To assess and compare durability of four barrier film products* over a 72 hour period on human volunteers.

**Background**

- **Days 1, 2, and 3**
  - Subjects were allocated to one of the four barrier film products according to randomization schedule.
  - Products applied over the ACP marker over which the barrier films were applied. The amount of ACP stain was monitored using digital photography and computer-assisted image analysis.

- **Study Design**
  - **Proactive, randomized, non-blinded**
  - **Four test products**
  - **18 subjects**
  - **Primary endpoint:** Percent of ACP marker remaining on test sites after 3 days of normal cleansing routine
  - **Assessments:** Computer-assisted image analysis of daily digital photographs to determine the percent of ACP marker remaining on test sites

**Subject Selection**

- **Age 18 to 74 years willing to participate**
- ** Fitzpatrick skin type I, II, or III
- **Healthy skin on back, no blemishes or uneven skin tones over test sites**
- **Willing to shower at least once daily**
- **Fitzpatrick skin type I, II, or III**
- **Healthy skin on back, no blemishes or uneven skin tones over test sites**

**General Procedures**

- **At least 3 days prior to study start**
  - Subjects began a washout period where normal cleanser was allowed on backs
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**Methods**

- **Test products**
  - Barrier Film A: E-Z Skin® (Smith & Nephew)
  - Barrier Film B: No-Sting Skin-Prep™ (Smith & Nephew)
  - Barrier Film C: Symmetry® (Smith & Nephew)
  - Barrier Film D: Skin-Prep™ Protective Barrier Wipes (Smith & Nephew)

**Test sites**

- **4 sites on the right and left sides of the back, for a total of 8 sites per subject**
- **Test sites were identified using a permanent marker**
- **Visible marker over which the barrier films were applied.**

**Assessments**

- **Computer-assisted image analysis of daily digital photographs to determine the percent of ACP marker remaining on test sites**
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**Results**

- **Day 0**
  - **Test sites identified and marked**
  - **Negative control close-up photos taken of each of the four quadrants**
  - **ACP marker applied to all test sites**

- **Day 1**
  - **Two coats of the barrier film test products applied over the ACP marker according to randomization schedule**
  - **Following package instructions for application**

- **Day 2**
  - **Positive control photographs (100% marker stain intensity) taken from each of the four quadrants**

- **Day 3**
  - **Subjects returned for daily follow-up**
  - **Daily photographs compared to Day 0 positive control photographs to determine the percent of marker stain remaining**

**Conclusions**

- **This test method provides a useful in vivo method for comparing the durability of barrier films over an extended wear time.**
- **The test method provides both quantitative and qualitative (visual) confirmation that differences exist in the durability of barrier films.**
- **After 72 hours of wear, barrier film A was more than twice as effective in preventing wash-off and wear-off of a marker substance from the skin as barrier film C.**
- **At 72 hours of wear, barrier film C appears to crack and flake off in large scales.**
- **Barrier films B and D appear to provide little barrier effectiveness even over 24 hours of wear.**

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