An Adjustable, Butterfly-Design, Titanium–Expanded Polytetrafluoroethylene Implant for Nasal Valve Dysfunction

A Pilot Study

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Objective: To investigate the design of a simple, adjustable, biocompatible nasal implant that consistently corrects nasal valvular dysfunction.

Methods: This study presents data on an adjustable titanium–expanded polytetrafluoroethylene (ePTFE) implant designed as a spanning butterfly graft. Each patient was measured for implant effectiveness subjectively by patient questionnaire and objectively with static and dynamic photographs as well as acoustic rhinomanometry data.

Results: Rhinomanometry studies, photographic evidence, and patient questionnaires revealed that a great improvement in the nasal airway can consistently be achieved at the level of the nasal valve using the titanium-ePTFE butterfly design implant.

Conclusion: The titanium-ePTFE butterfly-design implant provides a consistent and adjustable correction of the dysfunctional nasal valve.

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The nasal valve represents the smallest cross-sectional area of the entire upper and lower respiratory tract. The internal valve is bordered by the nasal septum medially, the lower aspect of the upper lateral cartilage laterally, and the nasal floor inferiorly. Mucous membranes within the valve area are erectile bodies, which when congested can significantly affect airflow. The nasal valve contributes 50% of the total airway resistance within the respiratory tract when it is functioning normally. The percentage is even higher if an abnormality exists. The valve acts to regulate nasal airflow through collapse and dilation during breathing. During inspiration, negative pressure tends to narrow the valve. Eventually, a point is reached when an increased force of inspiration does not further increase airflow, known as the Starling resistor effect. The nasal musculature, cartilaginous framework, and soft tissues of the nose work to offset the forces of negative pressure and to prevent valve closure during inspiration. A weakened nasal sidewall or valvular narrowing allows collapse to occur at much lower pressures, producing symptoms of nasal obstruction. The area of the nasal valve affects airway resistance both inversely and exponentially, assuming that sidewall resistance and strength is uniform, which is frequently not the case when dysfunction is present. Therefore, a minimal decrease in valve area or integrity can cause a significant increase in nasal resistance.

Nasal valvular dysfunction is becoming more prevalent as the US population ages. Changes that occur to the nose with age include elongation and weakening of the lower lateral cartilages, nasalis muscle atrophy, tip ptosis, and a generalized increased propensity for mucosal edema, particularly when supine. In addition, the surrounding facial soft tissues become ptotic, with the resultant development of nasal-pyriform misalignment. All of these factors in the aging nose adversely affect the function of the nasal valve, both statically and dynamically. Other causes of nasal valvular dysfunction include trauma, prior rhinoplasty, and septal anomalies. It is estimated that approximately 13% of the US population have valvular dysfunction to some extent, with estimates as high as 60% in the geriatric population. Since at least 50% of the total respiratory resistance resides in the region of the nasal valve, correction of valve dysfunction can be hugely beneficial for the patient.

Many surgical reconstructive techniques have been devised for correction of nasal valvular dysfunction, some incorporating cartilaginous or other implants.
Available techniques include spreader grafts, batten grafts, flaring sutures, and suspension sutures. One technique universally producing successful long-term outcomes is the “butterfly” cartilaginous spanning graft procedure. Problems with the currently available techniques include the following: (1) They are technically difficult; (2) None can be adjusted for additional correction once the procedure is completed; and (3) Flaring sutures and suspension sutures may not maintain their initial results owing to suture pull-through over time. Realistically, with suture techniques, no stabilizing scarification (as in a facelift) or remodeling of cartilage (as in an otoplasty) can take place for the desired long-term stability of the result. Of the non-surgical treatments, the Breathe Right external dilator (CNS Inc, Chanhassen, Minn) has been widely accepted as the most effective and widely used device for valvular correction. We have found that Breathe Right Strips were not well tolerated by our target geriatric patient population because of frequent adhesive allergies and a propensity for skin trauma at the time of removal. Therefore, although they were uniformly helpful in our study patients, they could not be tolerated over the long term. Also, they were only effective when in place, which left the patient symptomatic for the remaining portion of the day.

