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RADIESSE® VOICE INJECTION—PROVEN SAFE AND EFFECTIVE FOR GLOTTAL INSUFFICIENCY

Results of the largest, prospective study in injection laryngoplasty, utilizing Radiesse Voice (Calcium Hydroxylapatite, CaHA), found Radiesse Voice to be a beneficial and practical treatment for glottal insufficiency.[1]

March 2004 through June 2005, 100 patients were enrolled at 10 independent sites (half at academic medical centers, half in private practice, two in Europe) for this international, multi-center, open-label clinical trial.

List of Investigators CaHA (Radiesse Voice)	
UNITED STATES	
Tim Anderson, MD	Boston, MA
Gary Shaw, MD	Kansas City, MO
Lee Reussner, MD	Lawrence, KS
Sanford Archer, MD	Lexington, KY
Felicia Johnson, MD	Little Rock, AK
Roy Casiano, MD	Miami, FL
Robert Sataloff, MD	Philadelphia, PA
Clark Rosen, MD	Pittsburgh, PA
EUROPE	
Jean Abitbol, MD	Paris, France
Marc Remacle, MD	Yvoir, Belgium

Ninety-three patients received Radiesse Voice for vocal fold paralysis, vocal fold paresis, or vocal fold atrophy; 62 were available for follow-up analysis at 6 and 12 months. Investigators also plan a 24 month review. The vast majority of patients had unilateral vocal fold paralysis or glottal insufficiency with mobile vocal folds (vocal fold atrophy or vocal fold paresis).

At six months 84% of the patients reported moderate or significant voice improvement. At 12 months 73% of the patients reported they were greatly or significantly improved and 84% reported they were greatly improved, significantly improved or somewhat better. The cohort reported no major complications, e.g., airway distress.

Principal Investigator, Clark A. Rosen, M.D., F.A.C.S., Director of the University of Pittsburgh Voice Center and Associate Professor of Otolaryngology at the School of Medicine, notes, “One impressive finding was the substantive number—about half of the patients—who were treated in the office. The success rate for Radiesse Voice treatments in-office was equivalent to that of operating room procedures.” Dr. Rosen added, “to date, for the length of time of follow-up, we have found Radiesse Voice safe and effective.”

Consistently Favorable Outcomes (Objective Voice Testing and Clinical Measures)

Statistically significant and sustained voice function was found in a high number of patients—revealed through objective voice assessment measures—Maximum Phonation Time (MPT), S:Z ratio, and laryngeal diadochokinesis (L-DDK).

Clinical-based outcome measures included Con-sensus Assessment Perceptual Evaluation V (CAPE-V), clinician-based voice assessment, and stroboscopy research instrumentation (SRI). Baseline SRI readings were predominately open (50%) contrasted to post-procedure, predominately closed readings—47% at six months and 35% at 12 months.

Indication of Closure
as Scored by the Stroboscopy Research Instrument[1]

DURATION OF CLOSURE	BASELINE (n = 66)	6 MONTHS (n = 62)	12 MONTHS (n = 62)
Predominately closed	3%	47%	35%
Closed/open	15%	31%	49%
Predominately open	50%	19%	8%
Always open	32%	3%	8%

Patient-based measures (Voice Handicap Index (VHI) and VHI-10 scores) were also statistically significant.

High Patient and Physician Satisfaction Levels

Radiesse Voice yielded both high patient clinician satisfaction levels:

- Patients were surveyed at each time interval following vocal fold injection. The majority of patients reported that they were greatly or significantly improved.
- Physicians also rated patient's overall capabilities and function following each injection and 83% of the patients were rated as showing improvement (greatly improved, significantly improved, somewhat better).

Dr. Rosen notes that, "in selected patients, an in-office injection of Radiesse [Voice] is a treatment option that has been unavailable in the past." Clinician satisfaction includes the ease of use and convenience of Radiesse Voice. Supplied in 1cc syringe, Radiesse Voice requires no preparation or mixing, and does not need refrigeration. Radiesse Voice also does not require patient allergy testing or patient fat harvesting and poses no risk of infection transmission.

Study Results Support Clinical Practice Findings

Clinical trial results complement the experiences of practitioners. Two physicians, offering extensive experience with Radiesse Voice for Vocal Fold Augmentation (VFA), share their favorable patient outcomes.

Gregory N. Postma, M.D., Director, Center for Voice and Swallowing Disorders and Professor, Department of Otolaryngology at the Medical College of Georgia, uses Radiesse Voice for 85% of his injection-VFA patients. Based on six years of clinical practice with Radiesse Voice, Dr. Postma highlighted two ideal patient groups for Radiesse Voice treatments: (1) patients with "a unilateral, immobile vocal fold and (2) elderly patients with vocal fold atrophy."

Drawing from six years of clinical practice experience with Radiesse Voice, Peter C. Belafsky, M.D., Ph.D., M.P.H., Assistant Professor of Otolaryngology, School of Medicine, University of California, agrees with Dr. Rosen that injection-VFA with Radiesse Voice is "proven safe and effective." He notes that such injection techniques are best for small and medium glottal gaps.

The **only** injection laryngoplasty product cleared by the FDA for VFA, Radiesse Voice contains synthetic CaHA microspheres (25µm to 45 µm diameter) suspended in an aqueous gel carrier. Dr. Postma explains that the "key thing is to inject it deep in the muscle—if injected superficially, patients do not do well." Radiesse Voice is biocompatible, permitting effective augmentation up to 12 to 24 months. The product does not ossify and has shown no clinical evidence of implant migration or long-term granulomas.

VOCAL FOLD AUGMENTATION PRODUCTS
Radiesse® Voice 1.0 cc syringe
Radiesse® Voice Gel 1.0 cc syringe
Trans-oral Injection Needle 25 gauge, 1 cm needle tip 25 cm long, 16 gauge malleable needle shaft
Precutaneous Injection Needle 25 gauge, 1.5 in long Non-coring Huber point

To Learn More

BioForm Medical is dedicated to bringing doctors and their patients' safe and effective medical products for use in the ENT, plastic surgery, dermatology, and urology markets. To learn more about Radiesse Voice and other BioForm Medical products, call 1-866-862-1211, visit the Web site at www.radiessevoice.com, or email to info@bioformmedical.com.

Radiesse Voice contains no animal- or human-derived components, and remains soft after injection. It is indicated for vocal fold insufficiency including paralysis, paresis—partial or temporary nerve damage, presbylarynx, and unilateral or bilateral voice fold insufficiency.

Radiesse Voice Gel is an injectable implant containing synthetically derived polymers, and no CaHA microspheres. It is suitable for patients with short-term (1 to 2 months) VFA where reversible nerve damage is suspected—or for patients desiring to first try a shorter-term solution.

References:

1. Rosen, C.A., J. Gartner-Schmidt, et.al. Vocal fold augmentation with calcium hydroxylapatite (CaHA): Twelve month report. Presented on May 19, 2006 at the Annual Meeting of the American Bronco-Esophageal Association, Chicago, IL.