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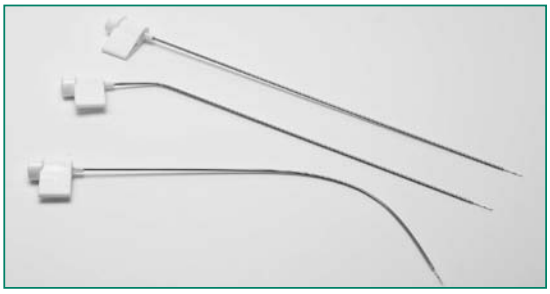
RECENT STUDIES VALIDATE SAFETY, EFFICACY OF CaHA AND CMC FOR GLOTTAL INSUFFICIENCY TREATMENT

RADIESSE® For Vocal Cord Medialization Safely Improves Voice Handicap In Both Long- and Short-Term Formulations

When medialization of the vocal folds is required due to the onset of vocal dysfunction, patients may opt for a temporary solution rather than undergo surgery. To serve this need, Merz Aesthetics (previously BioForm Medical, Inc.), a wholly-owned subsidiary of Merz Pharmaceuticals GmbH, provides two FDA-approved formulations, one for short term augmentation (RADIESSE® Voice Gel) and one for long-term (RADIESSE® Voice).

RADIESSE® Voice Gel and RADIESSE® Voice is supplied in a 1.0 cc syringe ready for use.



RADIESSE® Voice Gel and RADIESSE® Voice is supplied with a malleable trans-oral injection needle, or a percutaneous injection needle (not shown).

RADIESSE® Voice Gel
(Carboxymethyl Cellulose - CMC)
RADIESSE Voice Gel is an injectable implant containing synthetically derived polymers, suitable for 1-2 month, short-term vocal fold augmentation, in patients where reversible nerve damage is suspected, or in patients wishing a short term augmentation before making a decision to have a long term augmentation done with RADIESSE Voice.

RADIESSE® Voice
(Calcium Hydroxylapatite - CaHA)
RADIESSE Voice is an injectable implant containing synthetic calcium hydroxylapatite (CaHA) microspheres with a diameter range of 25 to 45 µm, suspended in an aqueous gel carrier. These consistently shaped and sized particles have proven safe and biocompatible while allowing gradual tissue growth for a long lasting augmentation shown to be effective up to 12-24 months.

Two notable, recent studies have examined the use of these synthetic implantable materials—carboxymethyl cellulose (CMC) and calcium hydroxylapatite (CaHA)—for vocal cord medialization.

Study Shows Carboxymethyl Cellulose (CMC) "Viable, Safe, Efficacious" For VFI
In a paper presented at the Annual Meeting of the Triologic Society in April 2011, "The Safety and Efficacy of Carboxymethyl Cellulose in the Treatment of Glottic Insufficiency," researchers concluded that **"**Carboxymethyl cellulose (CMC) is a viable, safe, and efficacious material for the temporary treatment of glottic insufficiency in vocal fold immobility and hypomobility, with minimal risk of permanent adverse voice outcomes."[1] This study was the first to examine the clinical safety and efficacy of carboxymethyl cellulose for vocal fold injection (VFI).

The study reviewed all patients who underwent CMC injection from three independent sites—University of Pittsburgh School of Medicine, Georgia Health Sciences University, and New York University School of Medicine—in a one-year period from May 2009 to May 2010. Voice outcomes in the form of voice handicap index-10 (VHI-10) and complications from injection were recorded, and 78 patients with VHI-10 results from 1 to 8 weeks

after CMC injection were evaluated. Patients showed an improvement in perceived voice handicap, as indicated by an overall decrease in VHI-10 scores.

Among the study's five contributors were Gregory N. Postma, M.D., Department of Otolaryngology, Center for Voice, Airway and Swallowing Disorders at Georgia Health Sciences University; and Clark A. Rosen, M.D., Department of Otolaryngology - Head and Neck Surgery, University of Pittsburgh Voice Center at University of Pittsburgh School of Medicine. Both Dr. Postma and Dr. Rosen state that they now regularly use RADIESSE formulations in their practices.

