

SKIN BARRIER DISRUPTION MEASURED BY TRANSEPIDERMAL WATER LOSS (TEWL) CORRELATES WITH TOTAL PROTEIN RECOVERED FROM RETAINED MEDICAL ADHESIVE TEST ARTICLES

Olivia Reiff^{1,2}, Madeline Hakala^{2,3}, Rick Pedersen², Tim Houser⁴, Tage Carlson², Abe Janis²

1. Dept of Biomedical Engineering, Northwestern University, Evanston IL; 2. Ostomy Technology Development Hollister Incorporated, Libertyville IL; 3. Dept of Biology, Loyola University Chicago; 4. Dermico LLC, Broomall PA

Background

A key metric of skin health and function is transepidermal water loss (TEWL), which increases when the integrity of the stratum corneum is compromised; TEWL is commonly used in clinical studies to measure the effects of repeated application and removal of medical adhesives. Disruption of the skin barrier can occur in people who have undergone ostomy surgery and must repeatedly apply & remove the adhesives used to affix ostomy pouching systems to the peristomal skin. Historically, skin barrier disruption demonstrated by TEWL has been observed to increase over sequential skin stripping events. However, our studies have been limited to observation of the in vivo physiologic response, without determination of mechanism of injury. In this work, we set out to determine if the amount of protein recovered from acrylate-based adhesive tapes, used as test articles in a repeated stripping study in healthy volunteers, correlated with TEWL values measured after each tape's removal from abdominal skin.

