P8097

A novel "system" to aid the prevention of stretch marks during pregnancy: Results of a clinical trial, using a combination of a maternity support device and synergistic cosmetic formulations

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Abstract: A first trial using a novel combination of synergistic topical creams and a specifically padded, skin support device in the prevention of Striae Gravidarum.

Background: Striae gravidarum occur during pregnancy in 50% to 90% of women and can be a cause of considerable cosmetic concern leading to significant psychological distress. The striae initially appear as red or purple lines that gradually fade, leaving white, thin skin. There are no treatments to date that have been shown conclusively to prevent the development of striae.

Aim: To asses a novel combination of synergistic topical creams and a specifically padded, skin support device using a novel alignment technology called Vector in the prevention of striae gravidarum.

Method: Women in weeks 12-14 of their first pregnancy were recruited from the Instituto de Maternidad Y Ginecologia, Tucuman, Argentina. The control group consisted of women who used no creams or device and the treatment consisted of women who used a combination of the device and day gel and night cream. The skin support device was worn only during the day; the participants were recommended to use the day gel twice daily and the night cream once, at bedtime. Photographs were taken at the end of the first trimester and at term and assessed by 6 independent clinicians. A visual scale was determined with 0 being no striae and 10 being multiple striae.

Results: The incidence of striae gravidarum in the control group was 66%, while in the incidence in the treatment group was 34%. The median severity score of the control group was 7, whereas in the treatment group it was 4.

Conclusion: The systems combination of the specifically padded, skin support device and creams has shown a significant reduction in the development of striae gravidarum. The contribution to significance of each component has not been trialed.

Commercial support: None identified.

P8434

A randomized, double-blind, split-face comparative study of a novel irritation-control retinol formulation versus tretinoin in photodamaged skin

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Retinol has been shown to improve the appearance of photodamaged skin when applied topically, and is generally considered to be approximately 10 times less potent than tretinoin. To assess this theory, a novel sustained-release retinol complex was specifically developed with a blend of antioxidants and antiinflammatory agents for optimal irritation control in 3 concentrations to correspond to commercially available tretinoin strengths. A randomized, double-blind, split-face comparison study was conducted to compare the 3 concentrations of the irritation-control retinol formulation (ICRe) including 0.25%, 0.5%, and 1.0%, against the respective 3 strengths of tretinoin (0.025%, 0.05% and 0.1%) in subjects with moderate to severe facial photodamage. Subjects were randomized into 3 groups: group 1 (ICRe 0.25% vs. tretinoin 0.025%); group 2 (ICRe 0.5% vs. tretinoin 0.05%); and group 3 (ICRe 1.0% vs. tretinoin 0.1%). Within each group, subjects were randomized to apply ICRe on one half of the face (left or right) and tretinoin on the other facial side, for a duration of 12 weeks. Clinical evaluations for efficacy and tolerability, as well as standardized digital photographs were conducted at baseline and at weeks 4, 8 and 12. Sixty-five subjects completed the 12-week study (group 1: n = 24, group 2: n = 20, and group 3: n = 21). At week 12 in all treatment groups, both ICRe and tretinoin produced statistically significant improvements from baseline in all efficacy parameters, including overall photodamage, fine line-s/wrinkles, coarse lines/wrinkles, skin tone brightness, mottled pigmentation and tactile roughness (all $P < .001$). There were no significant differences in efficacy between ICRe and tretinoin in these efficacy parameters. Mean tolerability scores remained mild or below for both treatments at all visits and there were no significant differences between treatments. Results from this comparison study suggest that this sustained-release retinol complex containing multiple agents for optimal irritation control provides comparable improvements to tretinoin in the appearance of photodamage.

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P8488

A prospective split-face double-blind randomized placebo-controlled trial to assess the efficacy of vitamin C and ferulic acid serum postfractional ablative laser for skin rejuvenation

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Abstract: The topical use of vitamin C is considered to be effective to stimulate fibroblast activity and hasten wound healing. We investigated the clinical efficacy of vitamin C, vitamin E, and ferulic acid serum in wound healing and for improvement in patient discomfort following fractional ablative laser surgery.