"We keep both RADIESSE compounds available in the office," reports Dr. Postma. "The RADIESSE Voice Gel gives us a reliable 2.5 to 3 months of improved glottic closure in patients. It's very convenient and easy to use. Injecting a temporary substance to improve the closure of the larynx allows us to see how a patient responds, and if they respond favorably, we can do something much more durable or permanent."

Dr. Rosen says, "The carboxymethyl cellulose product is my most common and frequently used temporary vocal fold augmentation material. We use it in patients when we're not certain whether they will have recovery after acute onset of vocal paralysis, such as after a viral illness or a thyroid surgery." He adds that CMC is "extremely well-tolerated and has a low complication rate."

Study Validates Long-Term Effectiveness of Calcium hydroxylapatite (CaHA) For VF Augmentation

Finding an ideal long-term injectable for vocal fold (VF) augmentation has been a goal of those who treat Glottal insufficiency (GI). Calcium hydroxylapatite (CaHA) has been available commercially since 2003 as RADIESSE Voice and has met many of the requirements of the ideal VF injectable, including being readily available, biologically inert, and passable through a small-gauge needle.

RADIESSE® Voice and RADIESSE® Voice Gel are pre-filled in a latex-free polycarbonate syringe in a volume of 1.0 cc.

Vocal Fold Injection Products
RADIESSE® Voice 1.0 cc latex-free polycarbonate syringe
RADIESSE® Voice Gel 1.0 cc latex-free polycarbonate syringe
Trans-oral Injection Needle 25 gauge, 1 cm needle tip 25 cm long, 16 gauge malleable needle shaft
Percutaneous Injection Needle 25 gauge, 1.5 in. long Non-coring Huber point

However, its rheologic properties and longevity remained uncertain until the results of a recent study validated its long-term effectiveness.(2)

The two authors of this study, Thomas L. Carroll, M.D. of Tufts Medical Center, and Dr. Rosen, already mentioned as a contributor to the previously discussed CMC study, came to the conclusion that the benefit of CaHA as a VF augmentation material was found to last an average of 18.6 months in the majority of patients.

Three complications were identified among 108 injections performed since April 2004, and all required operative removal of the CaHA. No complication was due to the CaHA material itself, and the technical problems encountered could have been seen with other injectables. The authors warn that attention should be paid to avoid superficial injection and subglottic injection. Their paper reports that "With appropriate experience and confidence by the injecting physician, CaHA is safe to inject in the office with use of local anesthesia. CaHA is a long-term injectable with an excellent track record that does not appear to warrant concern for permanent or late complications."(2)

Dr. Carroll remarks that he has been using the RADIESSE Voice and RADIESSE Voice Gel formulations in his practice since 2007. "I choose different materials based on the duration of benefit desired," he states. "There are other materials you can inject in an office setting, but for long-term benefits, RADIESSE Voice is easy to pull off the shelf and flows readily through a small needle, which makes an in-office injection easier."

According to Dr. Rosen, the RADIESSE formulations represent "by far the longest-lasting vocal fold injection material that can be used safely with a very minimal risk and complication rate available to otolaryngologists in the United States." Drs. Carroll and Rosen determined that most patients who had a good result from a trial vocal fold injection subsequently benefitted from a permanent augmentation procedure.(3)

RADIESSE formulations are readily available, easily injectable, and come packaged with an easy-to-use needle and injection system. The Merz Global Voice Business, a part of Merz Aesthetics Inc., is dedicated to bringing physicians and their patients safe, effective medical products for use in the ENT markets.

For more information about RADIESSE® Voice, RADIESSE® Voice Gel and other Merz Aesthetics products, please call Merz Aesthetics at 1-866-862-1211, visit the website at www.radiesse-voice.com, send an email to voice@merzaesthetics.com.

RADIESSE is a registered trademark of Merz Aesthetics, Inc.

References

1. Amin MR, et.al. The Safety and Efficacy of Carboxymethyl Cellulose in the Treatment of Glottic Insufficiency. Presented April 2011 at the Annual Meeting of the Triologic Society, Chicago, Il.
2. Carroll TL, Rosen CA. Long-term results of calcium hydroxylapatite for vocal fold augmentation. *Laryngoscope* 2011; 121:313–319.
3. Carroll TL, Rosen CA. Trial vocal fold injection. *J Voice*. 2010; 24:494-498.