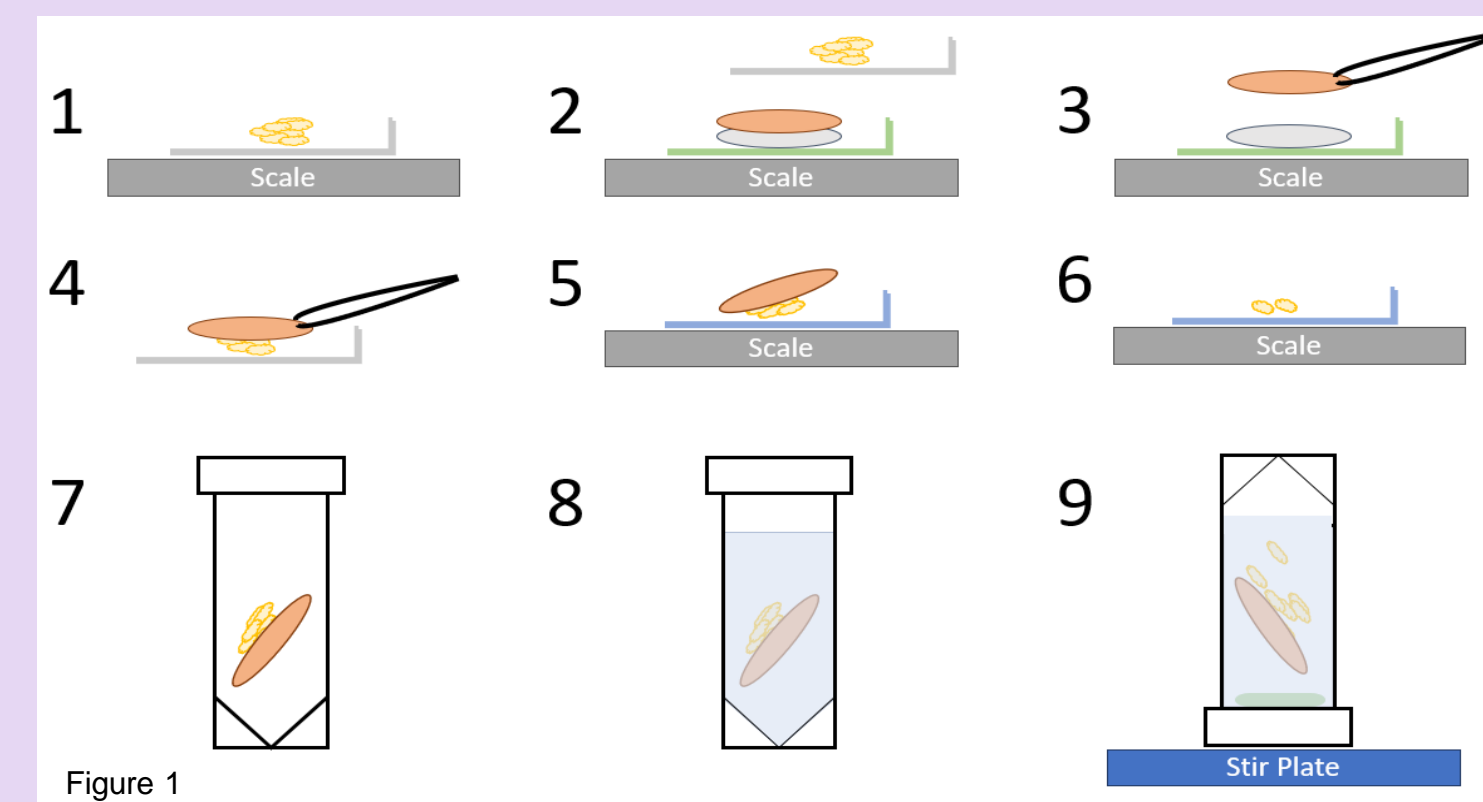
Known Protein Amount Tape Recovery

Procedure:

- 1-3: Weigh out protein and adhesive
- 4-6: Weigh protein stuck to adhesive
- 7-9: Mix adhesive solution on stir plate

Independent variables:

- Extraction time in NaOH or PBS (step 9)
- Solvent volume (step 8)
- Amount of protein. (step 1 & 4)
- BSA or hydrolyzed keratin powder



