Evaluation of a Novel Topical Anesthetic Agent for Cutaneous Laser Resurfacing: A Randomized Comparison Study

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BACKGROUND. A variety of topical anesthetic compounds are available for use prior to minimally or moderately painful cutaneous laser procedures. A novel lidocaine/tetracaine-based peel has recently been developed that is applied to the skin as a cream and, once air dried, is removed as a flexible film that may prove useful in providing adequate dermal anesthesia for dermatologic laser surgery.

OBJECTIVE. To evaluate the clinical efficacy of a novel topical anesthetic peel preparation for induction of local anesthesia prior to full-face cutaneous laser resurfacing.

METHODS. A series of 20 patients undergoing full-face single-pass CO₂ laser resurfacing were enrolled in a double-blind institutional review board (IRB)-approved study protocol in which two different topical anesthetic products were compared. A 4 cm × 4 cm area of one cheek was randomized to receive the novel lidocaine/tetracaine-based cream peel (S-Caine) while a 4 cm × 4 cm area on the contralateral side received EMLA cream with occlusion for 30 minutes prior to laser treatment. Patients rated the level of pain experienced during laser treatment on each side using a visual analog scale. Independent assessments of observed discomfort and side effects were recorded.

RESULTS. Pain scores were significantly lower using the novel lidocaine/tetracaine-based cream peel formulation compared with the EMLA cream. Side effects associated with application of the anesthetic peel were limited to mild transient erythema and skin blanching.

CONCLUSION. A novel topical lidocaine/tetracaine-based cream peel provides safe and effective dermal anesthesia for single-pass CO₂ laser skin resurfacing.

T. S. ALSTER, MD, AND J. R. LUPTON, MD HAVE INDICATED NO SIGNIFICANT INTEREST WITH COMMERCIAL SUPPORTERS.

THE USE of topical anesthetics is helpful during a variety of cutaneous surgical and laser procedures, as they typically provide effective dermal anesthesia with rapid onset of action and minimal side effects. Several agents are currently available for topical anesthesia including a eutectic mixture of lidocaine derivatives (EMLA cream; Astra Pharmaceuticals, Westborough, MA) and other lidocaine-containing formulations (e.g., ELA-Max, Ferndale Laboratories, Ferndale, MI).1-4

The S-Caine peel (Zars, Inc., Salt Lake City, UT) is a novel eutectic mixture of lidocaine and tetracaine in a cream base that is applied to the skin which upon drying forms a flexible film that can easily be peeled away. This investigational study was conducted to evaluate the efficacy of S-Caine peel compared to EMLA cream in providing adequate anesthesia prior to cutaneous laser resurfacing.

Materials and Methods

Twenty patients (3 men, 17 women; mean age 48.5 years; skin phototypes I-IV) were enrolled in this double-blind institutional review board (IRB)-approved study. Patients with a known sensitivity to lidocaine or tetracaine or women who were pregnant or breast-feeding were excluded from study entry.

A 4 cm × 4 cm patch of each cheek was randomized to receive either EMLA cream or S-Caine peel. Both investigators and patients were blinded to which cream was used on each cheek, as a third party (nurse investigator) applied and removed the creams. The creams were applied evenly to the areas and left intact for 30 minutes prior to the procedure. The EMLA cream was occluded under plastic while the S-Caine cream was air dried to form a flexible film. Upon removal of the anesthetic creams from the skin, the involved areas were immediately examined for evidence of erythema, edema, skin blanching, or other adverse effects (Figure 1).

All patients underwent single-pass CO₂ laser resurfacing to the 4 cm × 4 cm cheek areas by a single operator (T.S.A.) using the UltraPulse 5000C (Coherent Laser Corp., Palo Alto, CA) with an 8 mm² computer pattern generator (CPG).
Results

Nineteen patients (95%) experienced significantly less pain on the S-Caine peel-treated cheek than on the EMLA-treated cheek. Mean patient pain ratings using the visual analog scale on the EMLA- and S-Caine-treated sides were 5.25 and 2.66, respectively (Figure 2). Ninety-five percent of patients (19/20) reported adequate pain relief for the laser procedure with the use of S-Caine, compared to 20% (4/20 patients) with the EMLA cream.

