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.[1]

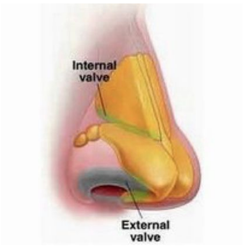


Figure 1: Shows the location of the internal and external nasal valves.

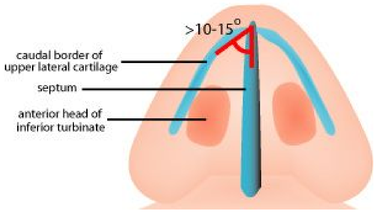


Figure 2: Shows the angle created by the internal nasal valve between the caudal region of the upper lateral cartilage and the septum.

- 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
  - t**urbinate 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[2] and the following symptoms:
  - Difficulty breathing
  - Symptoms of congestion

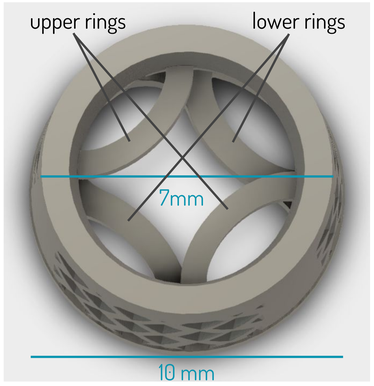
Clinical Need

- Approximately **28 million Americans** suffer from nasal valve collapse.
- Current treatments are $20 for temporary symptom reducers to over $8000 for surgery.[3]
  - Surgery is not financially feasible for some patients.
  - Existing solutions that are non-invasive are externally visible and are uncomfortable to use.

Figure 3: Image of the Rhinomed Nasal Dilator.

Figure 4: Image of Breathe Right Strip placed on a nose.

Product Design



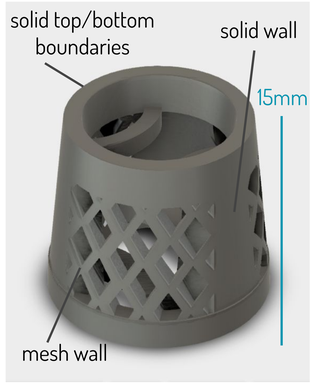


Figure 5:
The design of the nasal valve supporting device, which fits securely inside one nostril.
- Solid sections strengthen the device.
- Mesh areas provide flexibility.
- Upper and lower rings facilitate insertion/removal.

Figure 6: Proposed steps for insertion and removal of the nasal valve device from the nose.

Insertion: Place tweezers into top rings and insert into nose.
Removal: Place tweezers into bottom rings and remove from nose.

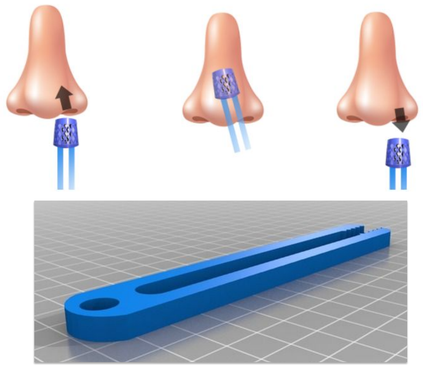


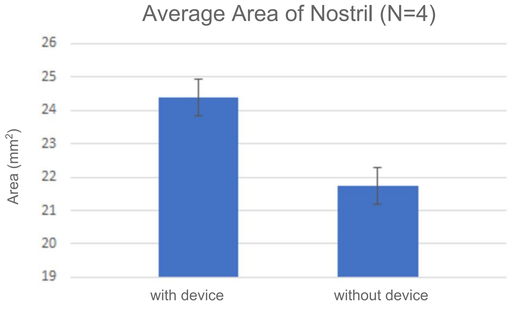
Figure 7: Proposed design for blunt end tweezers that can be used to insert and remove the device from the nose.

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.

Figure 8: Image of right nostril without (top) and without (bottom) nasal valve device.



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.

Figure 9: A comparison of the average area of the nostril normally and while using the device.

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 unseen 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.

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).

Acknowledgments

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