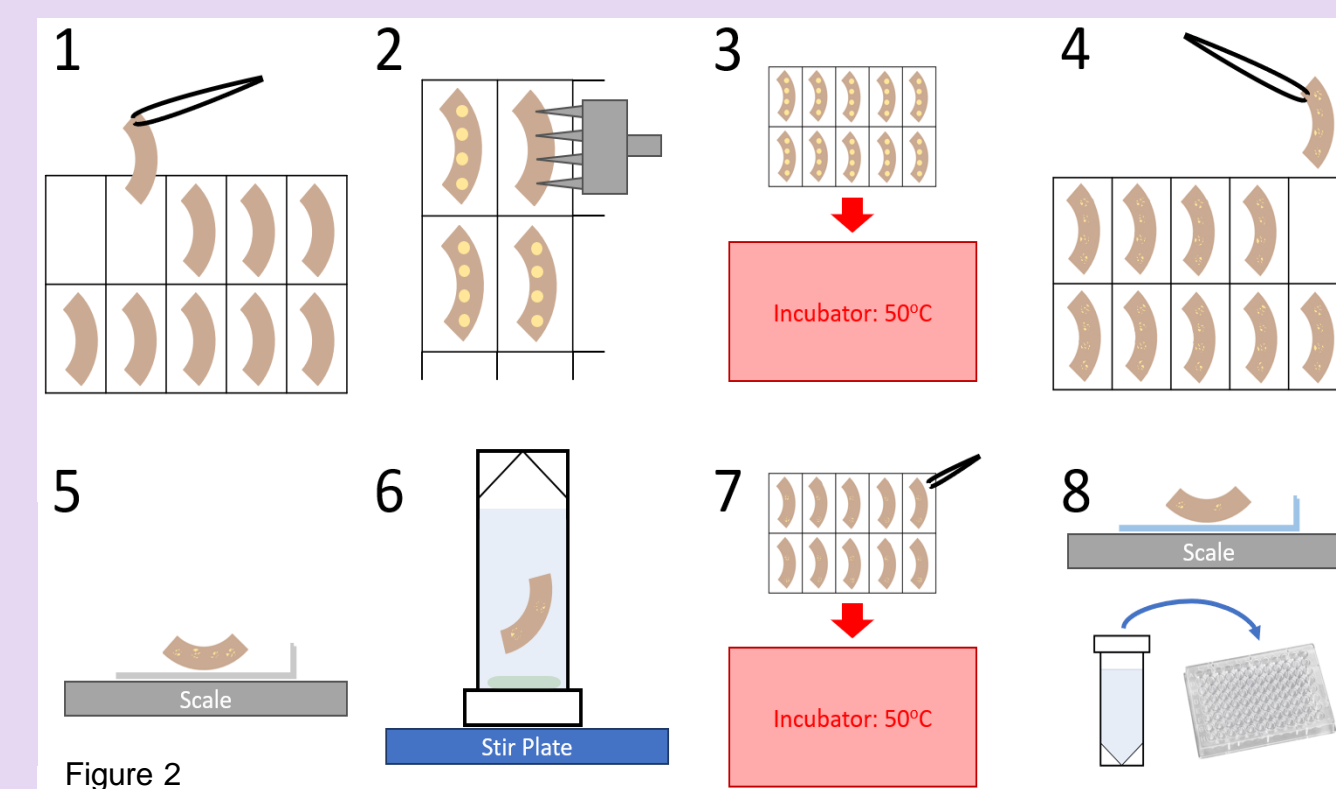
Reference Tapes via Evaporation

Procedure:

- Drop concentrated protein solution onto adhesive
- Evaporate water, leaving protein stuck to adhesive
- Mix protein-covered adhesive in solution
- Perform assay and calculate %recovery
- Compare to human samples

Goal:

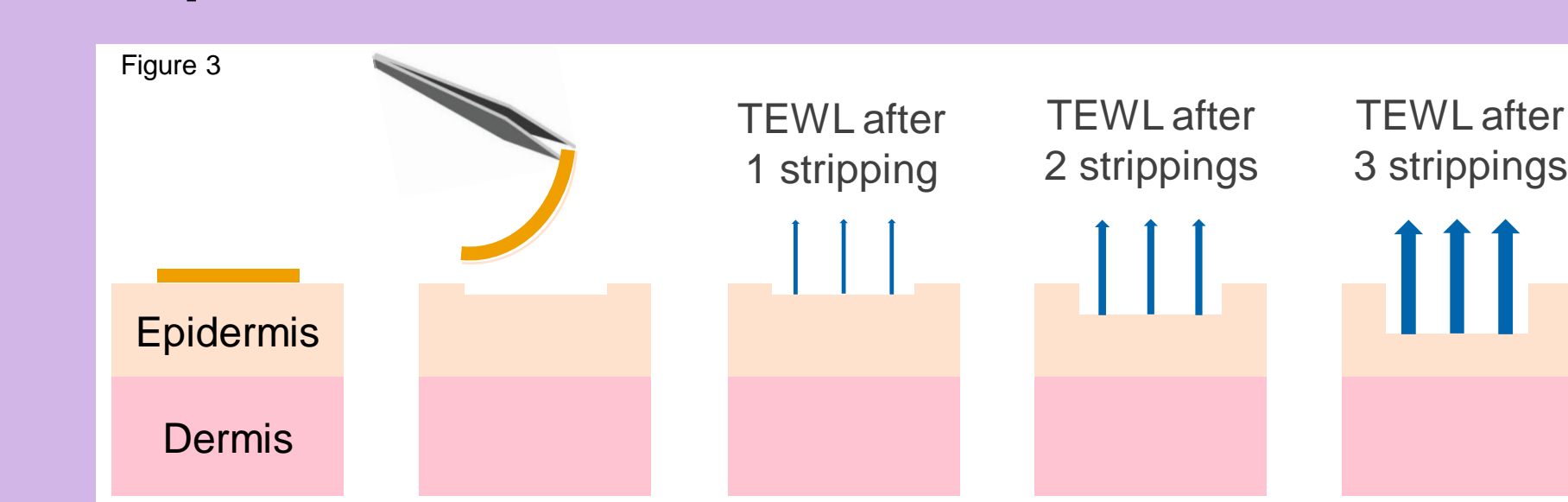
- Create a %recovery calibration curve for real samples i.e., don't assume 100%



