Radiofrequency Energy for Denervation of Selected Facial Muscles: Clinical Experiences at Six Months

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Citation

Abstract
The goal of treatment with a unique, bipolar radiofrequency (RF) ablation device is to provide the surgeon with a minimally invasive and neurotoxin alternative, percutaneous approach to glabellar frowning. Therapeutic RF energy delivered via the probe tip area produces thermal effects that inhibit the designated nerve and produce selective conduction block. In our prospective study, significant glabellar frown reduction was immediately achieved in 80% of patients (40). All 40 of these patients maintained significant results at the 3-month time period, and 78% at the 6-month time period. Bruising and swelling were seen in 6% and 92% of patients respectively, mostly during the first week and resolving within two weeks. The cohort continues to be followed for longer term follow up. Further studies will help determine mass market viability of thermal denervation as an alternative to injectable nerve paralytic agents.

INTRODUCTION
Radiofrequency (RF) energy has been used successfully in cardiac arrhythmias and facial pain conditions such as trigeminal neuralgia. Recently, a unique bipolar RF ablation device has been developed to produce selective thermal denervation of the eyebrow depressor muscles including the corrugator and procerus muscles. The goal of the procedure is to provide the surgeon with a minimally invasive, percutaneous approach to glabellar frowning without the use of temporary neurotoxins, such as botulinum toxin A (Botox®). The procedure uses an RF needle and generator specifically designed for peripheral motor nerves (RELAXED EXPRESSIONS® System, BioForm Medical Inc., San Mateo, California; Figure 1). Thermal denervation can be performed in an office-based setting or in conjunction with aesthetic facial surgery.

Figure 1
Figure 1: RF device and probe. With its tip insulated, the probe contains a button control switch for stimulation current.
energy delivery was first reported by Hernandez-Zendejas and Guerrerosantos in 1994. Investigators found significant reductions in glabellar frowning with long term follow-up, up to 18 months. A similar study at Stanford University showed shorter term results. Current thermal energy application reflects improvements of this original concept by coupling sophisticated engineering with a thorough understanding of facial neuroanatomy.

TARGETED MUSCLE DENERVATION
This technology can be used to weaken only the efferent pathway of the distal branches of the facial nerve as they enter the glabellar musculature. The result of the thermal energy delivery is selective relaxation of the forehead depressor function. Physicians use the RF probe to both locate and incapacitate the lateral nerve to the corrugators as well as the angular nerve to the procerus and medial corrugator complex, inclusive of the depressor supercili, oblique head of the corrugator and medial head of the orbicularis in conjunction with the procerus muscle (Figure 2). Stimulation of this nerve results in visible superior-inferior movement of the brow complex.

Figure 2
Figure 2: Illustration of facial nerve pathways innervating the depressor muscles of the forehead. Area of stimulation is the lateral nerve of the corrugators, between the nerve to the orbicularis and the nerve to the frontalis and the angular nerve, formed from both the zygomatic and buccal branches of the facial nerve.

GUIDELINES FOR OPERATION
Preoperative counseling and marking. Patients who are selected for thermal denervation undergo a thorough consultation to understand their personal aesthetic features, asymmetries, alternative treatments, and risks. Patients are informed about the two sites where the RF probe will be inserted: the outer corner of the orbital rim for the lateral approach and the latero-superior aspect of the nasolabial groove for approach to the angular nerve. Oral analgesics and anxiolytics are provided as needed. Physicians may opt to choose additional levels of anesthesia for patient preference including intramuscular or intravenous agents to provide discomfort relief during the procedure. Options include, but are not limited to, intramuscular meperidine and intravenous administration of ketorolac, midazolam, and fentanyl.

After cleaning the facial skin, specific markings are made on the skin surface (Figure 3). Depths of the frown lines and the lateral extent of the corrugator muscle are marked. Another reference mark is made vertically on the forehead to identify the parasagittal plane of the midpupillary line.

Figure 3
Figure 3: Patient in preparation for treatment, markings of the creases and the lateral dimple of the corrugator muscle. Insertion sites for the RF probe are shown as circles at the lateral canthus area.

Thermal Energy Delivery. With surface anatomy marked, the surgeon uses an external nerve stimulator to localize the approximate site of the nerves being sought. The internal stimulator on the RF probe allows the surgeon to select the right depth, be as close to the nerve as possible, and distinguish between frontalis, corrugators, and orbicularis stimulation.

