



Center for Clinical & Cosmetic Research
Center for Cosmetic Enhancement

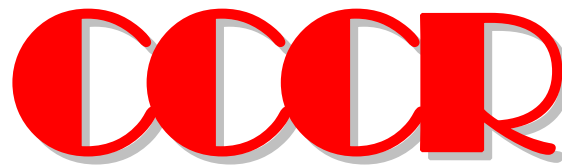
Abstract

February 3, 2005

Pilot clinical study to evaluate the efficacy of the Transdermal Ionto device to minimize pain and discomfort associated with dermatological cosmetic procedures

Mark Nestor, MD, PhD and Alex Cazzaniga
Center for Cosmetic Enhancement, Aventura, Florida

The Transderm Ionto (Mattioli Engineering, Italy S.p.A.) is a medical device that allows transferring active substances and drugs into the skin without the use of needles using a new method called “Dermoelectroporation”. The Transderm Ionto use special shaped pulsed currents to transfer alternately positive and negative ions of active substances into the skin. The purpose of this pilot study was to evaluate the efficacy of the Transdermal Ionto device to allow the penetration of an anesthetic solution into the skin and comparing with the standard methodology used for pain management of a dermatological cosmetic procedure. The abdomens of ten volunteers were used for this study. Each abdomen was divided into 4 zones of 8cm x 8cm and each zone was randomly treated by either A) topical anesthetic cream containing 5% lidocaine under occlusion for 60 minutes, B) Transdermal Ionto lidocaine hydrochloride 2% – 1:100,000 epinephrine after a light microdermabrasion with vibration level 2 and between 3 to 5 mA for 5-7 minutes dispensing 0.6ml/hr of solution via the Precision Liquid Dispenser (PLD), C) Transdermal Ionto dispensing water via the PLD at same rate after a light microdermabrasion with vibration level 2 and between 3 to 5 mA for 5- 7 minutes (control) and D) no pretreatment (control). Two of the 10 patients were sensitive to these treatment parameters and the treatment was done at 1-3 mA for the same length of time. Each volunteer used a 0 to 10 point visual scale to grade the sensation of pain. Pain sensation was induced using a radiofrequency device at energy levels ranging from 53 to 115 J/cm². The mean pain scores obtained were 4.3 for the area treated with the topical anesthetic cream; 3.4 for the Transdermal Ionto with the anesthetic solution; 6.7 for the



Center for Clinical & Cosmetic Research
Center for Cosmetic Enhancement

Transdermal Ionto with water and 7.6 for the untreated area. The results obtained from the Transderm Ionto with lidocaine were statistical significant vs. the topical anesthetic cream ($p < 0.01$) and all the other treatments ($p < 0.001$). The results clearly show that the Transdermal Ionto device can effectively allow the penetration of lidocaine into the skin at those settings and can be used as an anesthetic device to minimize potential pain and discomfort during dermatological cosmetic procedures. These results warrant future studies with different parameters for optimization of pain management and reduction of treatment discomfort.