Methods

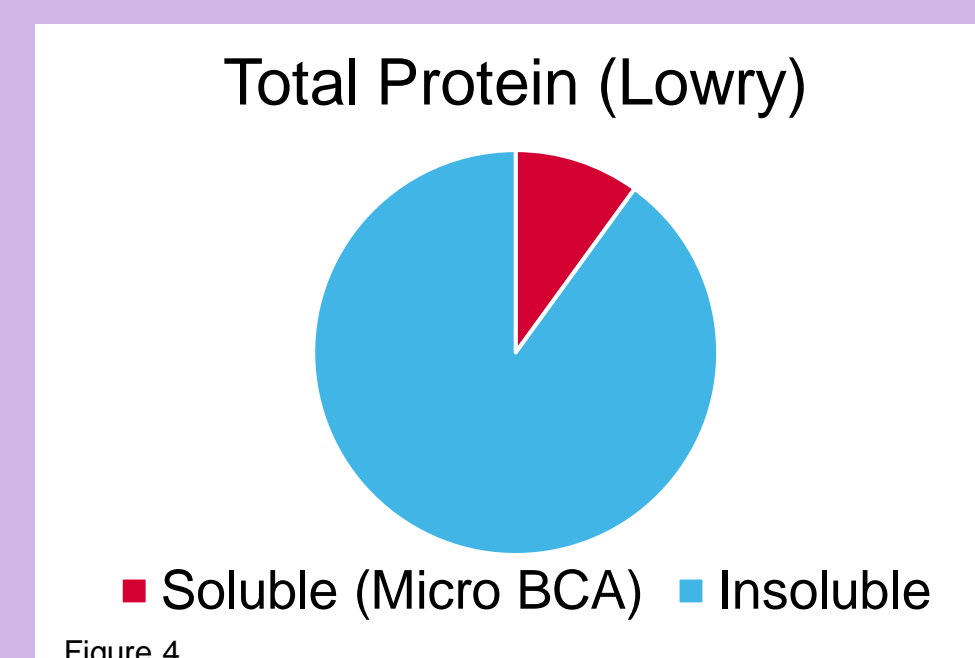
- 18 Subjects
- 2 randomized sites
 - 24-hour removal
 - 8/16-hour removal
- TEWL recorded after removal
- Samples stored at -80 °C

