Novel Lotion Formulation Using Polymeric Emulsion Technology for Improved Skin Moisturization and Drug Permeation in Patients With Psoriasis

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SYNOPSIS

- In the treatment of dermatologic disease, formulation characteristics drive efficient topical delivery and patient acceptance, with patients preferring less oily/sticky formulations (eg, foams, lotions)[1]
- Recently, a new lotion formulation that allows for simultaneous deposition of active ingredients and excipients on the skin surface was developed to be well-liked by patients, improve adherence, and normalize epidermal barrier function[2]
- This formulation—utilizing polymeric emulsion technology—is used to deliver lower-dose dermatologic products
  - Two for psoriasis: a combination halobetasol propionate 0.01%/tazarotene 0.045% (HP/TAZ; Duobrii®) and HP 0.01% (Bryhali®)
  - One for acne: tazarotene 0.045% (in development)
- Upon contact with salts on the skin, the polymeric matrix (3-D mesh) dissolves, allowing for uniform absorption of active ingredients and hydrating excipients (**Figure 1**)

OBJECTIVE

- To summarize properties of a unique vehicle lotion formulation and permeation of active drug of the HP/TAZ and HP lotion formulations

METHODS

- Skin hydration and epidermal barrier maintenance with the vehicle lotion were assessed through corneometry and transepidermal water loss (TEWL; N=30)
- Patient preference to several features of the vehicle lotion were assessed through a questionnaire (18 questions) administered to 15 participants
- Percutaneous permeation studies were used to evaluate in vitro dermal deposition of:
  - HP/TAZ lotion vs HP 0.05% cream (Ultravate) and TAZ 0.1% cream (Tazorac) individually
  - HP 0.01% lotion vs 0.05% cream

RESULTS

Polymeric Emulsion Technology Formulation

- With polymeric emulsion technology, the active ingredient and moisturizing/hydrating ingredients are encapsulated within oil droplets (**Figure 1A**)
  - Oil droplets are uniformly dispersed within an oil-in-water emulsion separated by a 3-D mesh matrix
  - Additional water-soluble moisturizing excipients are trapped within the 3-D matrix
- Once applied to the skin, the mesh instantly breaks apart, ensuring rapid, uniform, and simultaneous release of ingredients (**Figure 1B** and **C**)
- This technology has the potential to overcome several limitations of conventional topical drug delivery, including limited skin delivery and local cutaneous irritation[2]

Vehicle Lotion: Epidermal Barrier Function and Patient Preference

- The vehicle lotion formulation provided rapid and sustained increases in skin moisturization (**Figure 2**) and gradual decreases in TEWL (**Figure 3**) over 24 hours
- Most participants (93%-100%) responded favorably (strongly agree or agree) to questions asked about attributes of the vehicle lotion (hydrating, moisturizing, skin absorption, aesthetic), such as:
  - Skin does not feel greasy; Skin feels refreshed; Skin feels immediately soft and smooth; Skin feels lasting hydration; Skin feels more moisturized and hydrated than with what I currently use
  - Product absorbs quickly; Product absorbs quicker than what I currently use; Product provides lightweight moisturization

FIGURE 1. Novel Approach to Topical Lotion Formulation: Polymeric Emulsion Technology

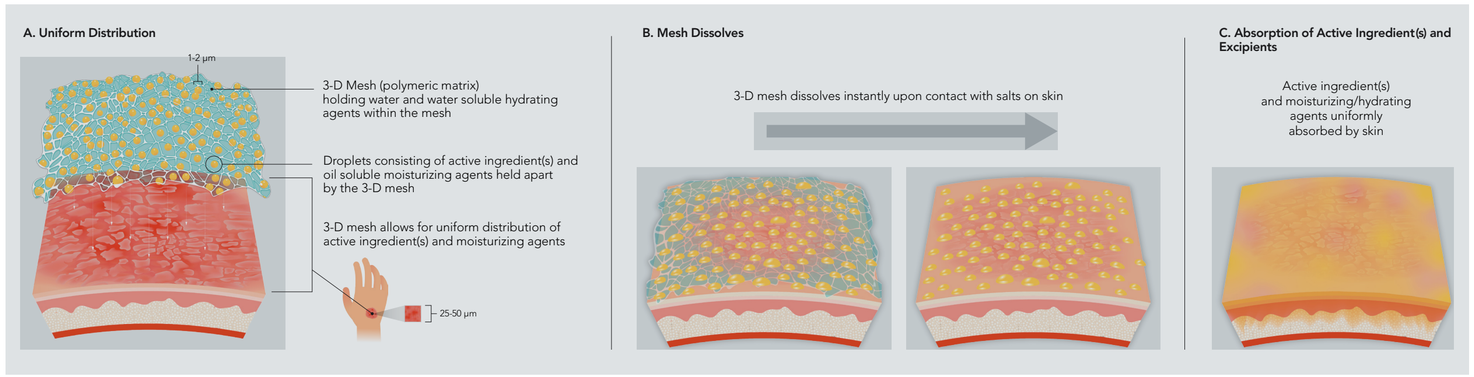
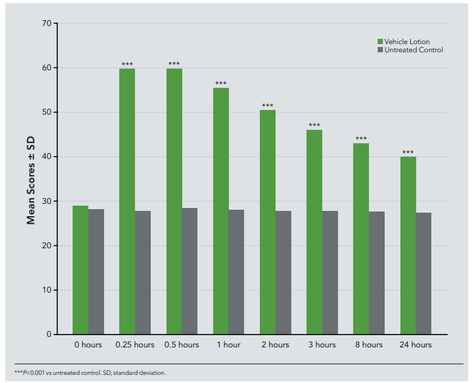
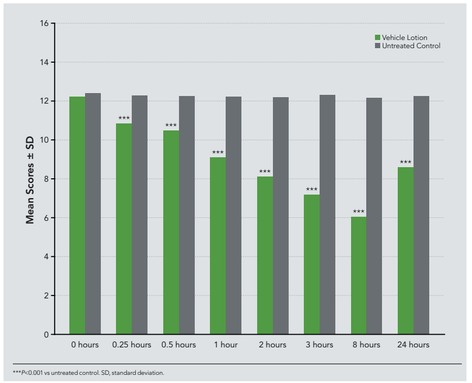


