phase III. Adjustments in the cleaning and humidification protocols are based on the clinical course between visits.

Phase III
Transtracheal Oxygen with an Immature Tract

<u>Phase III Cleaning Protocols</u>		
#	Humidifier	Stripping
BID	Hudson nondisposable	2nd week only
QID	Hudson nondisposable or Black top Salter disposable humidifier (PN 7600)	2nd & 3rd weeks prn
QID	Hudson nondisposable or Black top Salter disposable humidifier (PN 7600)	weekly Phase III
QID	Hudson nondisposable or Black top Salter disposable humidifier (PN 7600)	twice weekly Phase III
QID	Hudson nondisposable or Black top Salter disposable humidifier (PN 7600) or servo controlled heated humidifier	twice weekly Phase III

The initial cleaning, humidification and stripping protocols may require escalation or permit de-escalation based on actual clinical symptomology. The adequacy of cleaning should be assessed during each Phase III visit. Mucus balls can be treated in all patients, but a few with poor cough, copious secretions and/or high flow rates may need intense supervision which may include QID cleaning in place, use of a servo-heated humidifier and twice weekly catheter stripping throughout Phase III. ***The transtracheal team must master the art of preventing, recognizing and treating mucus balls.***

<u>Phase III Follow-Up Visits</u>
About 10 minutes
<ol style="list-style-type: none"> 1. Check necklace fitting 2. Check appearance and maturity of tract 3. Strip catheter over wire guide 4. Check oxygen saturation by oximetry

Subsequent scheduled and unscheduled visits during Phase III should always include a check of the bead chain necklace fitting, appearance and maturity of tract, catheter stripping and oximetry. These can often be accomplished in about 10 minutes. As previously stated, high risk patients should have scheduled visits 3 days and 7 days after starting TTO then weekly thereafter. Moderate risk patients should have scheduled visits at least one week and two weeks after starting TTO. Low risk patients should have at least one scheduled visit the week after starting TTO. The frequency of monitoring should remain flexible and be adjusted according to actual clinical outcome. The following table summarizes the steps involved in stripping the SCOOP catheter.

Phase III

Transtracheal Oxygen with an Immature Tract

Catheter Stripping Protocol - III

1. Patient uses nasal prongs during stripping
2. Clean crusts from tract opening
3. 1% plain lidocaine 2cc through catheter
4. Insert wire guide to 11 cm mark
5. Remove soiled catheter
6. Assistant holds wire at black reference mark
7. Wash catheter and apply water soluble jelly
8. Reinsert SCOOP catheter and connect necklace
9. Reconnect catheter and remove nasal prongs
10. Check oxygen saturation by oximetry

Catheter Dislodgement

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 since it tends to distort tissues. Often the tract will be open through soft tissues but closed at the intercartilagnious space of the trachea. Prolonged attempts at recovering the tract are not advised, since 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 which is too tight or a patient who buttons the top button of 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 which the patient may be applying to the tract. Patients should only clean with true soap (e.g. Ivory bar soap). Bacterial cellulitis is uncommon but would be treated with antibiotics. Tracheal chondritis is a special problem which deserves its own paragraph.

Phase III Transtracheal Tract Problems

Problem	Treatment
Maceration	Adjust necklace
Abrasion	Adjust necklace
Granulation tissue	AgNO ₃ cautery?
Contact hypersensitivity	Avoid "lotions & potions"
<i>Candida albicans</i>	Avoid antibiotic ointment
Cellulitis	Antibiotic
Tracheal chondritis	Antibiotics (3 weeks)

Phase III

Transtracheal Oxygen with an Immature Tract

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, but it is not fluctuant as an abscess would be. The bacteriology is unclear, but the knot appears to be a regional inflammatory response to colonization of exposed tracheal cartilage. Treatment with oral antibiotics (such as Keflex or Cipro 250 mg. TID-QID) or newer generation antibiotics effective against staphylococcus aureus for an additional three weeks is usually effective.

Phase III is the most challenging of the four phases, because minor morbidity is most likely to occur at this time. A skilled team will anticipate and avoid much of the morbidity, recognize and treat problems which occur and encourage the patient to ride out Phase III, because the clinical course usually becomes smooth in Phase IV.

Phase IV

Transtracheal Oxygen with a Mature Tract

Phase IV Goals

- Customize cleaning protocol
- Treat tract problems
- Pulmonary rehabilitation program
- Replace disposable supplies
- Health maintenance visits (HMTV)
 - monitor O₂ therapy

Phase IV begins 6 weeks after the transtracheal procedure in patients with slim and medium necks and 8 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 clinical symptomology. 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.

