TREATMENT OF NASAL VALVE COLLAPSE WITH TRANSCUTANEOUS AND INTRANASAL ELECTRIC STIMULATION

Michael Vaiman, MD, PhD; Nathan Shlamkovich, MD; Ephraim Eviatar, MD; Samuel Segal, MD

Abstract
We conducted a prospective, randomized, double-blind pilot study of patients presenting with symptoms of obstructed nasal breathing to determine whether electrotherapy could provide nonsurgical symptom relief. Forty patients were divided into an electrotherapy group (n = 20) and a placebo group (n = 20). All selected patients demonstrated nasal valve stenosis with a positive Cottle maneuver and clinically evident nasal valve collapse. Treatment consisted of high-frequency transcutaneous and intranasal electric stimulation of nasal muscles for 15 minutes, 3 times a week for 10 weeks. Treated patients were followed for 10 to 12 months. Twelve patients in the electrotherapy group (60%) exhibited subjective improvement; in 8 cases (40%), the improvement was proved objectively. In the placebo group, 7 patients (35%) indicated subjective improvement; and in one case (5%), the improvement was proved objectively. Follow-up visits showed a rapid decline of positive results when treatment was discontinued. Therefore, we concluded that sure relief of nasal valve stenosis and collapse cannot be achieved with treatment by electric stimulation alone, and this method appears to have limited application. However, further studies are needed to determine whether electrotherapy used in combination with other treatments (e.g., biofeedback training or nasal springs) may provide more lasting relief for patients who want to avoid endonasal surgical intervention.

Introduction
Electric stimulation of facial muscles is a well-known method of treatment, used mainly for therapy of Bell’s palsy (facial nerve paralysis) and occasionally in management of otorhinolaryngologic problems. Use of electrostimulation in rhinology is extremely rare and, when used, was performed either as a form of reflexotherapy or transcranially. Electric stimulation has not been used specifically for nasal muscle stimulation in patients with nasal obstruction resulting from nasal valve stenosis and/or collapse.

Symptoms such as nasal obstruction and congestion, which usually are described by patients as difficulties of nasal breathing associated with an unpleasant sense of fullness or heaviness in the nose, may result in different outcomes, ranging from chronic mouth breathing to a need for endonasal surgery. In evaluating patients with nasoseptal deformities, chronic rhinitis, hay fever, acute or chronic sinusitis, nasal allergy, scarring from burns or trauma, Bell’s palsy, stroke, senile atrophic changes of upper and lower cartilages and nasal muscles, and other disorders that can affect function of the nasal valve, a surgeon may suggest septorhinoplasty, implants, or suspension sutures to relieve obstructed nasal breathing. Some of these patients, however, try to avoid surgical intervention, seeking alternative, noninvasive methods of treatment.

The authors hypothesized that the muscles dilator nasi, nasalis, and apicis nasi probably contribute to the prevention of collapse of the nasal valve. If the nasal valve is narrowed by weakness of these muscles, it is predisposed to collapse prematurely, resulting in symptoms of nasal blockage. The nasal muscles are numerous. The dilator naris anterior and the alar part of the nasalis muscles are active in nasal valve regulation, while the procerus, the anomalous nasi, and the transverse part of the nasalis muscles do not affect the function of the nasal valve, because they are located above the nasal bone and the upper lateral cartilage. The direct influence of the depressor septi and the levator labii superioris alaeque nasi on the nasal valve is not yet clear.

The purpose of this study was to investigate the outcome of transcutaneous and intranasal electric stimulation of nasal muscles in cases of nasal valve stenosis and/or collapse. Constant electric stimulation can enhance the...
muscle force.\textsuperscript{11} We hypothesized that if electric stimulation could enhance the muscle force of nasal muscles, it could provide a nonsurgical treatment for nasal valve stenosis and collapse. The study also investigated the most effective way to provide electric stimulation of the muscles involved in nasal valve function, introducing intranasal placement of electrodes.

