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Evaluation of the safety and satisfaction of the advanced collagen products dermicol-P35 27G and 30G

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Objectives: The aims of this study were to (1) evaluate the safety of treatment with Dermicol-P35 27G and 30G in patients seeking soft tissue augmentation and (2) assess the satisfaction of patients and clinicians with the aesthetic results of these treatments.

Methods: This analysis was part of a multicenter data collection program in the United States and Europe. Health care professionals completed one questionnaire form for each patient at each visit, which included initial, follow-up, and touch-up visits. Immediate adverse events and patients' and health care professionals' satisfaction with treatments were recorded. A total of 1838 questionnaires were completed.

Results: A total of 1628 patients were treated at initial visits. Of these patients, 676 (41.5%) were treated with Dermicol-P35 27G, 873 (53.6%) were treated with Dermicol-P35 30G, and 79 (4.9%) were treated with a combination of Dermicol-P35 27G and 30G. The majority of patients were female (89.8%) and white (86.3%). The mean (min, max) patient age was 49.2 years (21, 82). The most popular treatment sites were nasolabial folds (37.0%), followed by upper and/or lower radial lip lines (18.4%), and corner of mouth lines (17.1%). The majority of patients (44.4%) were treated with topical anesthesia before the procedure. The mean (min, max) volume of product used was 1.14mL (0.1, 6.0). Evaluation ofi mmediate adverse events demonstrated slight or no erythema in 1436 (88.2%) patients, slight or no edema in 1456 (89.4%) patients, slight or no bruising in 1428 (87.8%) patients, and slight or no tenderness in 1437 (88.3%) patients. Severe erythema, edema, bruising, and tenderness were reported in eight (0.5%), six (0.4%), 40 (2.5%), and 10 (0.6%) patients, respectively. Most severe adverse events were downgraded in severity or were resolved during patient follow-up. After the initial visit, 1524 (93.6%) patients were satisfied or very satisfied with the aesthetic results. Similarly, 94.4% of health care professionals were satisfied or very satisfied with the results post-procedure. Comparable adverse event evaluations and satisfaction scores were recorded at follow-up and touch-up visits.

Conclusions: Most patients experienced slight or no adverse events immediately after treatment with Dermicol-P35 27G and/or 30G. Patients and health care professionals reported high levels of satisfaction with these products.

Commercial support: Sponsored by Johnson & Johnson.

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Clinical evaluation of a microablative/fractional carbon dioxide laser for the treatment of photodamage and scars

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Objective: Fractional (microablative) resurfacing with a CO_2 laser beam has shown promise in the treatment of photodamaged skin. This study evaluates the efficacy and safety of a microablative CO_2 laser device for the treatment off acial rhytids, hyperpigmentation, enlarged pores, skin laxity, and acne scarring.

Methods: Twelve subjects (11 women, aged 48.3 1 12.9 years of age, skin types II-IV) enrolled in the IRB-approved study. Subjects presented with hyperpigmentation (n ¼ 10), skin laxity (n ¼ 4), enlarged pores (n ¼ 10), fine lines and wrinkles (n ¼ 2), acne scars (n ¼ 1), and both photodamage and acne scars (n ¼ 2). Each subject was treated twice with the Affirm CO_2 (Cynosure, Westford, MA) microablative laser device at 3- to 5-week intervals. Results were evaluated at 1 week, 1 month, and 3 months after the final treatment.

Results: At 1 and 3 months, improvement (51-75%) was noted in hyperpigmentation, skin laxity, enlarged pores, fine lines and wrinkles, and overall appearance. Improvement in acne scars was observed, but not graded. Eleven subjects would recommend the treatment to family and friends. Posttreatment erythema lasted 4 days and subjects resumed normal activities 2 days after treatment. Serious adverse effects were not observed.

Conclusion: The microablative CO_2 laser device improves photodamaged skin with minimal downtime and adverse effects, and may also improve acne scars.

Commercial support: 100% sponsored by Cynosure

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The clinical safety and histologic changes associated with the use of a novel high-intensity focused ultrasound device for noninvasive body sculpting

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Background: A novel high-intensity focused ultrasound (HIFU) device is being developed for noninvasive body sculpting (LipoSonix, Bothell, WA). Preclinical animal studies have shown that HIFU selectively reduces the volume of adipose tissue without injuring adjacent tissue. Gross pathology over an 8-week period revealed excellent resorption of damaged adipose tissue. HIFU has not been associated with undesirable biochemical or metabolic changes.

