

Trial Summary | Voltaren Emulgel®

Dermaportation Enhanced Skin Diffusion of a Commercially Available Topical Diclofenac Formulation

Objective

Dermaportation is an electronic transdermal drug delivery technology. It mobilizes and directs drug molecules, resulting in steep diffusion increases during field exposure (Nernst effect). It also enhances skin permeability, an effect that might be present for longer. Here, the effect of short Dermaportation exposure on long-term skin permeability to an off-the-shelf topical diclofenac formulation was evaluated.

Method

Human epidermis was mounted in vertical Franz type diffusion cells (stratum corneum facing up), according to the method of Kligman and Christophers (1963). Voltaren Emulgel® (1g containing 1.16% diclofenac diethylammonium salt; Novartis) was applied to the donor compartment of diffusion cells, with PBS in the receptor compartment (3.0 mL; stirred continuously; 37°C). Dermaportation coils were placed around the exterior of 4 cells, with 4 additional cells without coils (passive control). Dermaportation energy was applied from time 30-60 min. Samples of the receptor solution were removed and replaced with fresh buffer over an 8 h period. All samples were analysed for diclofenac content by HPLC with UV detection by a validated method. The cumulative amount of diclofenac in receptor versus time was plotted and flux values calculated from the slopes per group. Statistical analyses used a *t*-test on the delta scores from the zero time point to the time point in question.

Result

Dermaportation enhanced skin penetration of diclofenac (flux 2.97µg/h) compared with passive administration (flux 1.58µg/h). At 8h the cumulative amount penetrated was 14.25µg for Dermaportation and 7.59µg for passive diffusion. The *t*-test delta score evaluation showed that at 360min and 480min Dermaportation cells had reached a far higher concentration than at the previous time points. Passive diffusion did not reach diffusion levels different from 0 at any time point. This demonstrates that Dermaportation outperformed passive diffusion (Figure 1).

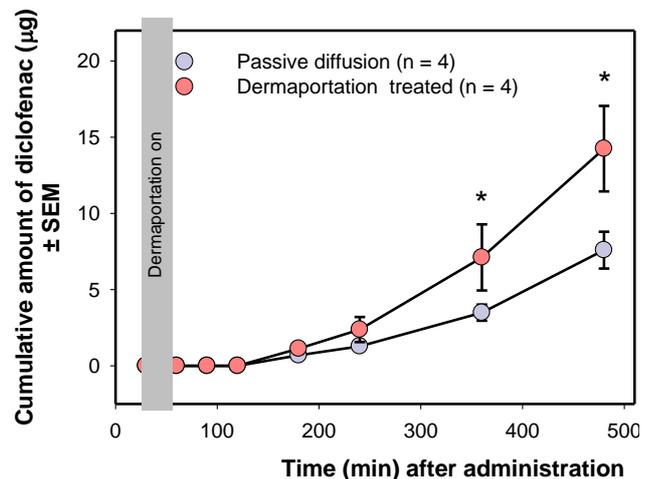


Figure 1: The averaged cumulative amount of diclofenac (Voltaren®) in the receptor chamber of a standard Franz-type diffusion set-up is depicted for either passive or Dermaportation induced penetration through excised human epidermis. Dermaportation was switched on from 30-60min only (grey bar).

Summary

A short exposure to Dermaportation increased skin permeability of diclofenac from Voltaren® Emulgel up to 8 h later, demonstrating the independency of the skin effect compared to the drug push effect. Moreover, the present study demonstrates the ability of Dermaportation to intensify transdermal drug delivery in existing topical formulations.

The standard Dermaportation fields provide a convenient method to enhance the onset of action, duration, and strength of efficacy of this topical anti-inflammatory gel.

References:

Kligman A, Christophers E. Preparation of isolated sheets of human stratum corneum. Arch Dermatol 88: 70-73 (1963).