Patients and methods

Patients. The patients were selected over a 4-month period for a prospective, randomized pilot study approved by the Medical Center Ethics Committee (outpatient department). Participants were selected from a cohort of 85 patients with symptoms of obstructed nasal breathing who wanted to avoid surgical treatment. Subjects for the study were selected based on their nasal anatomic changes: Patients with nasal valve collapse (or stenosis plus collapse) and positive Cottle maneuver were included in the study; patients with severe nasal valve stenosis and negative Cottle maneuver were excluded.

The Cottle maneuver is a simple test to detect any limitations in inhalation at the level of the ostium internum and the nasal valve by pulling the cheek laterally during gentle inhalation through the nose\textsuperscript{12,13} (figure 1). This sign is positive when inhalation noticeably improves with the maneuver.
Forty patients, all of whom demonstrated nasal valve stenosis with a positive Cottle maneuver and clinically evident nasal collapse, were divided into an electrotherapy group (n = 20) and a placebo group (n = 20) by a sealed-envelope, double-blind method.

The electrotherapy group included 20 adults, all Caucasians; 8 were women and 12 were men, ranging in age from 19 to 53 years (mean = 28.4 years). Before the study, each subject completed a questionnaire regarding his or her general health and medical history. Patients in the electrotherapy group had deviated nasal septum (12) and nasal valve collapse caused by trauma (3), previous rhinoplasty (3), and idiopathic weakness of nasal muscles (2).

The placebo group included 20 adults, all Caucasians; 7 were women and 13 were men, ranging in age from 20 to 55 years (mean = 27 years). These patients had deviated nasal septum (11) and nasal valve collapse caused by trauma (3), previous rhinoplasty (2) and septoplasty (1), and idiopathic weakness of nasal muscles (3).

None of the patients had nasal valve stenosis caused by irreversible anatomic alterations. All patients were examined by ENT physicians prior to participation in the study. Follow-up ranged from 10 to 12 months for patients in the electrotherapy group. No follow-up period was arranged for patients in the placebo group, because they underwent another treatment for their problems.

**Electrostimulation techniques.** Seven muscles were trained in the study: m. levator labii superioris alaeque nasi, m. anomalous nasi, m. nasalis, m. dilator naris posterior, m. depressor septi, m. dilator naris anterior, and m. compressor narium minor. All these muscles are superficial and are involved in nasal valve movements.

For electric stimulation we used the NeuroDyne 4 Channel MicroStim-1304D (NeuroDyne Medical Corp., Cambridge, Mass.) microcomputer-controlled muscle stimulator (classified as a Type II device by the FDA). It starts with a symmetric, biphasic waveform, which is then pulsed in trapezium-shaped impulses. This achieves good muscle contractions that patients experience as a soft and pleasant sensation. High-voltage therapy is recommended for treatment.11,14 We used a 40-Hz conditioning stimulation to enhance the muscle force. The stimulation level (range: 0.4 to 40 mA, peak-to-peak) was determined on an individual basis. The timer was set for 15 minutes. Pulse rate was set for 200 pulses per second (pps), with a pulse width of 600 μs.

For intranasal electric stimulation, we invented an intranasal electromyography (EMG) electrode tube. This device (figure 2) is a tube with an oblong shape designed to fill the nasal vestibule up to the nasal valve. It has two active electrodes and a wide breathing hole in the center. The device comes in small (10 mm), medium (12 mm), and large (14 mm) diameters. To achieve better electrode contact and to protect the mucosa from scratching, the
intranasal sensor should be used with a highly conductive electrode gel suitable for contact with mucosa (e.g., SIGNAGEL® from Parker Laboratories, Inc., Fairfield, N.J., or similar). Another variation of the electrode is a smaller (4 mm in diameter) tube with two active electrodes embedded in its plastic shell and no breathing hole (figure 3). This device can be used for direct stimulation of a specific small muscle.

Electrodes for transcutaneous stimulation were attached above the nasal muscles with the intranasal electrode gently inserted into a nostril (figure 4). The stimulation was performed under EMG control. Each patient received 10 weeks of treatment, which included 30 sessions of 15 minutes each every other day (3 times a week). Patients in the placebo group received the same procedure but without any actual electric stimulation.