Objective: This nonblinded study was designed to establish the safety and histologic changes following HIFU treatment for the noninvasive removal of subcutaneous adipose tissue in human subjects.

Methods: The HIFU device consists of an ultrasound transducer emitting a variable energy field capable of generating temperatures $ 568C (133 8F) in 1second and almost instantaneous coagulative necrosis. An X-Y positioning system enables precise HIFU delivery to targeted areas while preventing excessive overlap of successive treatment areas. Subjects were healthy women scheduled for elective abdominoplasty. Patients were treated with one offi ve different HIFU energy levels (N ¼ 16) or two treatments using one to two HIFU energy levels performed 4 weeks apart (N ¼ 3). Patients were evaluated after 1, 2, 3, 4, 7, 28, and 56 days. Abdominoplasty was performed 1 to 18 weeks following treatment. Safety measures included physical examinations and clinical chemistry, hematology and coagulation parameters, and reported adverse events. Before abdominoplasty, diagnostic ultrasound confirmed that the ablated areas were confined to the subcutaneous adipose tissue.

Results: Histology revealed discrete areas of coagulative necrosis limited to the targeted adipose tissue. Lesions did not affect the overlying dermis or underlying fascia or cause injury to intervening or surrounding tissues. There was no injury to major vascular and nervous tissue outside the targeted treatment areas. Most treated tissue was resorbed within 8 to 12 weeks and 95% was resorbed after 18 weeks. The majority of reported adverse events were mild and consisted of transient local discomfort. No significant changes in baseline hematology or clinical laboratory values occurred including plasma lipids.

Conclusions: HIFU is a novel and promising technology for removing unwanted subcutaneous adipose tissue and may represent a safe treatment option for noninvasive abdominal body sculpting.

Commercial support: Sponsored by Medicis Technologies.

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An analysis of the long-term safety data of repeat administrations of BoNT-A for the treatment of glabellar lines

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Background: A new US botulinum neurotoxin type A formulation (BoNT-A; Dysport [abobotulinumtoxinA]; Medicis Aesthetics, Scottsdale, AZ) has recently been approved by the US Food and Drug Administration for the treatment of moderate to severe glabellar lines.

Objective: The primary objective of this study is to assess the long-term safety of repeat administrations of BoNT-A in the treatment of glabellar lines, including the long-term safety of variable dosing based on gender and muscle mass, and any substantial changes to the risk/benefit profile.

Methods: This report summarizes an interim analysis of an open-label extension study following 1414 subjects who underwent retreatment with BoNT-A during a 24-month period after completing participation in at least one off our phase III BoNT-A studies. Patients were retreated with either 50 U of BoNT-A or a variable dose of 50, 60, 70, or 80 U of BoNT-A based on muscle mass if they entered from the variable-dose phase III study. The dose was divided among five injection points in the glabellar region. No subject received more than eight treatments of 50 U during this 24-month analysis period or four treatments with variable dosing (because of the timing of the studies). No retreatments were performed unless at least 85 days had elapsed between treatments and the glabellar line severity score was reassessed as moderate or severe. Patients were followed up at 7, 14, and 30 days after each injection, then monthly until retreatment, study completion, or early termination. Endpoints for this repeat administration phase were adverse events (AEs) and vital sign changes. Antibody testing was performed and is addressed in a separate report.

Results: Of the 1414 patients, 856 (61%) experienced at least one AE. The incidence of AEs in patients in the variable dose groups (17-33%, depending on dose and gender) was comparable to that of patients in the fixed-dose groups (48% of males, 58% off emales). Most reported treatment-emergent AEs (TEAEs) were mild (72%) or moderate (19%); 5% of TEAEs were rated as severe. All but three severe TEAEs, and the overwhelming majority (86%; 2727 of 3167) of all TEAEs, were considered not related or unlikely to be related to the study treatment. One serious AE in one patient (mild eyelid ptosis) was judged probably related to treatment. Another (myasthenia gravis in the immediate vicinity of the eye) was judged to be possibly related to