The titanium–expanded polytetrafluoroethylene (ePTFE) implant presented herein (Hanson Medical Inc, Kingston, Wash) acts much like the Breathe Right dilator, functioning to actively maintain valvular patency during inspiration. This implant has a bi-material design (Figure 1). The dumbbell shape, which is narrowest at its midpoint, creates limited additional midline dorsal fullness when implanted, while the broader lateral segment allows for a larger area of force distribution to the nasal sidewalls, which diminishes the chance for tissue distortion during dilation. The outer sheath of ePTFE (or reinforced silicone for earlier implants) encases the dumbbell-shaped titanium core that can be contoured in vivo or in vitro to obtain the desired valvular size and shape, while maintaining an acceptable cosmetic balance (Figure 2). Once in place and stabilized, it can be further adjusted in the office, if needed, to achieve the desired end result. A nonadjustable nylon core implant is also being designed for testing. Patients passing a preoperative Breathe Right screening test for valve dysfunction should have a 90% success rate with a butterfly-design surgical correction.

Seven patients were implanted with butterfly-design bi-material dilators. All patients had nasal valve narrowing or inspiratory collapse confirmed by direct examination, subjective symptoms, and rhinomanometry (RhinoMetrics; Interacoustics AS, Assens, Denmark). The primary cause of dysfunction in all cases was senile nasal changes. Criteria for implantation included elongated and thin or sometimes heavy and thick nasal sidewalls, lack of nasalis compensation, observed static or dynamic collapse, and subjective inspiratory obstruction. The mean age of all patients was 66 years (range, 52-84 years). All patients were improved by using the Breathe Right strip but were intolerant to long-term use because of allergy to the adhesive or skin trauma during removal. All patients, both before as well as 2 to 4 weeks after implantation, were examined to determine nasal valvular size and shape and for stability during inspiration. Preoperative and postoperative inspiratory photographs and acoustic rhinomanometry were also completed, allowing for measurement of dynamic and static improvement, respectively. The patients were also instructed to complete a questionnaire before and after surgery, addressing and scoring issues relating to snoring, apnea, nasal airway patency during the day and evening, observation for nasal collapse, mouth breathing, olfaction, and the need for medications or devices to improve the nasal airway.

IMPLANTATION PROCEDURE

All patients properly consented to take part in this study. Immediately prior to surgery, the patient was examined, and during forced inspiration, the point of maximal valvular collapse (PMVC) was marked on the nasal sidewalls bilaterally (Figure 3A). The appropriate implant template length, varying from 44 to 50 mm, was then chosen so that when placed and contoured in the proper position, with its midpoint immediately supratip, the lateral limbs would extend slightly beyond the PMVC (Figure 3B). The desired incision location and dissection pockets were then marked (Figure 3C). As the implant lies flush along the nasal sidewalls while bridging the 2 PMVCs, there is an obvious natural localization for the proper dorsal incision, allowing it to be as small as possible. An implant 2 mm smaller than the template was then chosen to compensate for skin and subcutaneous tissue thickness. The implant midline was marked as a later reference point to be used during final placement orientation.

