Novel tracheal stent for COPD treatment

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COPD affects millions worldwide

• 4th-leading cause of death globally in 2015, claimed 3.2 million lives
• Category of diseases including chronic asthma, chronic bronchitis, emphysema, cystic fibrosis
• Pathology – enhanced immune response to environmental toxins leading to physiological responses that vary by disease
Current treatment options include medication, mechanical physiotherapy, and stent implantation.

**Mucoactive Drugs**
- Function – act directly upon mucus to disrupt mucus-cell interactions, decrease thickness
- Problem – Moderate to low effectiveness

**Respiratory physiotherapy devices**
- Function – disrupt accumulated mucus using high frequency oscillations and high pressure
- Problem – labor-intensive and time consuming

**Traditional Tracheal Stent**
- Function – mechanically maintains airway patency
- Problem – impairs mucociliary function, restenosis

Figure 4 – High Frequency Chest Wall Oscillation device.

Figure 5 – Tracheal stent.

Figure 6 – OTC expectorant.
Better outcomes could be achieved via “3-in-1” treatment

1. Tracheal stent with anti-proliferative drug coating
2. Polymer-infused Mucolytic drug coating
3. Mechanical mimicry of mucociliary clearance
Design includes mechanical and biochemical features that combine for a more effective treatment.

Mucolytic (ex. Dornase alpha) + Polyethylene glycol (sustained release) on inner stent layer

Bioresorbable protrusions (ex. polycaprolactone) for low frequency oscillation

Anti-proliferation (ex. Paclitaxel) + Polyethylene glycol (sustained release) on outer stent layer

Figure 7 – Design proposal for Bilayered tracheal stent
Unique design introduces unique biocompatibility concerns

- Restenosis could bypass lumen-facing layer and cause further obstruction
- Shear stress on oscillatory protrusions due to air flow
- Delocalizing mucolytic drug
Device would address specific concerns with other therapies

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<tr>
<th>Treatment</th>
<th>Problem</th>
<th>3-in-1</th>
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<tr>
<td>Mucoactive Drugs</td>
<td>Low effectiveness</td>
<td>Delivery method bypasses some of the innate protections of the respiratory tract</td>
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<td>Respiratory Physiotherapy</td>
<td>Labor-intensive and time consuming</td>
<td>No need for active treatment on the part of the patient or clinician</td>
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<tr>
<td>Traditional tracheal stent</td>
<td>Impairs mucociliary clearance, restenosis</td>
<td>Compensates by mimicking mucociliary function, limits and confines restenosis</td>
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References


[2] [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1463976/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1463976/)


Analysis of shear stresses on protrusions

Peak mass flow rate (inhalation) = \( m' \approx -0.4 \frac{l}{s} \times 0.001429 \frac{kg}{l} \)
\[ = 0.000572 \frac{kg}{s} \]

\( F_{resistance} \approx 330 \left( Pa \times \frac{S}{l} \right) \times -0.4 \frac{l}{s} \times 0.00028 m^2 = 0.037 \text{ N} \)

At equilibrium, \( F_{inhalation} = F_{resistance} \)
\[ V_{inhalation} = \frac{F_{resistance}}{m'} = 0.49 \frac{m}{s} \]

Given velocity of air flow and measurements of oscillatory frequency of protrusions, one can estimate shear stresses on the protrusion using Newton’s 1st law, conservation of momentum, and constitutive relationships.