A Treatment for Nasal Valve Collapse

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Nasal Valve Collapse

- The nasal valve is a region inside the nasal passageway.
  - Internal valve sits about 2 cm above base of the nose.
  - It provides appropriate airflow resistance before air enters the trachea and lungs.

- Nasal valve collapse results in a piece of cartilage restricting the nasal valve, and can result from several causes:
  - Nasal septum deviation: the septum is displaced sideways, resulting in blockage of the nasal valve at the side of displacement.
  - Turbine hypertrophy: the turbinates enlarge to minimize the opening of the nasal valve.
  - Injury to the nose: the nasal valve is damaged and weakened.

- Negative pressure is created during inhalation, and weakened valve strength or valve area can lead to collapse and the following symptoms:
  - Difficulty breathing
  - Symptoms of congestion

Clinical Need

- Approximately 28 million Americans suffer from nasal valve collapse.
- Current treatments are $20 for temporary symptom reducers to over $8000 for surgery.
  - Surgery is not financially feasible for some patients.
  - Existing solutions that are non-invasive are externally visible and are uncomfortable to use.

Product Design

- The design of the nasal valve supporting device, which fits securely inside one nostril.
  - Solid sections strengthen the device.
  - Mesh areas provide flexibility.
  - Upper and lower rings facilitate insertion/removal.

Product Testing

- Qualitative Testing:
  - The device was worn in one nostril and comfort was assessed by the wearer over time.

- Quantitative Testing:
  - The average cross sectional area of the nostril opening with and without the device was determined using ImageJ.

Statistical Analysis:
- A two sample unequal variance t-test was performed on four area data samples, resulting in a p value of 0.000473.
- p <0.05, indicating statistical significance.

Future Work

- Create an accurate model of scaled nose prototype for better visual demonstration of how device works.
- Perform quantitative testing of device flow using tubing and gravity - a more robust set of testing is warranted to prove the clinical efficacy of the device.
  - Acoustic rhinometry is the gold standard for testing and can measure the cross-sectional area of the nasal passageways at different points.
  - Prototype device for insertion and removal.
  - Reinforce current device as needed (ex. if the insertion/removal device can tear it).

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Conclusions

This product design achieves the following design goals:

- Functionality: the device will provide mechanical support to the nasal valve by increasing the nasal valve area and thus increase airflow via inspiration.
- Aesthetic: the device is unsee and unnoticeable by an outside viewer once inserted.
- Safety: the device fits securely inside the nasal passageway and will not be inhaled or fall out.
- Comfort: the device does not cause any irritation or discomfort when inserted.
- Ease Of Use: the device is easily inserted and removed from the nose.
- Low Cost: the device is available as an inexpensive, easily accessible option.

References