Although intranasal and open techniques are options for implantation, for simplicity all implants were placed by the trans-
cutaneous route. The properly-sized implant was placed in a gentamycin antibiotic solution immediately after being opened. All patients were given 1 g of a first-generation cephalosporin. Ten minutes after injecting 1% lidocaine with 1:100 000 epinephrine and an appropriate skin preparation, a 1-cm midline vertical dorsal incision was placed, as marked in the supratip area. Here, the nasal subcutaneous tissues have maximal thickness, allowing for effective camouflage of the implant medially. The incision was carried down to the supraperichondrial plane. Precise pockets were then dissected bluntly in this plane, using a hemostat, to the limits of the preoperative markings ending just beyond the PMVC (Figure 3D). Laterally, the dissection extends somewhat more deeply into the supra-alar fibrofatty tissue. The pockets should be only slightly longer but not wider than the implant, which helps to prevent medial tenting or rotation of the implant after placement. The pockets were then irrigated with the antibiotic solution. The implant should be bent over a marking pen or other smooth, round device to produce a wide radius bend centrally, avoiding knuckling and subsequent bossa formation. The lateral ends are also rotated out slightly to allow for simpler placement (Figure 3E). During implantation, the device is grasped between the thumb and index finger and additionally compressed to bring the lateral ends together. It is then passed through the incision (Figure 3F), which is dilated with skin hook retractors, to allow the implant to be smoothly pressed into the previously dissected pockets and brought flush to the nasal dorsum (Figure 3G). Occasionally, a bit of gentle force is required to get the implant ends to track into the pockets. If there is significantly constricting the ends of the implant to track laterally during placement, the incision can be lengthened slightly, which makes placement easier. The implant is then digitally contoured to the nasal dorsum and sidewalls. If the pockets have been properly sized, the implant should fit flush on the nasal cartilaginous dorsum and not protrude medially. If there is significant middorsal prominence, a small notch may be created in the dorsal cartilage to accommodate the implant. This was not required in any of our patients. The implant midline marking should lie at the dorsal midline when in place. The incision is meticulously closed (Figure 4). The implant can now be slightly dilated. An assistant should compress the implant to the nasal dorsum in the midline, while the physician dilates the nasal sidewalls either digitally or with 2 knife handles (Figure 5). Oral antibiotics are used for the first week. At 1 week the implant can be adjusted in the office if needed to obtain the desired airway/aesthetic balance. At 2 to 4 weeks the nasal airway was reinspected, the questionnaire was resubmitted, photographs were taken, and rhinomanometry was again completed.

Two patients had concurrent posterior septoplasty surgery. An eighth patient was dropped from the study. This patient had 3 contributors to her airway problems including septal problems, turbinate hypertrophy, and valvular collapse. On the day of her surgery she opted against an implant and had only the septum and turbinates corrected.

RESULTS

A total of 7 patients were chosen for this preliminary study. Those not included were rejected based primarily on physical examination. Six patients who received implants obtained an immediate and sustained subjective improvement in their airways based both on their candid comments initially and questionnaire scores later. All patients had been asked to score (scale, 1-10) their daytime and nighttime nasal airways (10 as best), snoring (10 as worst), olfaction (10 as best), apnea (10 as worst),
and perceived activity restriction from nasal airway obstruction (10 as worst). The percentage of time spent mouth breathing during the day was also rated. A subjective decrease was seen in snoring and the prior propensity for mouth breathing, with scores dropping from 7.29 to 3.29 and from 58% to 14%, respectively. A uniform increase was experienced in the nasal airways, both during the day and night, with scores increasing from 5.3 to 8.7 and 2.6 to 7.1, respectively. There was also a perceived increase in olfaction and a decrease in apnea and activity restriction (Table 1).

Dynamic photographic evidence showed an expected increase in lateral sidewall stability with forced inspiration after implantation (Figure 6). Average increases in inspiratory vestibular cross-sectional areas after implantation were 119% right (range, 3% to 473%) and 103% left (range, 16% to 238%) (Table 2). Acoustic rhinomanometric data after implantation showed a substantial increase in static nasal cross-sectional areas at the level of the internal nasal valve with individual increases averaging 75% right (range, −11% to +229%) and 94% left (range, −3% to +245%). As measured, the actual average static nasal cross-sectional areas increased from 0.49 to 0.68 cm² right and from 0.30 to 0.50 cm² left (Table 2). Although there was a visible increase in nasal width as a result of the dilatory effect of the implant, the patients did not consider this troublesome in exchange for the improvement in their airways (Figure 7). The patient opting against the nasal implant subjectively experienced a worsening of her valvular symptoms after the posterior nasal airway had been improved due to a greater ability to generate negative pressure.