FIGURE 2. Skin Moisturization Assessment Using Corneometry (N=30)



***P<0.001 vs untreated control. SD, standard deviation.

FIGURE 3. Skin Barrier Assessment Using Transepidermal Water Loss (TEWL; N=30)

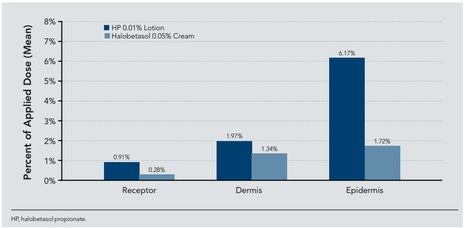


***P<0.001 vs untreated control. SD, standard deviation.

Percutaneous Absorption of HP/TAZ and HP

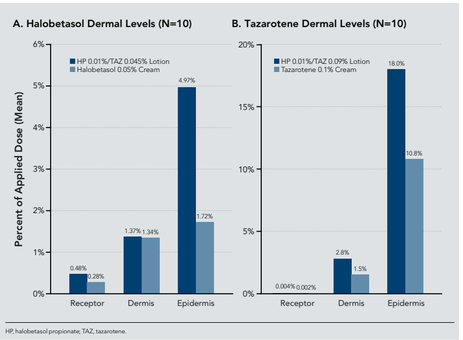
- Higher HP permeation efficiency was seen with 0.01% lotion than 0.05% cream (**Figure 4**)
- Similarly, HP/TAZ lotion demonstrated higher cutaneous permeation efficiency of active ingredients into the dermal layers than HP 0.05% cream or TAZ 0.1% cream alone (**Figure 5**)
  - The advantage of the HP 0.01%/TAZ 0.045% lotion formulation was further demonstrated when it was shown that simply layering TAZ 0.1% cream onto HP 0.05% cream decreased the cutaneous permeation of tazarotene[2]

FIGURE 4. Dermal Levels Following 24 Hours of Topical Exposure to Halobetasol 0.01% Lotion vs Halobetasol 0.05% Cream (N=10)



HP, halobetasol propionate.

FIGURE 5. Dermal Levels Following 24 Hours of Topical Exposure to Halobetasol/Tazarotene Lotion vs Halobetasol 0.05% Cream (A) or Tazarotene 0.1% Cream (B)



HP, halobetasol propionate; TAZ, tazarotene.

CONCLUSIONS

- Lotion formulations for the treatment of psoriasis and acne have been developed that utilize an innovative polymeric emulsion technology and an optimal selection of solvents, emollients, and humectants
- The vehicle lotion formulation is non-greasy, aesthetically pleasing, and provides enhanced barrier to the skin
- Further, application of the lower-dose HP/TAZ and HP lotion formulations resulted in higher permeation efficiency of the active ingredients compared with application of HP or TAZ cream alone
- These results suggest that this unique lotion formulation may provide a more effective, predictable, and patient-preferred treatment option than cream formulations

REFERENCES

1. Svendsen et al. *J Dermatolog Treat*. 2019:1-6.
2. Tanghetti et al. *J Dermatolog Treat*. 2019:1-8.

AUTHOR DISCLOSURES

Dr. Emil Tanghetti has served as speaker for Novartis, Ortho Dermatologics, Sun, Lilly, Galderma, AbbVie, and Dermira; served as a consultant/clinical studies for Hologic, Ortho Dermatologics, and Galderma; and is a stockholder for Accure. Dr. Linda Stein Gold has served as investigator/consultant or speaker for Ortho Dermatologics, LEO, Dermavant, Incyte, Novartis, AbbVie, and Lilly. Dr. James Del Rosso has served as a consultant, investigator, and speaker for Ortho Dermatologics. Dr. Stefan Weiss has served as consultant, speaker, advisor or research honoraria from AbbVie, Ortho Dermatologics, Jansen Biotech, Dermira, Almirall, Brickell Biotech, DermTech, and Scynexis. Dr. Tina Lin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company. Mr. Arturo Angel and Dr. Radhakrishnan Pillai are employees of Bausch Heal US, LLC and may hold stock and/or stock options in its parent company.

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