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Bronchial Thermoplasty

Agenda

- Burden of Severe Asthma
- Bronchial Thermoplasty (BT) Delivered by the Alair™ System
- How BT is Performed
- Long-Term Clinical Outcomes out to 5 Years
- Who are the Right Patients for BT?

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Boston Scientific

Burden of Severe Asthma

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Challenges in Severe Asthma

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- **Asthma is a heterogeneous disease** characterized by diverse symptom profiles and response to medications
- **Subset of patients remain symptomatic and experience quality of life limitations** despite standard of care medications
- **Medications have limited efficacy**, require adherence, and can have serious side effects
- Patients with severe asthma experience **higher rates of asthma exacerbations, increased morbidity and disproportionate use of healthcare resources**

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Quick Facts Canada

Asthma.ca
Asthma Society of Canada

- Canada has one of the highest incidences of asthma in the world affecting approximately **three million people** nationally. [1]
- **> 250 asthma related deaths** occur in Canada each year. [1]
- The cost of asthma to the Canadian economy is over **$600 million annually.**[1]
- In Canada, asthma is the leading cause of absenteeism from school and the third leading cause of work loss. [1]

1. Asthma Society of Canada. Asthma Facts & Statistics. Circa 2012.

Asthma Society of Canada

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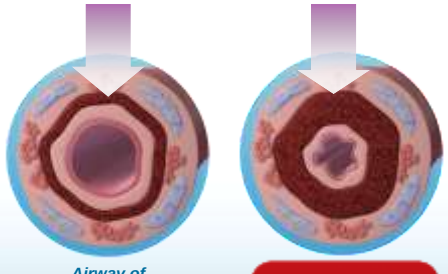
Role of Airway Smooth Muscle (ASM) in Asthma

Boston Scientific



Airway of Normal Patient

Asthma Attack

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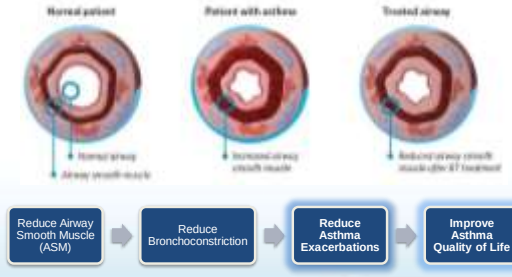
Bronchial Thermoplasty – Reduces Excess ASM



Reduce Airway Smooth Muscle (ASM) → Reduce Bronchoconstriction → **Reduce Asthma Exacerbations** → **Improve Asthma Quality of Life**

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Bronchial Thermoplasty (BT) Delivered by the Alair™ System

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What is Bronchial Thermoplasty (BT), Delivered by the Alair™ System?

- **Safe, minimally invasive, outpatient** procedure for the treatment of severe asthma:
  - Performed as 3 bronchoscopy procedures
  - Delivers controlled radiofrequency energy to the airway walls to reduce excessive airway smooth muscle, which limits the muscle's ability to constrict the airways
- **Clinically proven** to provide long-term reduction in asthma exacerbations out to at least 5 years, and improve asthma-related quality of life for patients with severe asthma*
- **Complementary treatment** to asthma maintenance medications that control inflammation by targeting ASM bronchoconstriction
  - Not a cure for asthma or a replacement for drug therapy

*Compared to a sham-control group at one year.

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The Alair™ System

- **Alair Catheter** – a flexible tube with an expandable wire array at the tip to deliver therapeutic RF energy to the airway walls via a standard bronchoscope

- **Alair Radiofrequency (RF) Controller** – designed to safely and accurately deliver precise, controlled RF energy through the Catheter to the airway walls

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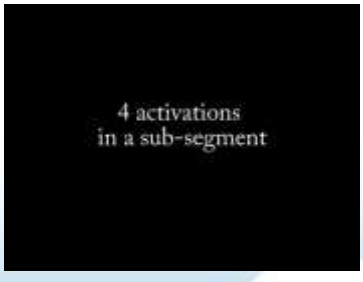
Application of RF Energy

- Temperature controlled energy (65º C) is delivered to airway wall for 10 seconds per activation



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BT Treatment Effect –

Airway Responsiveness to Local Methacholine Challenge

Canine Model: Airway on left treated with BT. Airway on right was not treated.

Cox et al. Eur Respir Journal. 2004;24: 659-663.

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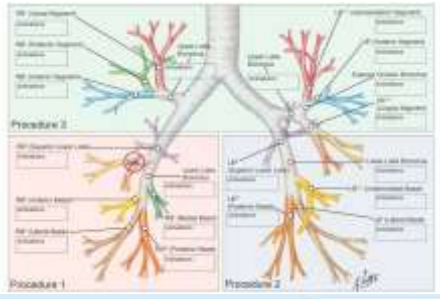
How BT is Performed

BT Completed in 3 Outpatient Procedures



BT is performed by a trained pulmonologist in 3 outpatient visits, typically scheduled 3 weeks apart.

Long-Term Clinical Outcomes out to 5 Years

Demonstrated Clinical Effectiveness at 1 Year[1]

- **Improved asthma-related quality of life compared to control (AQLQ score)**
  - **79%** of BT treated patients achieved ≥ 0.5 increase versus 64% of sham-treated patients (PPS 99.6%)
- **Improved clinical outcomes compared to sham-control:**
  - **84%** reduction in emergency room visits for respiratory symptoms
  - **32%** decrease in severe exacerbations requiring systemic corticosteroids
  - **66%** less days lost from work, school and other daily activities due to asthma

PPS = Posterior Probability of Superiority

1. Castro M, et al, for the AIR2 Trial Study Group. *Am J Respir Crit Care Med.* 2010;181:116-124.

Established Long-Term Effectiveness and Safety out to 5 Years[1]

The AIR2 Trial 5-Year Extension Study evaluated the sustained effectiveness of BT beyond 1 year, and the safety of BT out to 5 years in BT-treated patients from the AIR2 Trial.

- **Reduction in severe asthma exacerbations requiring systemic corticosteroids** seen at 1 year was maintained out to 5 years
- **Reduction in ER visits for respiratory symptoms** seen at 1 year was maintained out to 5 years
- **Long-term safety** maintained over 5 years

Wechsler ME, et al; for the Asthma Intervention Research 2 Trial Study Group. *J Allergy Clin Immunol.* 2013 Aug 30. doi:pii: S0091-6749(13)01268-2. 10.1016/j.jaci.2013.08.009. [Epub ahead of print]

Long-Term Safety Maintained out to 5 Years[1]

- No increase seen in hospitalizations, asthma symptoms, or respiratory adverse events over the course of 5 years
- No structural changes in airways that were clinically significant were due to BT at 5 years (based on HRCT review)
  - No evidence of increase in bronchiectasis
  - No evidence of bronchiolitis obliterans or pulmonary emphysema in any patient
- No clinically significant deterioration in lung function (FEV_1) at 5 years

Wechsler ME, et al; for the Asthma Intervention Research 2 Trial Study Group. *J Allergy Clin Immunol.* 2013 Aug 30. doi:pii: S0091-6749(13)01268-2. 10.1016/j.jaci.2013.08.009. [Epub ahead of print]

Who are the Right Patients for BT?

Bronchial Thermoplasty Indication

The Alair™ Bronchial Thermoplasty System has been approved by the FDA for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids (ICS) and long-acting beta-agonists (LABA).

Reference the Alair Bronchial Thermoplasty System Directions for Use for more information.

Questions?