

Multi-site Feasibility Study Using A New Textile With Silver[‡] For Management of Skin Conditions Located in Skin Folds

Presented at Clinical Symposium on Advances in Skin and Wound Care September 2006

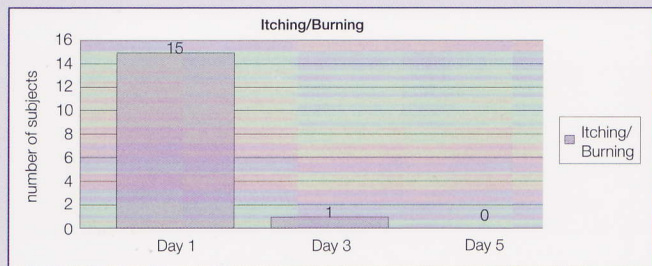
Table 1 - N = 21

Mean BMI	Skin Fold Location
54.75	Abdomen = 12 Breast = 4 Abdomen & groin = 3 Popliteal = 1 Posterior thigh = 1
- Sixteen (16) subjects were entered with intertrigo. - Five (5) subjects were entered with candidal intertrigo identified by clinical observation and currently using a topical antifungal.	

Twenty-one (21) subjects were entered into the study, with twenty (20) having complete data. Data was collected from each subject on Day 1 (Baseline), Day 3, and Day 5. Missing data was treated using the Last Observation Carry Forward (LOCF) technique. The following variables were analyzed: Erythema, Closed Odor, Separated Odor, Maceration, Denudement, Satellite Lesions, and Itching/Burning. The Paired Sign Test was used for all analyses.

ITCHING/BURNING

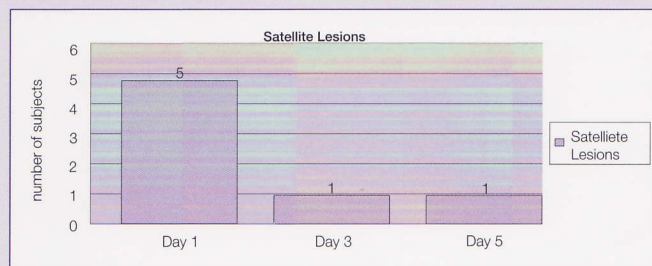
N = 15 Number of Subjects with Itching/ Burning



Fifteen (15) out of twenty-one (21) subjects had itching/burning on Day 1. There was a statistically significant reduction in Itching/burning ($p = .0001$) by Day 3 and ($p < .0001$) by Day 5.

SATELLITE LESIONS

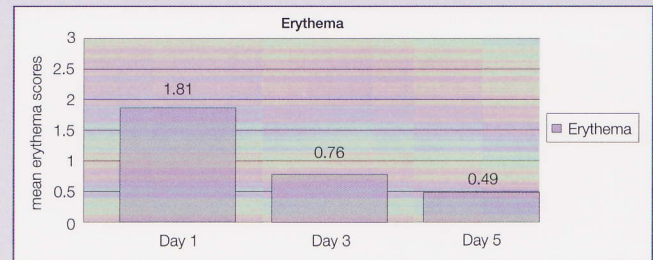
N = 5 Number of Subjects with Satellite Lesions



On Day 1, five (5) of the twenty-one (21) subjects had satellite lesions. On Day 3, one (1) of the twenty-one (21) subjects had satellite lesions. On Day 5, one (1) of the twenty-one (21) subjects had satellite lesions that were improving.

Erythema

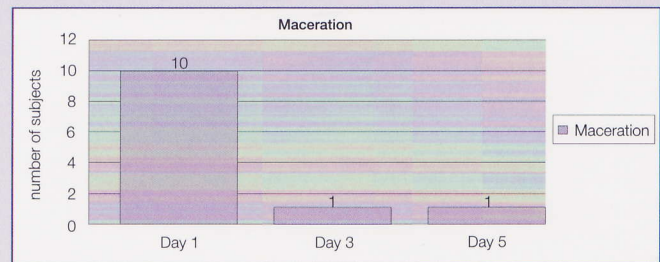
N = 21 Mean Erythema Scores



All of the subjects were entered into the study with erythema. There was a statistically significant reduction in erythema ($p < .0001$) by Day 3 and Day 5.

MACERATION

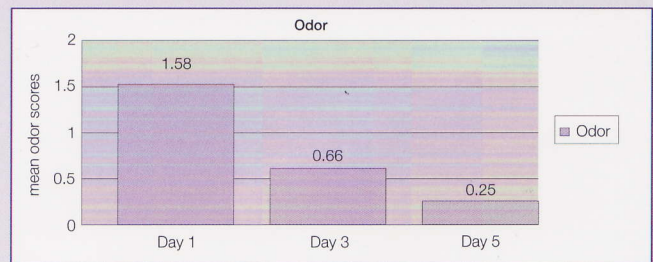
N = 10 Number of Subjects with Maceration



Ten (10) of the twenty-one (21) subjects had maceration on Day 1. One (1) subject had maceration on Day 3 and Day 5 resulting from the textile becoming soiled with urine and not removed immediately.

ODOR

N = 12 Mean Odor Scores



Twelve (12) subjects had odor on Day 1. The score was the same at 6 inches and 12 inches. There was a statistically significant reduction in separated odor ($p = .0020$) by Day 3 and ($p = .0034$)* by Day 5. See chart 4 for the twelve (12) subject that had odor on Day 1.

RESULTS

- Knitted textile with silver¹ provided the environment to relieve the subject's symptoms of intertrigo and/or candidal intertrigo in a five (5) day period.
- The new knitted textile with silver¹ product, eliminated the need for other multiple ineffective products.
- The subjects liked using the new knitted textile with silver¹ and appreciated the comfort of not having moist skin and the absence of messy powders or creams on their skin.

INVESTIGATORS:

[‡] Smith D. Kennedy-Evans KL, Henn T, Viggiano. Multisite feasibility study using a new textile with silver for management of skin conditions located in skin folds. 2006. Poster presentation, Clinical Symposium on Advances in Skin and Wound Care.

PRODUCT NOTATION:

1. InterDry™ Ag Textile with Antimicrobial Silver Complex, Coloplast Corp., Minneapolis, MN