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NOVIELLE VOICE—KEEP ON TALKING, AND TALKING, AND . . .

“I have observed an immediate and lasting return to normal phonation.”

—Peter Belafsky, MD

“Novielle Gel is a valuable addition to our armamentarium.” —Edward Damrose, MD

When the vocal cords no longer medialize, there is loss of voice and an increase in voice effort. However, the vocal cords may be volumetrically enhanced, resulting in a return of approximation and normal phonation.

Rosen, *et al.* evaluated the effectiveness of calcium hydroxylapatite (CaHA) vocal fold augmentation for glottal incompetence in a large, multi-center trial of 68 patients. Fifty percent of the procedures were done in the office. The design was an open label, prospective clinical study. Patient satisfaction at six months showed that 56 percent had significantly improved voice and 38 percent reported moderately improved

voice. The authors concluded, “Preliminary results in this large cohort of patients demonstrate excellent clinical results.”¹

Similarly, Rees and colleagues (including Dr. Belafsky) at University of California at Davis Medical Center reviewed the clinical results of the thyrohyoid approach for in-office vocal fold augmentation with calcium hydroxylapatite. They studied patients who had undergone the procedure during a two-year span from June 2005 to June 2007. Fifty-one procedures were performed, with two (six percent) self-limited complications. In 13 percent, the procedure was aborted due to inability to achieve an appropriate injection angle. They concluded, “In-office vocal fold augmentation with the use of thyrohyoid approach demonstrates excellent clinical results. It has become our technique of choice for vocal fold medialization with the patient under local anesthesia in the office setting. Complications are rare.”²

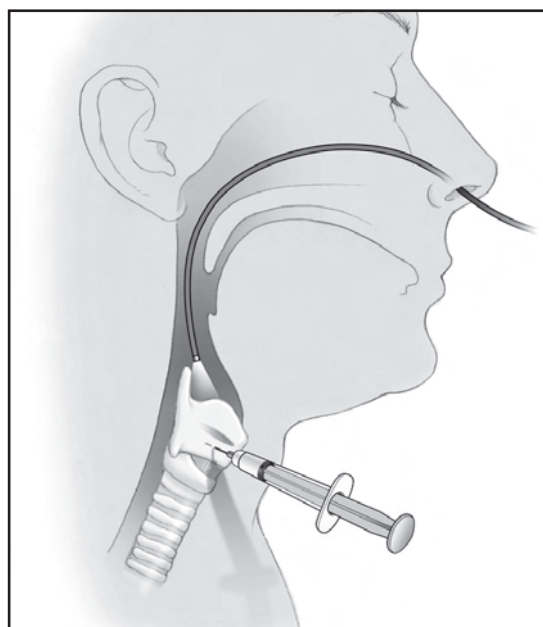


Figure 1: Anterior approach with visualization.

Injection into the vocal fold requires optimizing several important parameters:

- The material should be flexible, but firm enough to stay where it is injected
- The patient's voice should be returned to acceptable quality
- The injection process should be relatively simple
- The effects should be lasting
- Immunogenicity of the injected material should be low
- There should be acceptance of the procedure within medical reimbursement systems

Novielle Voice™ is a family of products created from a unique technology platform known as an **Acrylomer™ Complex**. The Acrylomer Complex is a high-strength, intermediate duration gel that melds well to native tissue. Post injection, the vocal fold remains flexible. Pre-clinical studies have shown that the **Coapt® Systems** gel material alone demonstrates more endurance than other vocal fold products that contain particles. **Novielle™ Voice** is available in two FDA-cleared formulations to meet your patients' needs: **Novielle Voice Gel** and **Novielle Voice GelPlus**.

Novielle Voice Gel contains high-quality synthetic components, including the Acrylomer Complex. It is created from water, mannitol, glycerin, and a proprietary hydrogel polymer, then pH neutralized. It is bioabsorbable and completely biocompatible. Pre-clinical and early clinical data demonstrate that the Gel remains in place, is benign in tissue, and maintains its integrity for nine to 12 months—longer than competing products. Over time, the Complex is metabolized by oxidation and excreted as carbon dioxide.

MEDICAL CODING

CPT (procedural) codes include:

- 31570 Laryngoscopy, direct, with injection into vocal cords, therapeutic;
- 31571 With additional use of operating telescope or microscope; and
- 31513 Laryngoscopy, indirect, diagnostic, with vocal cord injection.

ICD-9 (diagnostic) codes include:

- 478.30 Paralysis of the vocal cord;
- 478.33 Bilateral, partial paralysis;
- 478.31 Unilateral, partial; and
- 478.32 Unilateral, complete paralysis.

Figure 3: Related CPT and ICD-9 codes.



Figure 2: Ergonomically-designed syringe contains 1.3 cc of **Novielle Voice**.

In addition to the components of **Novielle Voice Gel**, **Novielle Voice GelPlus** contains calcium hydroxylapatite (CaHA) particles. The particles constitute 20 to 25 percent of the material by volume. An optimal percentage of particles balances material flexibility and extends its longevity. Duration of clinical effectiveness is expected to persist up to 24 months.

What about the injection process? As visualized in the accompanying graphics, the approach to injection is straightforward. **Novielle Voice** is packaged with two 25 gauge needles for percutaneous use. A reusable transoral needle is available as an option, and a disposable transoral needle is in development.

What about acceptance within the medical coding systems? Vocal fold injection is an accepted procedure. There are ICD-9 and CPT codes that readily apply to the procedure. For a listing of these codes, see Figure 3.

What about physician acceptance? Investigators are enthused. Peter Belafsky, MD observes, “Early results are very promising.” Edward Damrose, MD states, “I am impressed with our preliminary results and I trust that **Novielle** will prove useful in addressing

the longer-term needs of our patients with glottic insufficiency.”

With some competing products, the duration of effectiveness may be as short as a few weeks. Longer duration of effect is important in the majority of patient populations. Counter-balancing this are potential concerns about immunogenicity from “permanent” products. **Novielle Voice** seeks the best balance: low immunogenic potential with lasting benefit to the patient.

So, for the best balance of the factors important to you and to your patients, choose **Novielle Voice**. Your patients will keep talking, and talking—about you. ♦

To Learn More

To learn more about **Novielle Voice** and new customer evaluation programs, call toll free 1-800-963-7670; email to info@coaptsystems.com; or visit the company's Web site at www.coaptsystems.com

References:

1. Rosen CA, *et al.* Vocal fold augmentation with calcium hydroxylapatite (CaHA). *Otolaryngol Head Neck Surg.* 2007 Feb;136(2):198-204.
2. Rees CJ, Mouadeb DA, Belafsky PC. Thyroid vocal fold augmentation with calcium hydroxylapatite. *Otolaryngol Head Neck Surg.* 2008 Jun;138(6):743-6.