To move freely within the soft tissues of the face, local anesthesia is used at the insertion sites in conjunction with nerve blocks of the main sensory nerves. The RF probe is placed through the dermis and orbicularis muscle in the approach from the lateral canthas skin, then advanced just under the temporoparietal fascia to localize the desired
branch of the frontal nerve (Figure 4). Delivery of therapeutic RF energy to the probe tip area produces thermal effects that inhibit the nerve and produce a selective conduction block. At the conclusion of the thermal energy delivery a significantly diminished muscle activity is observed. Additional sites of RF energy delivery can then proceed in a distal direction.

**Figure 4**

Figure 4: Patient with probe in position after localization with the nerve stimulator. Application of therapeutic RF energy is controlled by a separate foot pedal control.

After the delivery to the target nerves, there is a selective preservation of frontalis function that produces an aesthetically pleasing brow elevation. More natural appearances of the forehead complex are achieved without overarching of the brows or brow ptosis sometimes seen with neurotoxin administration.

Postoperative procedures. Cool compresses are applied to the insertion sites and areas of thermal energy delivery to aid in the mitigation of swelling and bruising. Patients are instructed to sleep with their heads elevated above the level of the heart and to use oral acetaminophen for discomfort. No sutures are used; a simple band aid is applied for 24 hours.

**EARLY EXPERIENCES WITH SELECTIVE EFFERENT THERMAL DENERVATION IN A CLINICAL SETTING**

In our clinical setting, we have experience with over 100 patients who have been treated for thermal denervation. A cohort of fifty patients treated for selected denervation has been systematically followed, with results reported here. In addition, another 50 patients have been treated; their results are included in the adverse events section. In the first group, a prospective study using the RELAXED EXPRESSIONS RF generator and probe was begun in February 2007 with IRB approval. Post informed consent, adult patients with moderate to severe glabellar frowning with an absence of botulinum toxin A were treated through July 2007. Patients returned at monthly intervals to assess degree of glabellar frown reduction and any evidence of return to baseline frowning. A quantitative wrinkle score and pre- and post-treatment photography were used as efficacy assessment tools. Potential adverse events were monitored and reported during the study period.

Significant glabellar frown reduction was immediately achieved in 80% of patients (40). All 40 of these patients maintained significant results at the 3-month time period, and 78% at 6-months. In addition, browlift improvement was also noted due to protection of the frontalis muscle and denervation of the depressors.

Figures 5 and 6 are representative of our results obtained through RF energy delivery. Figure 5 shows a female patient with treatment of the lateral nerve to the corrugators, 7 months post treatment. Figure 6 shows a male patient with moderate frowning who underwent lateral corrugator treatment. This patient continues to maintain results at 8 months post treatment.

**Figure 5**

Figure 5a: Patient frowning maximally prior to treatment of lateral nerve to corrugators.
Adverse events. The thermal energy device and RF probe described herein have an excellent safety record in this practice; no serious adverse events have been observed in more than 100 cases. Edema is the most significant morbidity from the procedure, peaking 48-72 hours post procedure and then resolving within seven days. Ecchymosis is much less common. No cases of sensory neuromas or eyelid ptosis have been reported in our practice. In our 50-patient study described here, symptoms of bruising and swelling were seen in 6% and 92% of patients respectively, mostly during the first week. The majority of these minor adverse events resolved within two weeks. There was an absence of adverse events such as asymmetry, dysesthesia, burns, or scarring. The cohort continues to be followed for longer term follow up.

DISCUSSION

Results from this procedure represent the possibility of a significant advance in the treatment of glabellar furrowing. In a single treatment session, the RELAXED EXPRESSIONS System offers physicians selective targeting of the depressor muscles. The benefits are reduction of frown lines and addition of aesthetic lift to the brows. We have shown that significant reduction in glabellar frowning and improved brow aesthetics can be achieved with a new RF device at 3 months, 6 months, and beyond. Longevity of clinical effects appear related to the degree of hindrance to the motor (efferent) nerves and the dual incapacitance of the lateral innervation of the corrugators (nerve to corrugator) and the medial innervation of the glabellar complex (angular nerve).
Other applications will likely arise as adoption of this device accelerates. For example, thermal denervation may also be useful in an open surgery setting in which the patient is undergoing other procedures. At present, an optimized algorithm for RF treatment is currently in development by principal investigator. Further studies are required to determine the mass market viability of the procedure as an alternative to injectable nerve paralytic agents.

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Dr. Newman is in private practice in San Mateo, California, where the study was conducted. In addition, he is an Assistant Clinical Professor, Department of Otolaryngology Head & Neck Surgery, Stanford University (Palo Alto).

DISCLOSURES

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References

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