Sample Collection



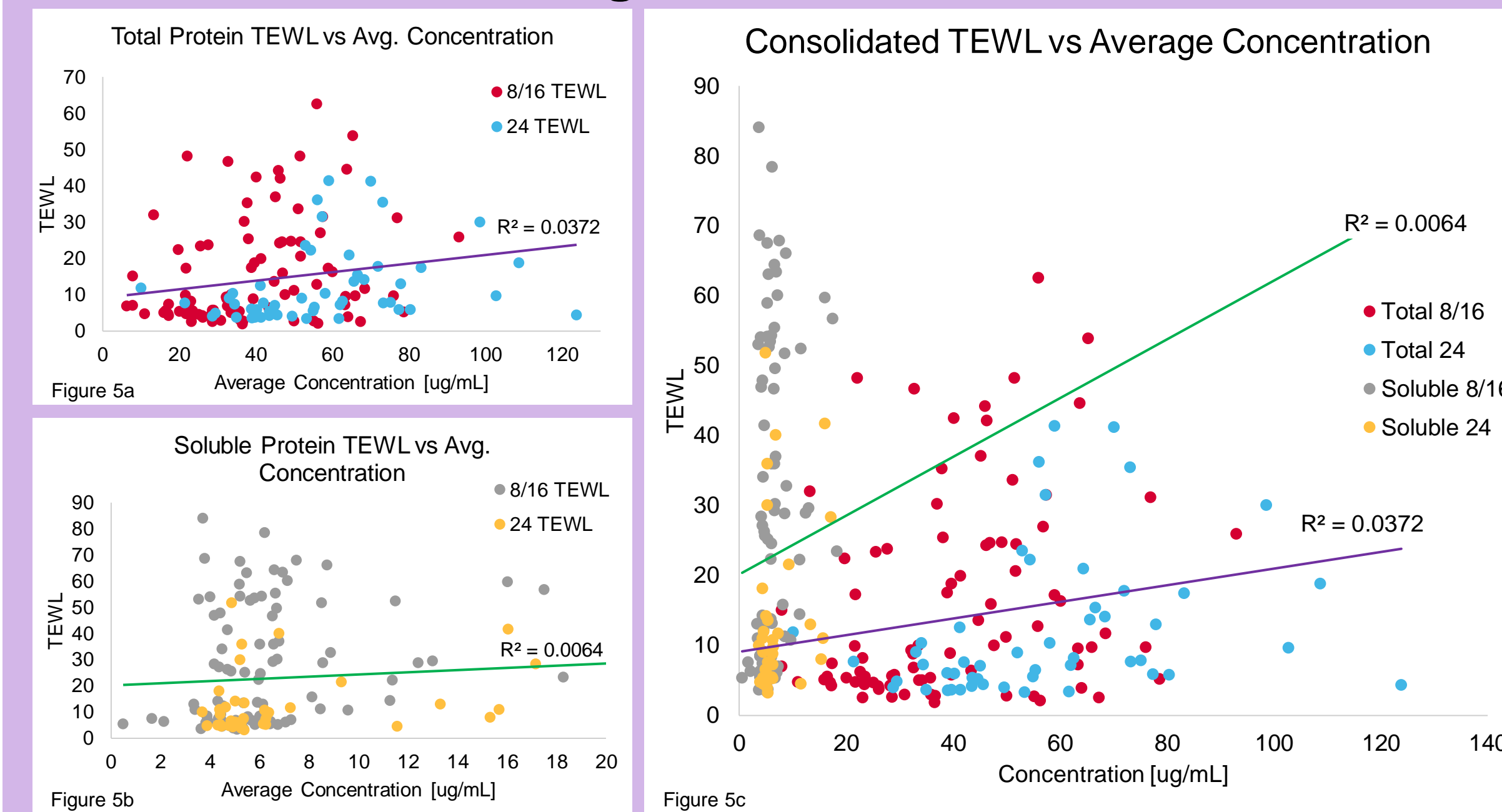
Protein Recovery

	Total Protein	Soluble Protein
Number of Subjects	10	9
Assay Type	Lowry	Micro BCA
Solvent	NaOH + HCl	PBS
Volume	16 mL + 16 mL	16 mL
Extraction Time	60 minutes	60 minutes