This is a preliminary study, with only a small number of patients represented and a relatively short follow-up period. Because of manufacturing delays for the ePTFE implant, the first few implants were produced using a reinforced silicone outer sheath with identical mechanical properties to the ePTFE design. Regardless, the early results are encouraging, and underscore the value and simplicity of this technique. At present, additional study is under way with a larger patient base and longer-term follow-up. Designs with alternative materials are also being developed using an ePTFE outer sheath with a nylon core. This latter design would not be adjustable but would not be prone to knuckling or bossa formation over time.
Concerns that arise with this surgical technique include the following:

- **Infection or rejection**, although with ePTFE, studies show that this should be no more than 2% or 3% for nasal implants.\(^{18}\)

- **Cosmetic deformity**: Patients in this study were not bothered by the slight change in nasal appearance in exchange for the airway gains achieved, preferring function over form. The slight increase in nasal width was actually desirable in some noses that appeared abnormally pinched preoperatively secondary to their valve dysfunction. The dilation actually produced a more natural appearance in this subgroup and was noted by some patients. In addition, many older noses tend to be thicker and fairly sebaceous, thus more easily camouflaging this implant. This technique is probably not a good option for thin-skinned patients or those who are appearance conscious.

- **Widening and bulging of the pocket over time with loss of effectiveness**: The implant is placed to support and slightly dilate the nasal sidewalls. If there is no excess lateral pressure, this should not be an issue. The ePTFE design biointegrates, while the silicone design produces a fibrous capsule, both of which would create a stabilizing effect and further limit this tendency. Also, the broad lateral wings of the implant distribute the dilation forces over a larger area, making this less likely. If bulging is noted to occur, this indicates that there is excess dilation whereby the implant can be either readjusted (compressed) or removed as needed.

- **Bossa formation**: With proper placement, limited re-adjustment and avoidance of trauma should not be an issue. Small irregularities are manageable with digital reshaping in the office by gently pressing and contouring the implant over the nasal dorsum with or without local anesthesia. Still, if significant irregularity occurs, the solution would be removal and replacement of the implant. A nylon core design would not be prone to this problem.

In the present study all patients underwent implantation by the transcutaneous technique for simplicity, which could make it an office procedure. This implant can also be place by an endonasal marginal approach for those wanting to avoid a nasal scar or an open approach if better implant contouring is expected to be needed. The latter would allow for suture fixation of the implant to the upper and lower lateral cartilages if needed for contouring and support. With the transcutaneous approach used herein, a small midline vertical nasal scar should be fairly cosmetic and was acceptable to our patient population.

Even though rhinomanometry data showed a large increase in the nasal valvular area after implantation, this only partially measured the true benefit that these patients experienced with valve stabilization. Rhinomanometry is a measurement of the static area of the nasal airway and does not take into account the dynamics of the valve area. In the static state some valves that are measured as having an adequate cross-sectional area may have inadequate sidewall support or nasalis dilation and therefore factor significantly into the patient’s symptomatic inspiratory obstruction. Improvement in dynamic function postoperatively was better documented by photo-

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**Table 1. Patient Questionnaire Average Scores**

<table>
<thead>
<tr>
<th>Time of Questionnaire</th>
<th>Nasal Airway (Day), Score*</th>
<th>Nasal Airway (Night), Score*</th>
<th>Snoring, Score†</th>
<th>Apnea, Score†</th>
<th>Olfaction, Score*</th>
<th>Activity Restriction, Score*</th>
<th>Mouth Breathing, % of Daytime Respiration</th>
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<tbody>
<tr>
<td>Before implantation</td>
<td>5.3</td>
<td>2.6</td>
<td>7.3</td>
<td>5.3</td>
<td>5.7</td>
<td>5.7</td>
<td>58</td>
</tr>
<tr>
<td>After implantation 2-4 wk</td>
<td>8.7</td>
<td>7.1</td>
<td>3.3</td>
<td>3.8</td>
<td>7.7</td>
<td>2.6</td>
<td>14</td>
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</table>

*Based on a 1 to 10 scale, with 10 as the best.
†Based on a 1 to 10 scale, with 10 as the worst.
graphic and video evidence of valvular function when viewed during inspiration.

