Using a Skin Mimic Substrate Model for Medical Adhesive Evaluations

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Background

- Current bench level peel tests to evaluate adhesion performance are typically conducted on rigid stainless steel, polyethylene, or polypropylene, as they are standardized substrates with relatively high repeatability and accessibility.
- These rigid substrates do not match most mechanical properties of human skin, and thus leave room for improvement in terms of representing how our adhesives will perform when adhered to patients.
- As such, there is an industry need for a bench level system that closely mimics the surface energy and viscoelastic properties of human skin, which would ultimately improve adhesive evaluation speed and efficacy.

Purpose

- The purpose of this study is to evaluate a new substrate for its ability to produce peel force results similar to that of peel force results gathered from human skin.
- Using the layers of human skin as a basis for its construction, a prototype skin mimic was created as a multi-layered assembly.
- The mimic was subsequently used to generate peel force data with nine medical tapes, which were then compared to internal clinical peel force data (t=0) of the same tapes for a performance evaluation.

Methods

- Four skin mimics of varying thickness were created to evaluate one of the mimic's layers.
- A tensile tester was used to conduct 180-degree peel tests, based off of ASTM D3330/D3330M-04(2018), in order to gather average peel force data for nine distinct medical tapes.

Figures

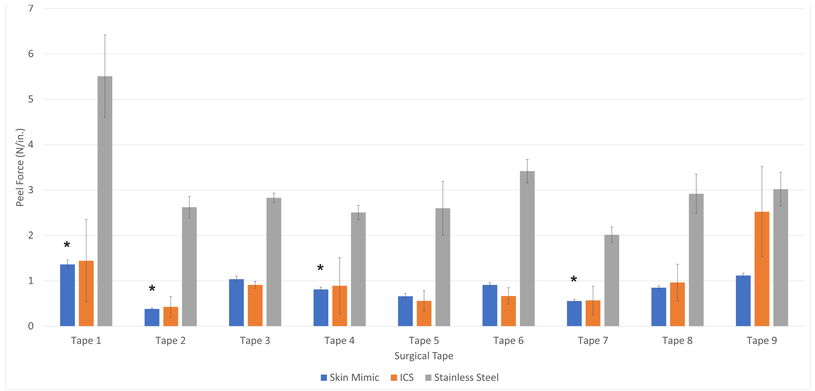

Figure 1. Peel force applied by nine medical tapes on the skin mimic (blue), healthy human skin (orange), and stainless steel (grey). * indicates skin mimic did *not* statistically differ from ICS. ICS=Internal Clinical Study

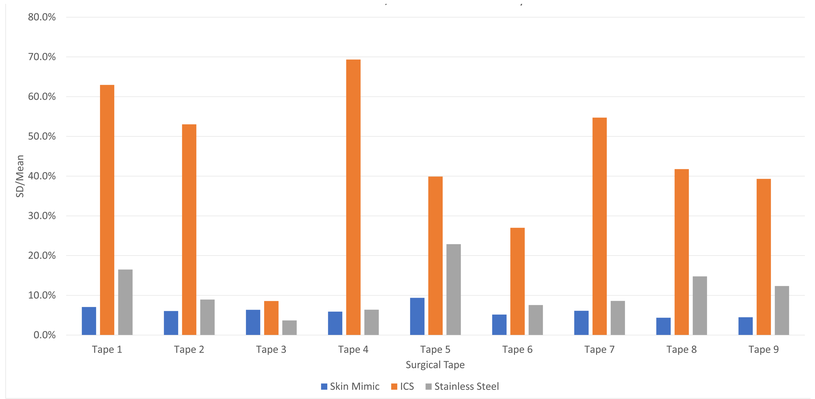

Figure 2. The coefficient of varation (standard deviation/mean) of nine medical tapes on the skin mimic (blue), healthy human skin (orange), and stainless steel (grey). ICS=Internal Clinical Study, SD=Standard Deviation

Methods (Cont'd)

- Each tape was cut into 1"x5" strips, adhered with a standardized roller onto the skin mimic substrate, allowed to dwell for a specified duration, and peeled off the substrate with the tensile tester.
- The average peel force for each sample (N/in) was calculated through the average value of a function (integral method) across a 3" peel interval.
- Resulting peel force averages for each tape, generated with the skin mimic, were then compared with peel force averages generated from a clinical study performed on humans, which utilized the same nine medical tapes.

Results

- Four out of nine tapes (n=10) showed a statistically significant similarity between mean peel forces on the skin mimic versus human skin (**Figure 1**).
- The remaining did not exhibit similarity, primarily due to the large variability of the clinical data versus the high repeatability of the skin mimic data (**Figure 2**).

Conclusions

- The skin mimic showed that it could produce peel force means similar to peel force means gathered on human skin, but with a higher level of repeatability as indicated by the low standard deviation of skin mimic data.
- A high level of repeatability will be critical when evaluating adhesives for changes in performance, as it becomes increasingly more difficult to attribute differences in adhesion results to variations in the adhesive, specifically when variability is high due to the method and/or study participants.

Presented at Symposium on Advanced Wound Care Spring/Wound Healing Society, May 14-17, 2024, Orlando, FL

The authors thank Mikaela Sifuentes (Solventum) for assistance with poster preparation.