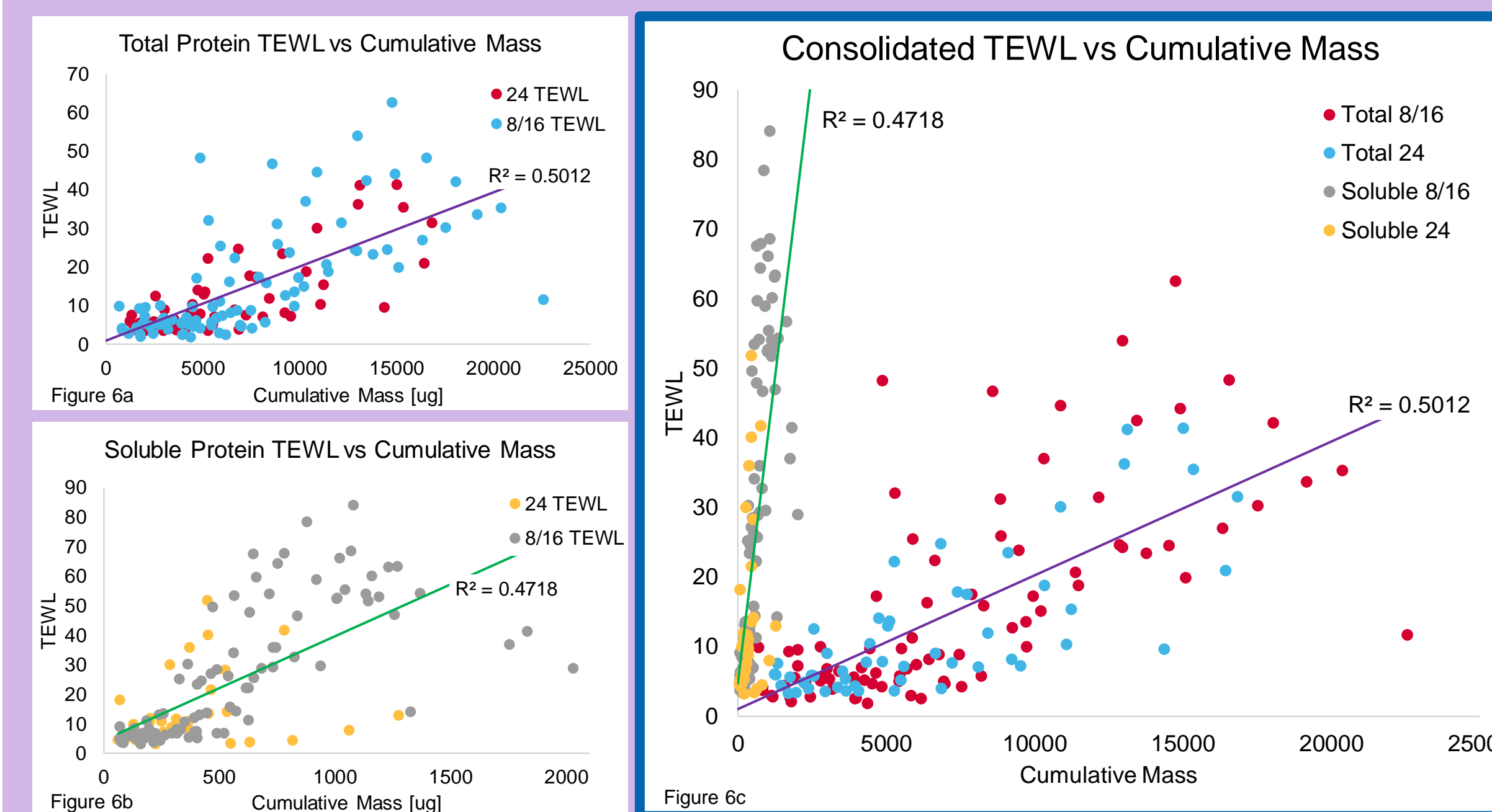


7-Day Study to Assess the Irritation Potential of Different