

DERMAL PATCH FOR THE TREATMENT OF ACNE

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AIM OF THE WORK

Nicotinamide is the amide of the pyridine-3-carboxylic acid. During the last 50 years, many clinical reports have identified nicotinamide as a beneficial agent in the treatment of a variety of inflammatory skin disorders; moreover, its exceptional safety profile at pharmacologic doses makes it a potentially ideal long-term oral therapy for patients with inflammatory skin diseases. Having no bactericidal effect on *Propionibacterium acnes*, it does not induce the onset of resistances.

Salicylic acid, representing a pseudo beta-hydroxy acid, is often used in the treatment of acne, psoriasis and photoaging effect. According to the concentrations of salicylic acid used the keratolytic effect desired is different. At the moment the way of action of salicylic acid in the skin, is not very clear, but it seems to have an impact on the stratum corneum structure affecting intercorneocyte and desquamation.

In fact, this molecule allows to decrease the thickness of the skin, avoiding the obstruction of the pores. Furthermore, a concentration of 2% have an effect less irritant than benzoyl peroxide.

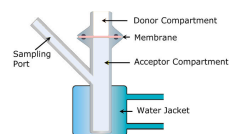
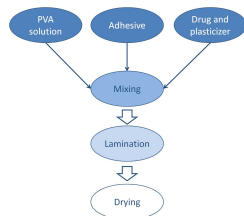
The aim of this work was to prepare and to test a bioadhesive film named Patch-non-Patch[®] containing nicotinamide and salicylic acid for the treatment of acne.



METHODOLOGY

Film preparation

A solution or suspension of nicotinamide and/or salicylic acid in water/plasticizer was added to PVA water solution and to the adhesive (PVP 21% (w/w) in water/PEG 400 solution). The resulting mixture was stirred overnight. All mixtures were laminated on siliconized paper using a film casting knife and then oven dried at 80 degree for 30 minutes. The composition of the films prepared is reported in the table.



Permeation experiments

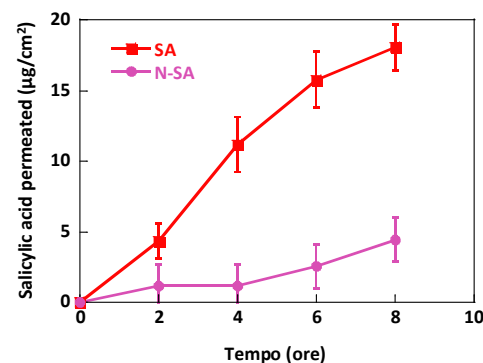
- Franz diffusion cells
- Barrier: pig ear skin
- Receptor solution: PBS pH 7.4
- Donor: Patch-non-Patch[®]
- Temperature: 37°C

Components	N	SA	N-SA
PVA (20% solution) ^(a)	60	64.5	60
PVP (21% solution) ^(b)	26	31	26
Sorbitol	4	4	4
Nicotinamide	3	-	3
Salicylic acid	-	0.5	0.5
Water	7	-	6.5

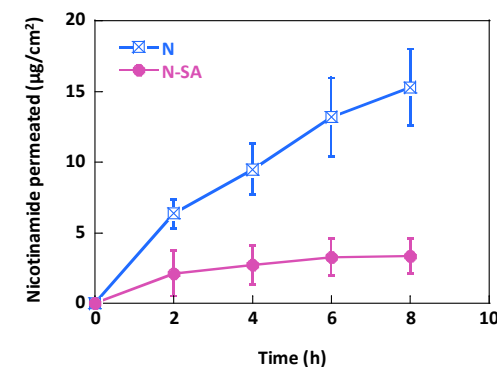
^(a) in water
^(b) in water:PEG400 (85:15, w/w)

RESULTS

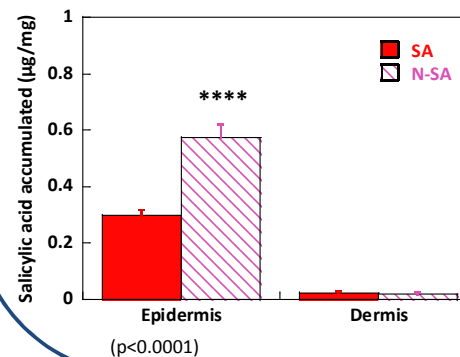
Permeation profile of SA (average±SD)



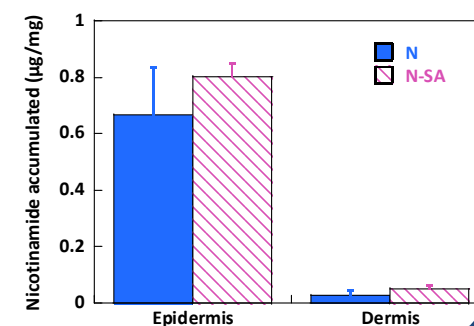
Permeation profile of N (average±SD)



Accumulation of SA (average±SD)



Accumulation of N (average±SD)



CONCLUSIONS

- ✓ The presence of both drugs in the same patch produces a decrease in the flux both for salicylic acid and nicotinamide.
- ✓ Even if permeation profile from N-SA was lower, the amount of salicylic acid accumulated resulted to be higher in the epidermis (p<0.0001) and equivalent in the dermis to that obtained from SA film.
- ✓ Skin retention of nicotinamide is not influenced by the presence of salicylic acid in the same film.