Objective: To determine whether vitamin C, vitamin E, and ferulic acid serum shows efficacy immediately after fractional laser surgery and in the following week after laser skin resurfacing in improving the severity and duration of postoperative pain, erythema and wound healing.

Methods: Fifteen patients received a topical application of vitamin C, vitamin E, and ferulic acid serum to randomly selected facial halves immediately after undergoing full-face fractional laser skin resurfacing with 2940 nm erbium laser and twice a day for 1 week after the laser treatment. All laser procedures were performed by a single operator. Clinical improvement was evaluated by participants an two blinded physicians by reviewing the comparative photographs. The rate of re-epithelialization, duration of pain, erythema, and presence of complications were recorded immediately after the procedure and 1 hour, 24 hour, 2, 3, 4, 5, 7, 30, 60 days posttreatment.

Results: The facial halves administered vitamin C, vitamin E, and ferulic acid serum observed less pain duration in 60 % of the patients 1 hour after the initial application. The erythema was more intense in the treated facial halves in 50% of the patients in the day 1. The average time to reepithelialization was 3 days in the treated facial halves and 4 days in the untreated facial halves. No side effects were observed. Additional tests are ongoing to determine dermal remodeling by noninvasive imaging analysis.

Conclusions: We believe that application of vitamin C, vitamin E, and ferulic acid serum after fractional ablative laser skin resurfacing will make the procedure less painful, enhance the natural wound healing process, and more quickly return the patient to a pretreatment level of activity.

Commercial support: None identified.

P7884

A randomized, evaluator-blinded, controlled study of the effectiveness and safety of small particle hyaluronic acid plus lidocaine (SPHAL) for lip augmentation

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Background: Voluminous lips are associated with youth and beauty, and are an important aesthetic feature of the lower face. Small Particle Hyaluronic Acid plus Lidocaine (SPHAL) has the same chemical composition as the 20 mg/mL family of injectable hyaluronic acid gels currently approved in the United States and differs in that the SPHAL gel particle is smaller. Thus, it may be ideally suited for lip augmentation.

Objective: To compare the safety and effectiveness of SPHAL versus no treatment for lip augmentation.

Methods: Adults (n = 221; 18-65 y) scoring 1-2 on the validated Medicis Lip Fullness Scale (MLFS; 1 = very thin, 5 = very full) for both lips were randomized (3:1) to SPHAL or no treatment. Treatment success was defined as a blind-evaluated MLFS increase = 1 point at week 8. Secondary effectiveness assessments (lip fullness augmentation and subject satisfaction) included the Global Aesthetic Improvement Scale (GAIS) score at weeks 8, 12, 16, 20, 24 weeks; and 2, 4 weeks after optional 6-month retreatment/treatment. Safety was assessed throughout the trial (adverse events [AEs], standardized assessment of lip function).

Results: Overall, significantly more subjects treated with SPHAL for the upper lip (80.2% v 11.9%), lower lip (84.2% v 18.4%) and upper and lower lips combined (76.1% v 11.6%) were treatment successes at week 8, compared with subjects receiving no treatment ($P < .001$ for all outcomes). GAIS response rates based on subject and investigator assessments demonstrated significant improvement at week 8 (90.1% and 96.5%, respectively [$P < .001$]) and week 24 (75.6%, and 83.8%, respectively [$P < .001$]), for upper and lower lips combined. Treatment emergent AEs (TEAEs) were less likely to occur in control subjects, compared with subjects treated with SPHAL. Most common anticipated TEAEs in the initial SPHAL treatment group included lip bruising, swelling, and pain, and were mostly mild or moderate in severity. No anticipated device-related AEs or significant changes in lip function were noted; few serious AEs were reported, and all unrelated to treatment. In general, TEAEs were transient in nature and resolved in approximately 15 days or less.

Conclusion: Treatment with SPHAL was effective and well tolerated for augmentation of lip fullness with improvement evident up to 6 months.

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