As would be expected, when nasal valve dysfunction is present, the propensity to collapse increases as the ability to generate negative pressure increases. This was witnessed in the patient who chose not to undergo implantation but had her posterior airway improved. This example highlights the importance of accurately identifying dysfunction of the nasal valve and the need to concurrently correct it when other nasal airway problems are to be improved.

Two types of age-related nasal change tend to be prone to valve obstruction with time. The nose undergoing generalized elongation with concurrent weakening of the lower lateral cartilage tends to suffer from dynamic collapse. Both internal and external nasal valves can be involved. Most of these cases tend to occur in female patients. A nose that develops significant sebaceous thickening with age, a more common male change, tends to create pressure in the scroll region, which produces a more static internal valve collapse. Both of these nasal types are demonstrated in this study and were corrected by implantation.

The most valid application of this device is likely in the geriatric subgroup, in whom advancing senile changes of the nose can lead to nasal valvular dysfunction, either static or dynamic. Other possible applications would be patients experiencing valve dysfunction long after rhinoplasty surgery, as an alternative to septoplasty for caudal deflections, as well as correction of nasal valve collapse in the cleft lip nasal deformity, which is frequently the largest component of nasal obstruction in these patients.

In conclusion, this study presents a bi-material butterfly-styled nasal implant designed to correct nasal valvular dysfunction, both static and dynamic. The preliminary results are encouraging, with stability and dilation occurring at the levels of both the internal and external nasal valves. Patients in this study greatly exhibited both subjective and objective improvement in their nasal airways after implantation with a decrease in other symptoms related to nasal obstruction. Additional study with increased patient numbers and longer-term follow-up will be needed to further support the value of this technique.

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Table 2. Static Acoustic Rhinomanometry and Dynamic Photographic Data

<table>
<thead>
<tr>
<th>Measure</th>
<th>Patient No.</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Rhinomanometry: static nasal valve area, cm²</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before implantation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>0.60</td>
<td>0.41</td>
</tr>
<tr>
<td>Right</td>
<td>0.89</td>
<td>0.59</td>
</tr>
<tr>
<td>Percentage increase in area</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>−3</td>
<td>+56</td>
</tr>
<tr>
<td>Right</td>
<td>−11</td>
<td>+59</td>
</tr>
<tr>
<td>Photographic data: % increase in dynamic nasal valve area, inspiratory after implantation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>+41</td>
<td>+40</td>
</tr>
<tr>
<td>Right</td>
<td>+24</td>
<td>+30</td>
</tr>
</tbody>
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Figure 7. Preoperative (A) and postoperative (B) anteroposterior view in implantation patient 1; preoperative (C) and postoperative (D) anteroposterior view in implantation patient 4.
Financial Disclosure: Dr Hurbis is licensed by Hanson Medical Inc, Kingston, Wash, as codesigner in the development of this nasal valve implant and will have financial ties to the company if any sales of this device result in the future.

REFERENCES


Announcement

Calendar of Events: A New Web Feature

On the new Calendar of Events site, available at http://pubs.ama-assn.org/cgi/calendarcontent and linked off the home page of the Archives of Facial Plastic Surgery, individuals can now submit meetings to be listed. Just go to http://pubs.ama-assn.org/cgi/cal-submit/ (also linked off the Calendar of Events home page). The meetings are reviewed internally for suitability prior to posting. This feature also includes a search function that allows searching by journal as well as by date and/or location. Meetings that have already taken place are removed automatically.