IMPACT: Acoustic-Pressure Ultrasound for the Enhancement of Cosmetic Products for Aesthetic Applications.

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Background and Objectives:. The study objective was to measure and analyze skin permeation and trans-epidermal enhancement of cosmetic product delivery in a rat model.

Materials and Methods: Skin perforation (SP) followed by ultrasound (US) for acoustic-pressure cosmetic product delivery (IMPACT, Alma Lasers Ltd.), were studied in five different conditions: normal skin (control); topical Evans blue (EB); topical EB+US; topical SP+EB; topical SP+EB+US. Frozen sections from skin biopsies were taken at 0 and 15 min incubation time for histological examination using a high resolution digital microscope.
Penetration area (penetration depth + width) and coloration between distances of penetration were analyzed by advanced imaging software. Reflectance intensity by spectroscopy was measured under two wavelengths conditions: 665-nm (EB-sensitive) and 772-nm (EB-insensitive). The 665/772-nm ratio was used as a penetration indicator - low ratio denoted to higher EB penetration and high ratio to low EB penetration.

Results: Skin permeation was performed at two different depths, EB penetration was significantly higher at the deeper depth at 0 and 15 min incubation time, respectively ($p<0.01$)EB color intensity vs distance (depth and width) were significantly higher for the SP+EB+US (99.66±23.67 pixels) vs SP+EB (52.33±25.34 pixels) and SP+EB+US (80.83±15.41 pixels) vs SP+EB (66.83±28.56 pixels), respectively ($p<0.05$-0.01). Similarly, topical EB (2.1±0.4) and topical EB+US (1.8±0.3) spectrometry reflectance intensity ratios were high, indicating low EB penetration. In contrast, SP+EB+US (0.4±0.02) vs SP+EB (1.4±0.08) ratios were low, indicating significant higher EB penetration for the former ($p<0.01$). Histology frozen sections of high resolution digital photographs were in agreement with the objective measurements.

Conclusions: US acoustic pressure (IMPACT) following skin permeation significantly enhances the amount of EB penetration as evidenced by depth, width and color intensity.

IMPACT TECHNOLOGY

The IMPACT ultrasound handpiece (Figure 1) is an acoustic pressure wave proprietary technology that operates at low frequency in the kHz domain. The IMPACT is a sonotrode that emits gentle acoustic waves and air pressure which help to advance topical cosmetic products into the top layers of the skin, creating a "push and pull" effect within the channels to release the buildup of intra-cellular fluid and help the cosmetic product more rapidly advance into the skin to the targeted tissue depth. The mode of operation is based on mechanical (acoustic) pressure and torques by propagation of US wave via the sonotrode to the distal horn and the creation hammering-like effect (push &pull) in the thin layer between the cosmetic products and the distal surface of sonotrode. The Impact sonotrode is applied perpendicular to the surface of the skin and with continuous contact with the skin surface. The vibrational cycles (push-pull) enhance its delivery via the skin micro-channels. Thus, The IMPACT emits acoustic waves and air pressure and creating a push & pull effect within the channels to release the buildup of intra-cellular fluid and enhances the cosmetic ingredients to the tissue depth.

Ultrasound is applied via a sonotrode, also termed an acoustic horn. The sonotrode serves various functions such as conversion of the acoustic waves, by increasing the amplitude of the oscillations, modifying the distribution and matching acoustic impedance to that of the substrate. Resonance of the sonotrode, which increases the amplitude of the acoustic wave, occurs at a frequency determined by the characteristics of modulus elasticity and density of the material from which the

(a)  (b) 

Figure 1. IMPACT handpiece (a); sonotrode (b)