Phase IV - Catheter Cleaning Guidelines

- Cleaning in place
 - clean in place at 8AM, 4PM and prn
 - cleaning frequency may be increased or decreased based on the patient's clinical symptomology
 - feeble or anxious patients may prefer cleaning in place
 - tender tracts - minimize further tract trauma
 - patient preference
- Removal for cleaning
 - remove catheter as often as twice a day at 8AM and 4PM
 - do **not** remove more than BID
 - remove catheter once a day, every other day or once a week based on the patient's symptomology

Daily or twice daily catheter removal reduces risk of mucus ball formation and is recommended.

About 95% of tracts will be mature if the suggested maturation intervals are followed. A mature tract is fully lined by squamous epithelium which 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 nasal prongs are put on. Topical lidocaine is optional during this visit. A new catheter is made ready by removing it from the package, 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 physician or respiratory therapist 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.

Phase IV

Transtracheal Oxygen with a Mature Tract

During the remainder of the *first visit in phase IV*, the patient's necklace fitting is evaluated, the appearance of the tract is noted, a hematocrit is obtained, oximetry is used to adjust flow rates and education is emphasized. The Ten SCOOP Rules, 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 and should master the "Removal for Cleaning" patient instructions. Patients also observe the removal for cleaning segment in The SCOOP Oxygen Program for Patients training video.

Patients do 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 patient 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.

Patients who successfully remove and reinsert the catheter for one week may advance to BID removal for cleaning. BID removal for cleaning should always be done at 8 am and 4 pm so that any difficulty which 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.

Helpful tips for the patient include the following suggestions: Hold the catheter at the tip within the last inch so that it gives more control during insertion. Insert the catheter straight back and not at an angle. It should follow the tract's path and slip easily into place. Twirl the catheter when inserting. Some coughing is normal during insertion. If coughing occurs, continue advancing the catheter. Do not to force the catheter in, because once the catheter is inserted, the coughing should subside.

Customize the patient's cleaning and changing protocol according to clinical course as well as his or her ease with catheter change. The patient should clean and/or change the catheter BID. Encourage the patient to do the cleaning and changing protocols between 8:00AM and 4:00PM, so that if any questions or problems arise, it would be easier to get in touch with a knowledgeable respiratory therapist, physician or nurse.

Health Maintenance Visits (HMV)

- Three month interval
- Interval history and physical exam
 - activity level (SAL)
 - cough, sputum, dyspnea, wheezing
 - appearance of tract
 - chest exam
 - peripheral edema
 - check necklace fitting
- Laboratory evaluations
 - hematocrit
 - resting oximetry
 - exercise oximetry
 - arterial blood gas (annual HMV)
 - PA and lateral CXR (annual HMV)
- Replacement of supplies
 - patient contacts DME for replacement of 2 SCOOP catheters and a hose every 90 days per recommended replacement protocol

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The second visit one week into Phase IV marks the end of the intense portion of the program. Hereafter, the clinical course is usually smooth and emphasis can be placed on optimizing oxygen therapy and rehabilitation. Many patients can be enrolled in rehabilitation programs to exploit the superior exercise tolerance and mobility offered by transtracheal oxygen therapy.

No universal standards exist for monitoring long-term continuous oxygen therapy. The SCOOP program has found regular *Health Maintenance Visits* (HMV) every 3 months helpful in optimizing oxygen therapy. Frequent brief check ups seem to be cost effective in avoiding hospitalizations which are expensive. The content of the health maintenance visits is noted above.

Late tract problems may appear months or years following the procedure. Abrasion, maceration, contact hypersensitivity 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 which 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 (e.g. Kenalog, Depomedrol) directly into the keloid. Large keloids and chronic tract problems which do not respond to simpler methods require a minitracheotomy to continue transtracheal oxygen therapy. Problematic patients who continue to experience chronic tract problems can be successfully treated using a variation of a standard minitracheotomy called Fast Tract™.

The Fast Tract™ was developed by the manufacturer as an alternative to the modified Seldinger technique. Fast Tract™ allows the surgical creation of a controlled tracheocutaneous tract. During the procedure, a small window of cartilage is removed from the trachea. The procedure is performed under local anesthesia in the operating room with an anesthesiologist administering conscious sedation anesthesia. A modified Bivona tracheostomy tube is inserted overnight as a stent. The next morning, a SCOOP catheter is exchanged over a wire guide for the modified Bivona trach, and transtracheal oxygen may be initiated. Phase III is reduced to 2-3 weeks. The incidence of keloids, lost tracts and chondritis are greatly reduced. For further information, refer to the Fast Tract™ Clinical Guide.

In summary, SCOOP transtracheal oxygen therapy offers the typical oxygen patient many benefits over conventional nasal prongs and is the best method for delivering ambulatory oxygen therapy 24 hours per day. This booklet summarizes the current SCOOP program and addresses most of the problems encountered earlier in the evolution of this new technology.

For additional copies of this guide or for ordering information concerning SCOOP transtracheal products, call or write to:

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