P3506

Comparative effectiveness of two nonanimal derived hyaluronic acid dermal gels (NADGs): Diepoxyoctane cross-linked NADG/lidocaine versus 1,4-butandiol diglycidylether cross-linked NADG for nasolabial fold augmentation

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Background: Addition of an anesthetic directly to the gel formulation of a dermal filler is the latest approach towards reducing injection-related pain. We report the effectiveness of a new diepoxyoctane cross-linked nonanimal derived hyaluronic acid—based dermal filler formulated with 3 mg/mL lidocaine (DEO-NADGL) versus 1,4-butandiol diglycidylether cross-linked NADG (BDDE-NADG) for correction of nasolabial folds (NLFs).

Methods: In this prospective, multicenter, split-face design, evaluator-masked trial, 107 subjects were randomly injected with DEO-NADGL in the right or left NLF, with the contralateral NLF injected with BDDE-NADG. Initial treatment was ≤ 3 mL with touchup ≤ 1 mL/NLF permitted at the day 14 follow-up visit. Effectiveness assessments by unmasked investigators and masked independent reviewers were performed on day 14 and at 1, 4, 6, 9, and 12 months using a validated, 6-point categorical rating scale with corresponding photographs of wrinkle severity.

Results: DEO-NADGL was demonstrated to be noninferior (inferiority rejected; $P = .006$) to BDDE-NADG at the 6-month primary effectiveness endpoint and at all other time points through 12 months posttreatment. Per the investigator and independent reviewer, the mean 6-month severity ratings were 2.01 and 2.04 for DEO-NADGL versus 1.97 and 1.98 for BDDE-NADG. The average injection volume for initial treatment was 1.45 mL of DEO-NADGL and 1.37 mL of BDDE-NADG ($P = .008$) and 0.82 and 0.79 mL (NS) for touch-up, respectively. The effects of both treatments persisted for ≥ 1 year without retreatment in $\geq 50\%$ of treated subjects. Subject global assessment also showed that both treatments were comparable across all time points. Eighty-eight of 107 subjects (82%) experienced adverse events involving both sides of their face, which were primarily transient and mild to moderate in severity. Rates of adverse events after DEO-NADGL and BDDE-NADG injection were not significantly different with regard to bruising, pain/tenderness, redness, firmness, inflammation, and swelling.

Conclusions: DEO-NADGL, a hyaluronic acid lidocaine-containing product, provided excellent correction of NLF wrinkles, comparable in magnitude and duration to BDDE-NADG for 1-year posttreatment. DEO-NADGL was well tolerated with a safety profile similar to BDDE-NADG.

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P3507

An evaluation of antiwrinkle effects of a novel cosmetic containing niacinamide using the guideline of Japan cosmetic industry association

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Numerous cosmeceutical products have been focused on various clinical signs on photoaging skin including dyspigmentation, fine wrinkles, and roughness. In 2006, the Japan Cosmetic Industry Association (JCIA) published guidelines for the evaluation of antiwrinkle cosmeceuticals. Niacinamide is known to have effectiveness on sallowness, wrinkling, red blotchiness, and hyperpigmented spots in aging skin. In this study, we have evaluated antiwrinkle effects of a new cosmetic containing niacinamide using the JCIA guidelines. A randomized, placebo-controlled, split-face study was performed in 30 healthy Japanese females who had wrinkles in the eye areas. The tested cosmetic containing 4% niacinamide, was applied on wrinkles of one side for 8 weeks, and a control cosmetic without niacinamide on another site. Antiwrinkle effects were evaluated with two methods: (1) overall assessment of wrinkle grades in the guideline, and (2) average roughness of skin surface (Ra value) using skin replica. This cosmetic showed marked and moderate improvement in 64% of the subjects with a significant difference as compared with the control site ($P < .001$). Wrinkle grades in the tested area significantly reduced more than pre-application ($P < .001$) and the control ($P < .001$). Reduction in Ra value on the tested area was more than preapplication ($P < .01$) and the control site ($P < .05$) with significant differences. Only one subject stopped the study with minimal irritation. These results indicated that the tested lotion was well tolerated and may be an optional preparation for the treatment of wrinkles in the eye areas.

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P3508

Exploratory investigation to increase the action halos of similar doses of botulinum toxin type A in the treatment of compensatory hyperhidrosis: A case report

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Background: Compensatory sweating is one of the most common postoperative complications after thoracic sympathectomy. Although botulinum toxin type A (BT-A) is already an established treatment for hyperhidrosis, there are few studies using this therapeutic option for the treatment of compensatory hyperhidrosis.

Objective: The objective of this investigation was to check if different dilutions and depths of a BT-A injections are able to increase the action halos, to allow the treatment or large areas of the body with less injections.

Case report: We report a case of a 41-year-old white female who presented with compensatory hyperhidrosis on the trunk and back plus relapse of axillary hyperhidrosis after thoracic sympathectomy.

Methods: Three vials of 500U BT-A were diluted in 0.9% of saline solution in three different volumes (2, 4, and 6 mL). Five units of each diluted vial were injected in three different depths (2, 3, and 4 mm) on the patient's back. Furthermore, an additional point was injected with 5U of BT-A diluted in 0.06 mL was applied at 4 mm depth followed by 60 seconds of local massage. The evaluation of the size of the action halos by the Minor test was performed after 7, 28, and 55 days after the injections.

Results: After 7, 28, and 55 days of the injections, visual assessment of the action halos resulted from 10 different techniques seem to be similar and did not present significant differences, also when the application were followed of local massage, in the back of the patient.

Conclusions: BT-A is safe and effective in the treatment of compensatory hyperhidrosis and differences of 2- to 4-mm depth as well as 2- to 6-mL dilution did not show significant differences in the action halos, even when the injection was followed by massage in this area. All the areas around the injected points were regular, round, or slightly oval under the Minor test. The injections at the midline resulted in smaller halos and the large halo was observed in the injection of 500U BT-A diluted in 6 mL and injected at a depth of 4 mm.

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P3509

Digital three-dimensional imaging for quantifiable measurement of lip augmentation with a 24 mg/mL hyaluronic acid gel implant

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Background: Lip augmentation is a popular cosmetic procedure, but evaluating the effects of lip augmentation has usually been done using nonquantified variables—until now. Digital software in combination with three-dimensional (3D) images has been used in a clinical study of lip enhancement with a 24 mg/mL hyaluronic acid gel implant to quantitatively measure lip height, projection, surface area, and volume.

Methods: Enrolled subjects in this multicenter, open-label study were asked to make a reusable dental mold by biting down on a sheet of warm wax at the initial visit. This mold was used at each follow-up visit to consistently orient the subject's jaw and lips for the 3D photographs taken before and after treatment in the vermilion, vermilion border, Cupid bow, philtral columns, and oral commissures. Exploratory analyses of effectiveness of lip measurements obtained from 3D digital images included vertical red lip heights, anterior lip projection, lip surface area, and volume change estimates. The volume change was estimated through proprietary software incorporating results from before and after images that were aligned via facial landmarks.

Results: All of the measurements of lip height demonstrated increases from baseline to each timepoint through 12 weeks. Overall, the mean surface area of the lips increased from 6.83 cm^2 at baseline to 8.77 cm^2 at week 2 (33% increase) and 8.28 cm^2 at week 12 (25% increase). Examples of the 3D images will be presented.

Conclusions: This study demonstrates the usefulness of 3D imaging in determining objective, quantifiable changes in lip height, projection, surface area, and volume following treatment with a 24 mg/mL hyaluronic acid gel implant.

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