Adhesive Tapes

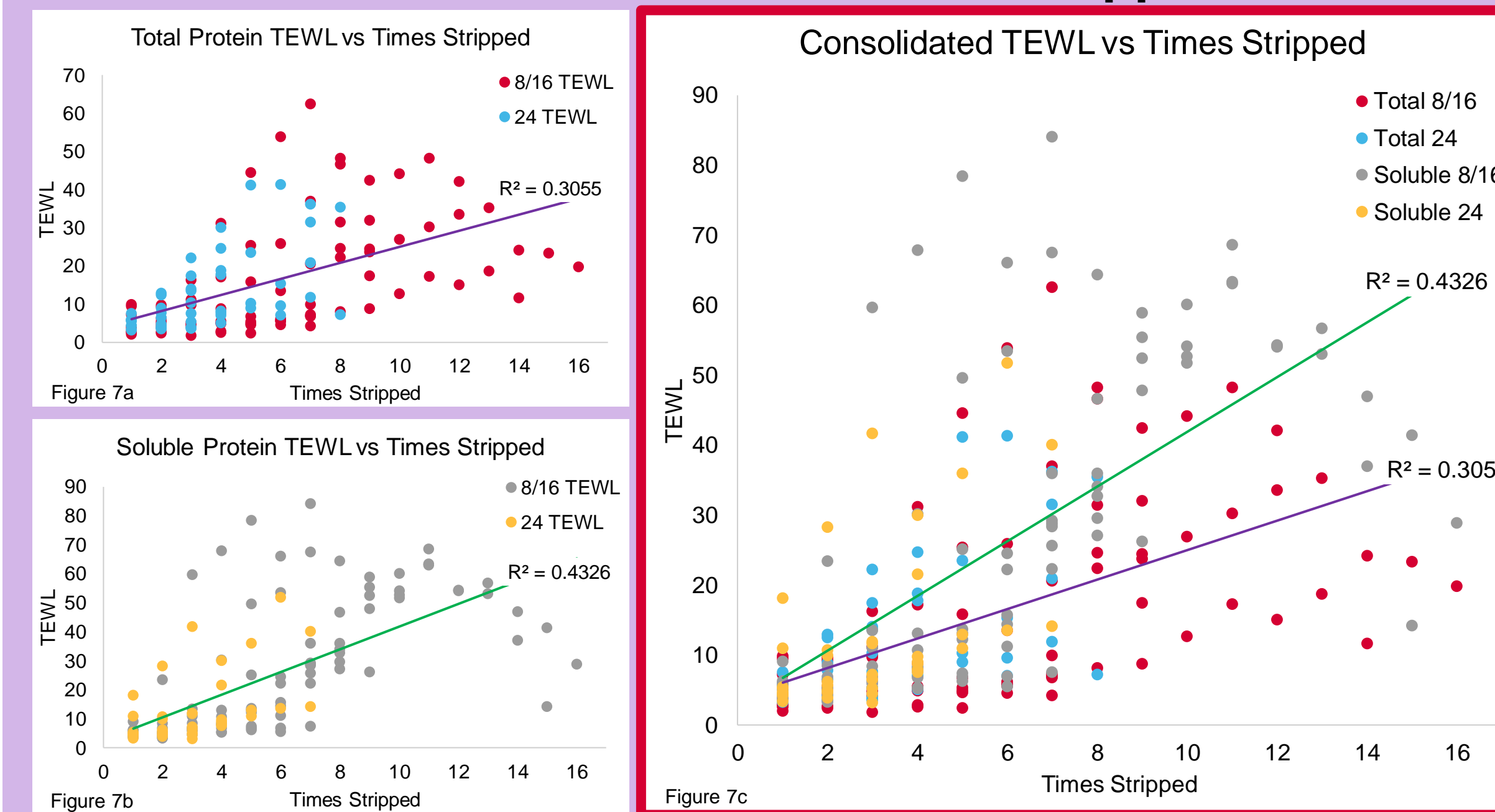
TEWL vs Average Concentration Correlation