Results
Subjective self-assessment data for nasal airflow were collected. Objective data were provided by:

- pre- and posttreatment observation;
- photographic analysis (nasal endoscopy) during the treatment and follow-ups (figure 5);
- anterior rhinomanometric evaluation (Rhinomanometer NR6, GM Instruments, Kilwinning, Scotland);
- acoustic rhinometry evaluation (A1 Acoustic Rhinometer, GM Instruments, Kilwinning, Scotland); and
- surface and intranasal EMG records (NS/3 4 Channel EMG, NeuroDyne Medical Corp., Cambridge, Mass.) before treatment, during treatments, and during follow-up visits.

Multivariate analyses of variance for repeated measures were used to analyze the results before and after training (mean interval, 41.3 weeks). For acoustic rhinometry and
rhinomanometry (table 1), data were also analyzed using the t-test. Values of $p<0.01$ were considered significant. After 10 weeks of treatment, 12 of the 20 patients in the electrotherapy group (60%) exhibited variable subjective improvement; in 8 cases (40%), the improvement was proved objectively. Seven of these patients (35%) had significantly increased airflow (i.e., bilateral inspiratory nasal flow increased, $p<0.001$). Nasal inspiratory resistance decreased significantly ($p<0.0001$) in 6 patients (30%).

In acoustic rhinometry, the first minimal cross-sectional area (1.Amin) represents a cross section of the nasal valve. Before treatment, this area varied among patients from 0.282 cm$^2$ to 0.632 cm$^2$ (mean = 0.483 cm$^2$, SD = 0.19) in a predecongestant test. The 1.Amin in the nasal valve area significantly increased in 5 of 20 patients (25%), with a mean of 0.748 cm$^2$ (SD = 0.265) in a predecongestant test.

Figure 5. Endonasal pictures of nasal valve (left nostril) are shown before treatment (A) and immediately after electric stimulation (B).
Although 3 other patients also presented some increase in the cross-sectional area of the nasal valve, it was not statistically significant.

EMG-recorded amplitude of muscle tension of the nasal muscles (in μV) increased significantly ($p<0.001$) in 10 patients (50%); that is, the strength of the nasal muscles was increased (table 2). Twelve patients (60%) did not show significant objective improvement in nasal functions and were recommended for endonasal surgery.

In the electrotherapy group, follow-up visits showed a rapid decline of positive results when treatment was discontinued (tables 1 and 2). One month posttreatment, nasal valve condition had declined in comparison to immediate posttreatment results. In 3 to 4 months, the nasal muscles had returned to almost pretreatment levels in patients who showed good results immediately following treatment.

In the placebo group, 7 patients (35%) indicated subjective improvement; and in one case (5%), the improvement was proved objectively. Thus, electric stimulation had significant benefit for patients in the electrotherapy group in comparison to patients in the placebo group ($p<0.001$). Patients from the placebo group were allocated to surgical or palliative treatment immediately after the study was finished.

No side effects of the application of electric stimulation were detected.

**Discussion**

In general, an electric muscle stimulator repeatedly contracts muscles by passing electric current through electrodes to relax muscle spasm, increase local blood circulation, prevent disuse atrophy, and maintain or increase range of motion. It also can be used for immediate postsurgical stimulation of muscles. In biofeedback training, muscle stimulation can be used for muscle reeducation. The positive effects of this treatment for facial muscles are well described. 15,16

Our results showed that electric stimulation of nasal muscles had significant benefit in the treated patients when compared to a control placebo group, in terms of muscle strength and nasal airflow. This benefit, however, did not last long. When treatment was discontinued, the condition of treated nasal muscles quickly returned to pretreatment levels. Observing these results, we cannot recommend electric stimulation as a substitute for surgical intervention or supportive devices in cases of nasal valve stenosis and/or collapse. Indeed, electric stimulation alone rarely provides long-term positive results. 17 We feel, however, that the positive results observed might be more beneficial if electric stimulation is combined with other methods of nasal muscle training, such as EMG biofeedback muscle training and/or an exercise program of specific nasal movements. Additional research is needed to determine the benefits from such combinations.

Another possible combination might be pairing electric stimulation with nasal springs. Nasal springs, particularly intranasal springs, are effective in treating nasal breathing problems. 18,20 Electric stimulation might be used for immediate postsurgical stimulation of muscles, and the patient later referred for placement of springs. Some of these devices are surgically implantable (intranasally); others are adhesively mounted (externally). Further research is needed to determine whether combining electric stimulation with nasal insert devices will improve breathing in cases of nasal stenosis and/or collapse.

