Controlled, Randomized Study of Pain Levels in Subjects Treated with Calcium Hydroxylapatite Premixed with Lidocaine for Correction of Nasolabial Folds

Ellen Marmur, MD,* Lawrence Green, MD,† and Mariano Busso, MD‡

BACKGROUND Calcium hydroxylapatite (CaHA) has been administered after nerve block injection of anesthetic agents.

OBJECTIVES This prospective, randomized, split-face, single-blind study (50 subjects) assessed the pain reduction, safety, and effectiveness of premixing CaHA with 2% lidocaine for the treatment of nasolabial folds (NLFs).

METHODS AND MATERIALS Subjects were randomized to receive treatment with CaHA alone in one NLF (control) and with CaHA premixed with lidocaine in the other NLF (treatment). Subjects completed pain assessments using a validated visual analog scale at specified time points immediately after injection, 1 hour after injection, and 1 month later. Subjects also indicated relative pain experience and preference assessments. Investigators completed aesthetic assessments at 2 weeks and 1 month. Subjects and investigators recorded adverse events.

RESULTS Subjects reported statistically significantly less pain in the treatment fold than in the control fold and expressed unanimous preference for the treatment injection over the control. Aesthetic results were essentially equivalent for both treatments.

CONCLUSION Investigators concluded that CaHA premixed with lidocaine results in significant pain reduction during dermal filler injection while maintaining the aesthetic improvement of CaHA without lidocaine and demonstrating comparable local transient adverse events for treatment and control.

BioForm Medical (San Mateo, CA) provided the soft tissue filler, lidocaine, and other necessary supplies used in this study. All authors are members of the Bioform Medical Education Faculty.

In clinical trials and commonly in regular clinical use, calcium hydroxylapatite (CaHA; Radiesse, BioForm Medical, San Mateo, CA) has been administered after nerve block injection of some anesthetic agent, usually lidocaine. One published study has recently reported the use of CaHA mixed with lidocaine.[1] In that study, the authors reported how the mixture appeared to reduce subject discomfort considerably during hand rejuvenation. Other studies on the use of CaHA combined with lidocaine or with lidocaine and epinephrine for treatment of the aging hand have also confirmed the original report from Busso and Applebaum.[2–4] In addition, published in vitro experiments[5] indicate that, when Radiesse is mixed with 2% lidocaine, the mixture does not separate or settle for at least 24 hours after mixing. Moreover, the admixture is homogenous from the front to the back of the syringe after approximately 10 back-and-forth movements of CaHA to lidocaine and lidocaine to CaHA syringes.[5]

In contrast to anecdotal reports, published studies on treatment of the hand, and in vitro experiments, this controlled investigation of CaHA combined with

*Department of Dermatology and Cosmetic Surgery, Mount Sinai Medical Center New York, New York; †Department of Dermatology, School of Medicine, George Washington University, Washington, District of Columbia; ‡Department of Dermatology, University of Miami, Coral Gables, Florida

 • Published by Wiley Periodicals, Inc. • ISSN: 1076-0512 • Dermatol Surg 2010;36:309–315 • DOI: 10.1111/j.1524-4725.2009.01435.x