The blinded investigator and independent assessor observed similar degrees of patient discomfort. On the EMLA-treated side, both the investigator and independent assessor each rated one of 20 (5%) patients as having no pain at all. The investigator rated 17 patients (85%) with moderate pain and 2 patients (10%) with mild pain on the EMLA-treated side. The independent assessor rated 2 patients (10%) with severe pain, 13 (65%) with moderate pain, and 4 (20%) with mild pain on the EMLA-treated side. On the S-Caine-treated side, both the investigator and independent assessor rated 6 patients (30%) as having no pain at all. The investigator further rated 14 patients (70%) with mild pain, whereas the independent assessor rated 12 patients (60%) with mild pain and 2 (10%) with moderate pain. There were no reports of severe pain experienced by patients on the S-Caine peel treatment side.

Side effects related to application of the topical anesthetic creams were mild and self-limited, including transient erythema, edema, and skin blanching. The EMLA-treated side was associated with erythema and edema in 10% of patients, with mean grades of 0.15 and 0.10, respectively. Skin blanching was seen in 90% of patients on the EMLA-treated cheek, with a mean grade of 1.15. The S-Caine-treated side demonstrated mild erythema in 75% of patients (mean grade 0.90), no edema, and skin blanching in 15% of patients (mean grade 0.15). Application of these creams was generally well tolerated by patients, with no serious adverse sequelae.
Discussion

An increasing number of physicians are performing outpatient cutaneous laser resurfacing. With recent trends focusing on less aggressive laser resurfacing procedures (e.g., single-pass CO2 laser ablation, nonablative laser remodeling), novel topical anesthetic agents are being sought to obviate the need for intravenous sedation. Although there are several topical anesthetic agents that are effective in alleviating the pain associated with moderately painful cutaneous procedures, most are limited by a necessarily prolonged preoperative application time (average 1–2 hours).1-4

Our double-blind study demonstrated superior clinical efficacy of a novel lidocaine/tetracaine-based peel (S-Caine peel) compared with EMLA cream applied under occlusion for 30 minutes. It is quite possible that relative efficacy of the two products would have been equivocal with a longer application time (e.g., 1 hour); however, previous dose-response studies with S-Caine peel determined its optimal application time to be 30 minutes.5 Since one pass of the CO2 laser at standard treatment parameters penetrates tissue to a depth of 20–60 μm,6-10 adequate dermal anesthesia to this level was achieved in the majority of patients studied. Treatment evaluations from both patients and independent assessors demonstrated a significant decrease in pain on the S-Caine-treated cheek compared with the EMLA-treated cheek. Its low incidence of side effects coupled with its rapid onset of action also makes the S-Caine peel a favored treatment alternative.

This novel anesthetic may prove useful for a variety of cutaneous surgical and laser procedures. In fact, based on the study reported herein, we have successfully used the S-Caine peel as the sole anesthetic in several patients undergoing full-face ablative laser skin resurfacing. It may be necessary in some patients to additionally use injectable local or nerve block anesthetics in those anatomic areas (such as the eyelids) that are more technically difficult to achieve adequate cream application and absorption of anesthetic.

Conclusion

The S-Caine peel can provide safe and effective dermal anesthesia for single-pass CO2 laser skin resurfacing. Side effects related to the use of this formulation are minimal, including mild transient erythema and skin blanching. Further study is needed to define the role of the S-Caine peel in other cutaneous procedures.

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References


Commentary

The development of new cosmetic procedures and advancements in laser technology have vastly increased the number of in-office procedures being performed by dermatologists. While many of these lunch-time procedures can be performed quickly with essentially no downtime, treatment-associated discomfort may be a concern for patients. Some individuals cannot tolerate botulinum toxin injections or the use of filler substances without the use of topical anesthesia.

Longer-wavelength lasers with millisecond pulse durations and higher fluences are now being employed for the treatment of larger diameter vascular lesions, hair removal, and nonablative laser rejuvenation. While the introduction of a variety of epidermal cooling methods has provided significant analgesia, the adjunctive use of topical anesthetic preparations is often required for these procedures. In order to achieve deep dermal anesthesia, these topical anesthetics often require application times of 1 hour or longer.

In this article Alster and Lupton demonstrate the induction of effective local anesthesia for one-pass ablative laser resurfacing, following a 30-minute application of a novel lidocaine/tetracaine-based anesthesia cream. This material forms a flexible film after air drying and does not require occlusion.

The rapid induction of local anesthesia and easy applicability of this substance should decrease the morbidity of a variety of cosmetic and dermatologic procedures, and improve patient acceptance.

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