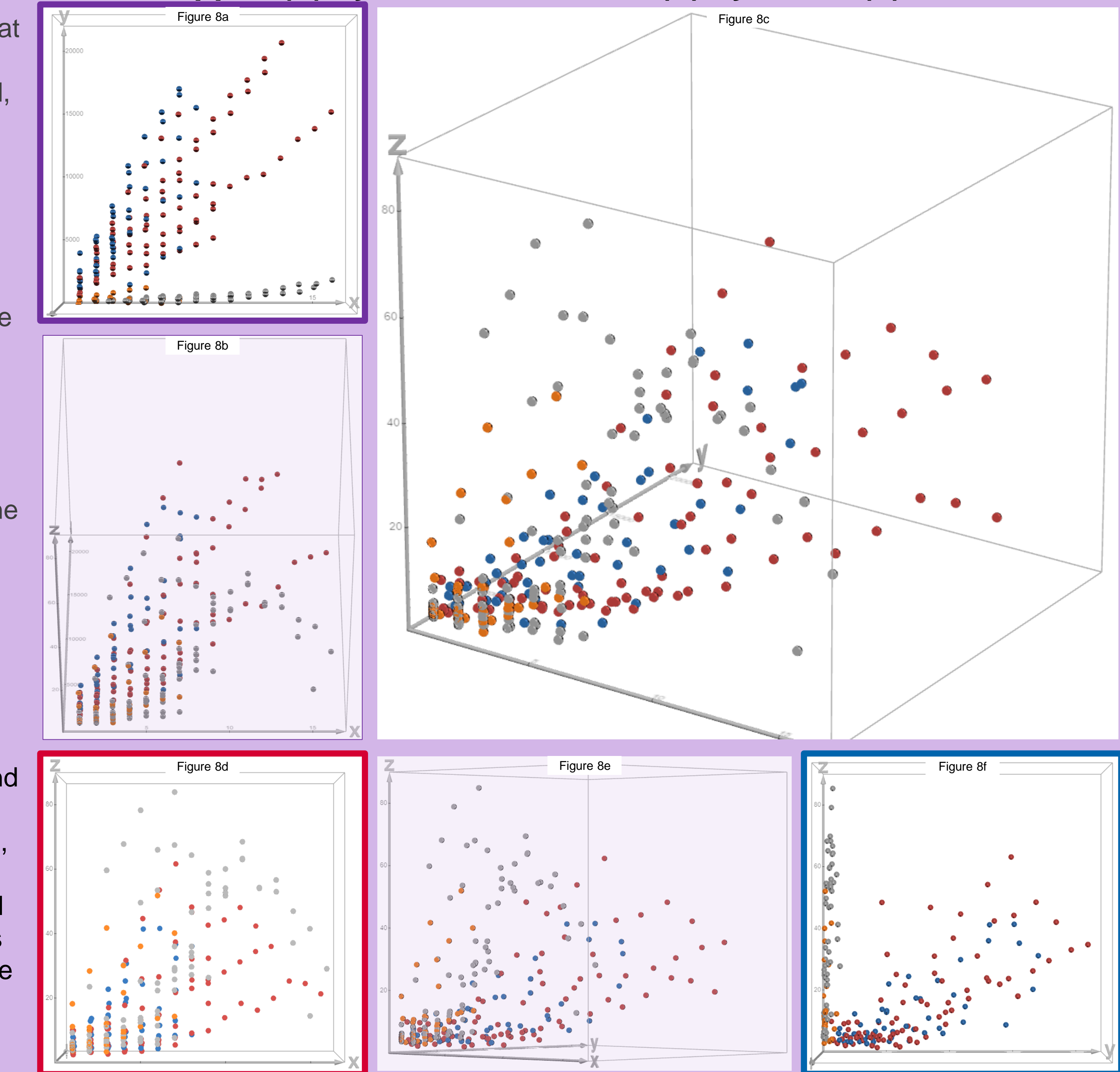
TEWL vs Cumulative Mass Removed



TEWL vs Number of Times Stripped



Times Stripped (X) by Cumulative Mass (Y) by TEWL (Z)



When looking at cumulative mass removed, there is an obvious trend with times stripped (though more difficult to see with the soluble subjects).

Some of the lines do not make it to 16 strips due to the subject's skin accumulating too much damage from the repeated tape stripping.

While mass and times stripped appear related, cumulative mass removed (blue) has less scatter than the times stripped (red).

Discussion

As an initial analysis, the thought was to correlate TEWL readings with the most straightforward metric given by the spectrometer: concentration calculated resulting from absorbance. As seen by the R^2 values in Figures 5a-5c, the confidence of those relationships were low. The next step was to use mass collected per strip, but that would not help much, just being a multiplier of concentration. Calculating the cumulative mass removed at that site and the corresponding TEWL reading made for a much more obvious trend: more protein removal meant higher TEWL readings because of the accumulated damage to the stratum corneum (Figures 6a-6c). The last variable considered was the number of times the site itself was stripped. It was the similarity in behavior between Figures 6b and 7b that posed the question of how the cumulative mass removed was related to the number of times the site was stripped. Figure 8a demonstrates that relationship with the rest of Figure 8 showing all the graphs in context with one another.

Skin stripping has been done in the past, but this is the first time that medical adhesives related to ostomy are being retained from clinical studies and used as test articles in bench studies to understand the mechanism of injury observed in clinical setting

Let me know if you have more questions!

Olivia Reiff
LinkedIn

