

A Randomized, Bilateral, Prospective Comparison of Calcium Hydroxylapatite Microspheres versus Human-Based Collagen for the Correction of Nasolabial Folds

STACY SMITH, MD,* MARIANO BUSO, MD,† MARLA McCLAREN, MD,‡ AND LAWRENCE S. BASS, MD§

BACKGROUND Current soft tissue fillers are a compromise between ease of use, duration of correction, reactivity, and cost. A product utilizing calcium hydroxylapatite (CaHA) is currently being used as a soft tissue filler.

OBJECTIVE The objective was to compare the efficacy and safety of CaHA microspheres versus human-based collagen for the correction of nasolabial folds.

MATERIALS AND METHODS Four centers enrolled 117 subjects with moderate to deep nasolabial folds. Subjects received CaHA on one side of the face and human collagen on the other. Up to two touch-ups were allowed. A blinded panel of experts evaluated subject photographs from initial and follow-up visits.

RESULTS Seventy-nine percent of subjects had superior improvement on the CaHA side through 6 months ($p < .0001$). For optimal correction, significantly less volume and fewer injections were needed for CaHA than for collagen ($p < .0001$). Adverse event rates were comparable, with some increase in bruising and edema for CaHA-treated sides. Adverse event duration was similar for both groups and generally resolved within 14 to 21 days.

CONCLUSION This CaHA-based product gives significantly longer-lasting correction of nasolabial folds compared to human collagen. Less total material and fewer injections are required. The adverse event profile of the product is similar to the collagen-based product.

Radiesse soft tissue filler, supplies, and equipment for photographic documentation for this study were provided by BioForm Medical (San Mateo, CA). The investigators were paid an honorarium to conduct the study. Drs Busso and Bass have received compensations for presentations about Radiesse to the medical community.

Soft tissue fillers are a growing category of minimally invasive therapy for the treatment of age-related changes of the face.¹ After the introduction of bovine collagen in 1981, the search has continued for a longer-lasting, well-tolerated material. United States commercial acceptance and use has shown a significant trend toward longer-lasting dermal filler products.² The list of materials currently used in the United States, both approved and nonapproved, includes bovine collagen, autologous fat, hyaluronic acid (HA), polylactic acid, human collagen from recombinant technology, cadaveric human collagen, silicon, various acrylics or acrylates, and calcium hydroxylapatite (CaHA).

CaHA (Radiesse, San Mateo, CA) is a mineral complex with a molecular weight of 502 Da. It is found in the human as a normal component of bones and teeth. CaHA has been used as implant or coating material in dentistry for more than 20 years.³ Additionally, it has been used to coat prosthetic joint components to assist in fixation to normal bone.⁴ During this time CaHA has proven to be an inert, reliable, well-tolerated material.⁵

To create a material with ease of injection, CaHA has been fashioned into 25- to 45- μ m microspheres and suspended in an aqueous gel carrier composed of carboxymethylcellulose, glycerin, and water. This

*Therapeutics Clinical Research and UCSD Division of Dermatology, San Diego, California; †Private Practice, Coconut Grove, Florida, and University of Miami, Miami, Florida; ‡Private Practice, Sacramento, California; §Department of Surgery, NYU School of Medicine, New York, New York

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