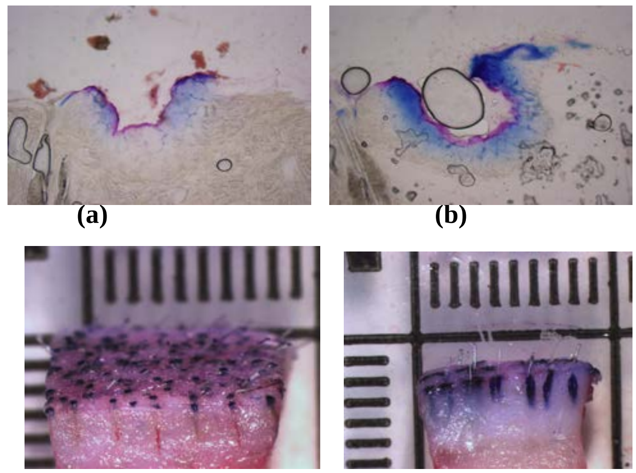
sonotrode is made, the speed of sound through the material and the ultrasonic frequency. The size and shape (round, square, profiled) of a sonotrode will depend on the quantity of vibratory energy and a physical requirements for each specific application.
The IMPACT sonic waves are associated with thermal and non-thermal effects. Heat increases the kinetic energy of the cosmetic product molecules and the proteins, lipids, and carbohydrates in the cell membrane. The mechanical effects may facilitate cosmetic products diffusion by oscillating the particles in the tissue, decreasing membrane potential, altering the lipid structure, increasing cell permeability increasing ion conductance, or disrupting the cell membrane (Table 1).

- Cavitation effects
- Thermal effects
- Mechanical effects
- Induction of convective transport

Table 1. IMPACT skin interaction effects

IMPACT IN-VIVO RAT MODEL STUDY

Rats (Sprague Dawley, either sex) were anesthetized with a mixture of ketamine (60 mg/ kg) and xylazine (10 mg/kg) injected ip or im. Rats were shaved and prepped on their orsal and lateral sides. Skin perforation followed by ultrasound (US) (IMPACT, Alma Lasers Ltd.), were studied in five different conditions: normal skin (control); topical Evans blue (EB); topical EB+US; topical SP+EB; topical SP+EB+US. Frozen sections from skin biopsies were taken at 0 and 15 min incubation time for histological examination using a high resolution digital microscope. Penetration area (penetration depth + width) and coloration between distances of penetration were analyzed by advanced imaging software. Reflectance intensity by spectroscopy was measured under two wavelengths conditions: 665-nm (EB-sensitive) and 772-nm (EB-insensitive). The 665/772-nm ratio was used as a penetration indicator - low ratio denoted to higher EB penetration and high ratio to low EB penetration. Biopsies were taken and frozen for histological examination, using digital microscope (Olympus, Japan). Data analysis using image processing IMAGEJ software (Burger and Burg, Hagenberg, Austria). Penetration area was defined as the colored area divided by the crater area and expressed in %. Penetration width was defined as width line divided by crater width, expressed in %. Penetration depth was defined as depth line divided by crater depth, expressed in %. To visualize and analyze the IMPACT effect, a polarization imaging system was used. A CCD camera (Olympus, Japan) was located above the prepared skin sample slide for image acquisition.
EB color intensity vs distance (depth and width) were significantly higher for the SP+EB+US (99.66±23.67 pixels) vs SP+EB (52.33±25.34 pixels) and SP+EB+US (80.83±15.41 pixels) vs SP+EB (66.83±28.56 pixels), respectively ($p<0.05$-0.01) (Figure 2). Similarly, topical EB (2.1±0.4) and topical EB+US (1.8±0.3) spectrometry reflectance intensity ratios were high, indicating low EB penetration. In contrast, SP+EB+US (0.4±0.02) vs SP+EB (1.4±0.08) ratios were low, indicating significant higher EB penetration for the former ($p<0.01$). Histology frozen sections of high resolution digital photographs were in agreement with the objective measurements.



(a) (b) (c) (d)

Figure 2. Microscopic (a-b) and macroscopic (c-d) histology of Evans Blue. Significantly higher EB in SP+EB+US (b-d) when compared to SP+EB (a-c) for color intensity vs distance penetration, respectively.

Figures 3 & 4. Before and after body and face results with IMPACT + cosmetic product for skin revitalization.

CONCLUSIONS

Pre-clinical and clinical results have demonstrated that the IMPACT technology with cosmetic products enhances the delivery of topical creams and lotions in a variety of skin imperfections.