---

**Table 1. Statistical analysis of rhinomanometric data before, during, and after treatment**

<table>
<thead>
<tr>
<th></th>
<th>Median</th>
<th>SD</th>
<th>p Value</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment</td>
<td>0.65</td>
<td>0.21</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediately after treatment</td>
<td>0.31</td>
<td>0.08</td>
<td>&lt;0.0001</td>
<td>8.7</td>
</tr>
<tr>
<td>After 1 month of treatment</td>
<td>0.39</td>
<td>0.09</td>
<td>&lt;0.001</td>
<td>6.9</td>
</tr>
<tr>
<td>After 3 months of treatment</td>
<td>0.58</td>
<td>0.18</td>
<td>&gt;0.05</td>
<td>1.34</td>
</tr>
<tr>
<td>Follow-up after 6 months</td>
<td>0.61</td>
<td>0.20</td>
<td>&gt;0.05</td>
<td>1.13</td>
</tr>
<tr>
<td>Follow-up after 9 months</td>
<td>0.62</td>
<td>0.31</td>
<td>&gt;0.05</td>
<td>1.12</td>
</tr>
</tbody>
</table>

**Table 2. Real mean* of electric activity of nasal muscles (in μV) recorded during normal breathing from the skin location (m. transverse nasalis)**

<table>
<thead>
<tr>
<th></th>
<th>Mean voltage</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment</td>
<td>4.36 ± 2.76</td>
<td></td>
</tr>
<tr>
<td>Immediately after treatment</td>
<td>8.22 ± 3.04</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>After 1 month of treatment</td>
<td>7.12 ± 2.95</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>After 3 months of treatment</td>
<td>5.26 ± 2.64</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Follow-up after 6 months</td>
<td>4.88 ± 2.54</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Follow-up after 9 months</td>
<td>4.42 ± 2.86</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

*Real mean = computer-calculated mean of a trial (raw) – 2.82 μV (mean electric tension of the relaxed nasal muscles)
Prior to this study, intranasal electric stimulation of nasal muscles combined with transcutaneous stimulation had never been used for the purpose of strengthening nasal valve walls and widening the cross-sectional area of the nasal valve, although electric stimulation of nasal mucosa was successfully used more than 30 years ago in patients with postoperative anosmia. It was also important for us to learn whether intranasal electric stimulation causes side effects; our study demonstrated no side effects of endonasal application of electric stimulation.

The intranasal electrode designed for this study was used to introduce variations in stimulation, aiming to involve as many nasal muscles as possible and, at the same time, to avoid stimulation of other groups of facial muscles. Our patients reported that use of the intranasal sensor was pleasant and did not irritate the nostrils. The intranasal electrode is a simple and inexpensive device that is compatible with existing transcutaneous electric nerve stimulators (TENS devices). We found it well suited for the treatment procedure. The smaller intranasal electrode is useful for delicate mucosa or for reaching a specific location close to the nasal valve.

In electric stimulation of nasal muscles, the stimulated area is small. Although electrode position and geometry are important for electric current distribution in tissues during electrotherapy, it has been argued that larger electrodes may make treatment more effective. Combined stimulation of nasal muscles through both transcutaneous and intranasal electrodes helps, we feel, to achieve a more even distribution of electric current in nasal tissues.

Conclusions
Sure relief of nasal valve stenosis and collapse cannot be achieved with treatment by electric stimulation alone, and it appears to have limited application. Electric stimulation of nasal muscles was shown to have only a short-term clinically beneficial effect on muscle strength and nasal airflow. However, electrotherapy may be useful as an additional mode of treatment for patients who want to avoid endonasal surgical intervention or external nasal supports. It is possible that electrotherapy can provide longer-term benefit if combined with other methods of treatment, such as biofeedback training. Although initial data suggest that the value of electric muscle stimulation in the treatment of nasal valve stenosis and/or collapse is limited, further research is encouraged to determine whether its combination with other nonoperative methods of treating nasal valve collapse will prove more effective.

References