Preliminary Results of a New Temporary Vocal Fold Injection Material

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Summary: Temporary vocal fold injection is a valuable procedure for vocal fold paralysis or paresis of uncertain permanency and as a trial augmentation to decide the value of vocal fold augmentation. A new material made from glycerin, carboxymethylcellulose, and water has recently been developed for temporary vocal fold augmentation. Eleven patients underwent vocal fold injection for the treatment of glottal incompetence with this material. The duration of effectiveness of this injection material was 2 to 3 months depending on the injection amount. This new material satisfies several requirements for an ideal temporary vocal fold injection material in terms of injectability, convenience, duration of effectiveness, and safety. The authors conclude that this new material is a good option for temporary vocal fold augmentation.

Key Words: Temporary vocal fold injection—Injection laryngoplasty—Gelfoam—Carboxymethylcellulose—Vocal fold augmentation—Vocal fold paralysis.

INTRODUCTION

Historically, the oldest treatment for glottal insufficiency is vocal fold injection. Since Brunings injected paraffin into a vocal fold in 1911,[1] various injection materials have served as the treatment of glottal insufficiency. In recent years, vocal fold injection for treating glottal insufficiency has gained popularity because of its convenience, noninvasiveness, and the availability of new injection materials.[1–3] Duration of augmentation is one of the most important factors for selection of a vocal fold injection material. The main purpose of temporary vocal fold injection is to restore laryngeal function during the process of recovery from acute unilateral vocal fold paralysis or paresis. In addition, vocal fold injection may be performed as a trial augmentation to see whether permanent vocal fold augmentation will be successful.[4]

Gelatin (Gelfoam; Pharmacia and Upjohn Company, Kalamazoo, MI) has been successful in temporary vocal fold augmentation since 1978 even though several limitations exist in terms of injectability, convenience, and postinjection vocal fold vibration.[5] Before Gelfoam, glycerin was injected via indirect

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laryngoscopy, liquid gelatin,[6] and sesame oil.[7] The duration of their effectiveness was less than 1 week and usually only 2 to 3 days. Schramm et al[5] first used Gelfoam and reported it remained for 8 to 10 weeks of duration. Since the introduction of Gelfoam, no other injection material has been reported for temporary vocal fold augmentation. Various forms of collagen-based materials have served in temporary vocal fold augmentation, but they have been not formally studied or approved by the U.S. Food and Drug Administration (FDA). To date, only a paucity of information exists concerning materials other than Gelfoam that could serve as temporary vocal fold injections materials.

This article describes a new material for temporary vocal fold augmentation with several distinct advantages compared with Gelfoam.

MATERIALS AND METHODS

The vocal fold injection material is a gel type of material made by Bioform Medical Incorporated (San Mateo, CA) and is FDA-approved for vocal fold augmentation. The material composition consists of water (82.3%), glycerin (14.5%), and sodium carboxymethylcellulose (3.2%) (CMC). CMC is an organic polymer that has served for over 20 years as a carrier for injectable pharmaceutical medicines and a common food additive that makes food gelatinous. CMC is an FDA-approved food and medical component.

This material is also a gel carrier for calcium hydroxylapatite (Radiesse; Bioform Medical, Inc.) that has recently served as a permanent vocal fold augmentation material.[8] This material is provided in a sterile 1-mL syringe and is colorless, odorless, and has a gelatinous consistency similar to hair gel (Figure 1).

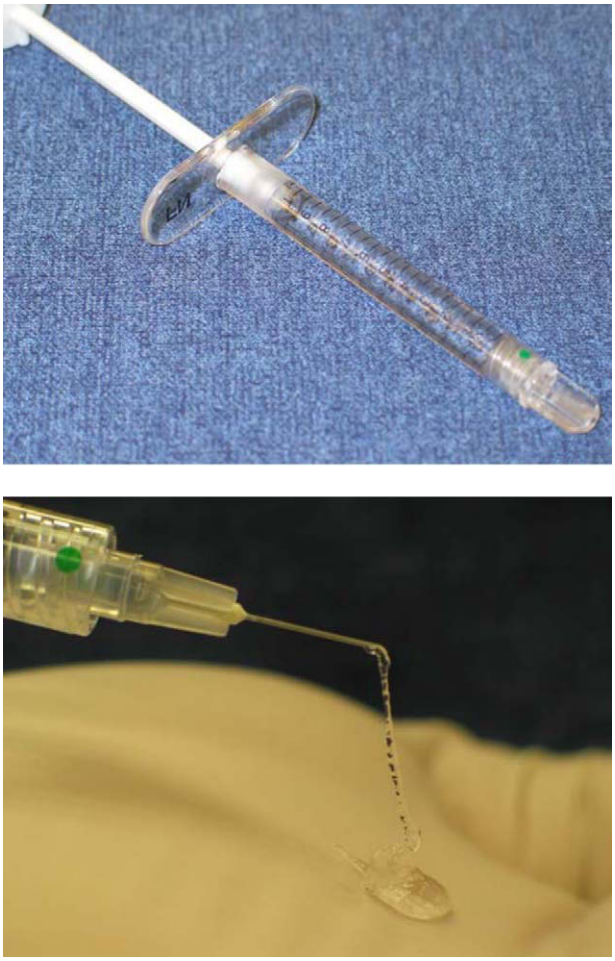

FIGURE 1. New temporary vocal fold injection material. The injection material is provided in a 1-mL sterile plastic syringe (upper picture). It is colorless, odorless, and has gelatinous consistency. It is easily extruded through a 27-gauge, 2-cm needle (lower picture).

Subjects

From February to April 2004, 11 patients with dysphonia from glottic insufficiency were injected consisting of 6 men and 5 women. The age of the patients ranged from 20 to 78 years with a median age of 54 years. All patients underwent a comprehensive, multidisciplinary preoperative voice evaluation.[9] Six patients were injected in the operating room, and five were injected in the clinic. In the operating room, each patient underwent general anesthesia and suspension microlaryngoscopy. With a 25-gauge, 30-cm vocal fold injection needle, the material was injected deep and lateral into the vocal fold.

Office injections were performed with the patient seated upright. Local anesthesia with 4% Lidocaine was topically applied on the vocal folds with an Abrahams cannula. We used a transnasal flexible laryngoscope (Endo Eye Model ENF-V, Olympus America Inc, Melville, NY) for visualization of the vocal folds. Transoral vocal fold injection was performed with a 25-gauge, 30-cm needle. Injection