Studies on Skin Biophysics and Ostomy Skin Barriers: Comparison of Peel Force Measurements and Skin Structure Between Peristomal and Normal Surrounding Skin

Richard I. Murahata, PhD[1], Michael G. Taylor, PhD[1], Jonn Damia[2], Timothy Houser, BS[2], and Gary L. Grove, PhD[2]

(1) Hollister Incorporated, Libertyville, IL (2) cyberDERM, Broomall, PA

Introduction

Understanding the properties of peristomal skin is a critical requirement for the design of ostomy skin barriers. The adhesive properties of skin barriers are often characterized in the laboratory using artificial substrates, such as steel or plastic surfaces, and less frequently using normal human skin as the substrate. However, it is not clear how well these measurements can predict adhesive properties on peristomal skin. In this poster, continuing work on the characterization of peristomal skin is described and, in particular, the adhesive properties of skin barriers on peristomal skin are presented.

Methods

Depending on the amount of peristomal skin available, a 0.5 inch or 1 inch wide strip of barrier material was allowed to adhere to the peristomal skin and adjacent normal skin for one hour prior to measuring the adhesive strength utilizing a previously reported methodology. Peel force measurements were taken using the cyberDERM Peel Tester, which measures the amount of force required to peel the barrier from the skin (Figure 1). The technique was improved from that used in the previous study by incorporating an integral restraint to reduce the influence of skin stretching during the peel force measurement (Figure 2). Based on consumer observation, a 90 degree peel angle was used. The peel angle was kept constant by using a novel pulley system and a peel rate of 150 mm/minute.

Figure 1 cyberDERM Peel Tester

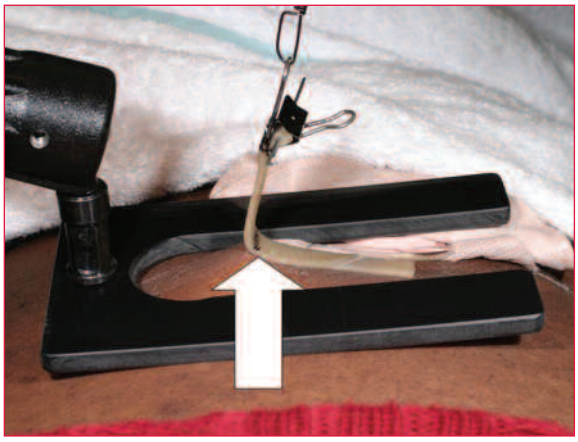

Figure 2 Placement of adhesive barrier strip and skin restraint. Mark indicates location of transition from normal to skin chronically covered by barrier (peristomal skin).

The biophysical characterization of the skin was carried out prior to the peel measurements using the following battery of well-established, non-invasive methods: Transepidermal Water Loss (TEWL) was assessed using a cyberDERM RG1 Evaporimeter System with TEWL Probes manufactured by Cortex Technology; skin surface pH was measured using a standard flat surface probe; biomechanical properties were obtained using a DermaLab® Suction Cup; skin moisture content was measured employing an IBS Skicon-200 Conductance Meter equipped with a Measurement Technologies probe; and visualization of the skin structure was accomplished using an in vivo reflectance confocal microscope from Lucid Technologies. The images were evaluated by an independent expert.

Results

Seven (7) qualified subjects were enrolled in the study, including two who had participated in a previous study. The subjects consisted of six females and one male with an average age of 64 years (SD=11; range 47-80) and were an average of 11 years post original surgery (SD=7.4; range 4-22). Four had an ileostomy and three had a colostomy. The subjects wore products from a range of manufacturers and one subject 'picture framed' the barrier with Hy-Tape® Waterproof Tape. Peel force data from two subjects were confounded due to technical issues (hair on the site of interest and an extreme curvature of the test site). For the five subjects in which the peel data was usable, it required significantly (paired t-test, $p=0.003$) more force to remove the barrier strip from the peristomal skin than from the normal skin (Figures 3 and 4 and Table 1). The data from subjects one and two were similar to those obtained with these particular subjects in the previous study, indicating a stable effect over time.

Analysis of images obtained via confocal microscopy showed signs of irritant dermatitis in the peristomal skin area as evidenced by spongiosis (dermal edema) and the presence of inflammatory cells. In addition, the presence of parakeratosis (abnormal retention of nuclei in the keratinocytes) speaks to aberrant differentiation, and we also observed significant disruption of the stratum corneum structure. Figure 5 shows an image of one of the normal skin sites, showing typical stratum corneum features. Figure 6 shows the presence of keratinocytes with retained nuclei in one of the peristomal skin images. Disruption of the stratum corneum layer in peristomal skin is illustrated in Figure 7. The stratum corneum thickness was not different between normal and peristomal skin sites while the epidermis was significantly ($p=0.031$, signed rank test) thicker in the peristomal skin area.

The TEWL values were significantly higher ($p=0.030$, signed rank test) for the peristomal skin than adjacent normal skin (Table 2). However, the elevation is generally lower than have been reported by other investigators. Based on clinical observations of the skin condition and the similarity of values obtained for peristomal vs. normal skin on at least three of the subjects, increased TEWL is more likely related to acute irritation rather than long-term changes to the structure of the skin.

In this small study, peristomal skin did not appear to be different from normal skin with respect to elasticity, moisture content, or pH.

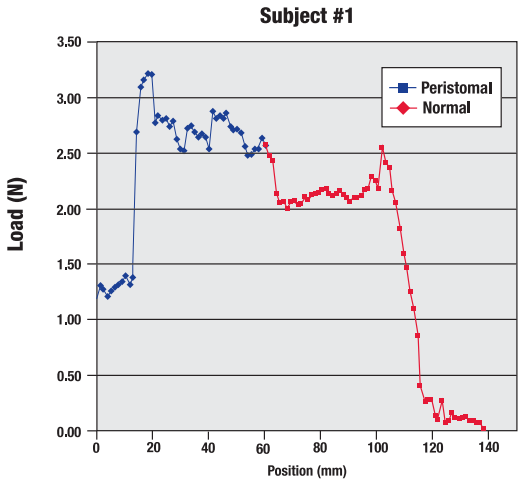

Figure 3 Peel force required to remove skin barrier test strip from skin.

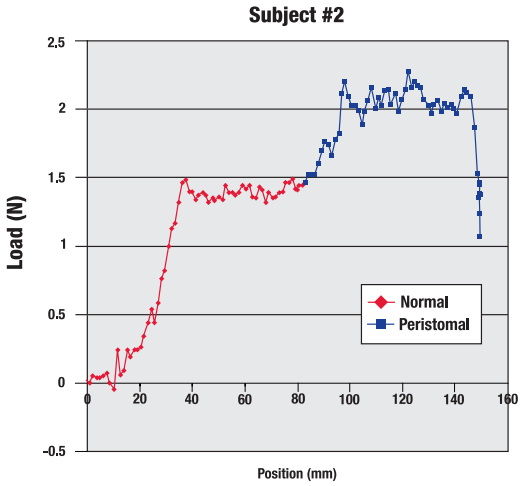

Figure 4 Peel force required to remove skin barrier test strip from skin.

Area of Measurement			
Subject #	Normal	Peristomal	Increase in Peel Force
1	2.12	2.69	27%
2	1.40	2.06	47%
3	1.42	2.53	78%
5	3.31	3.95	19%
7	1.90	2.37	25%

Table 1 Peel Force Measured in Newtons

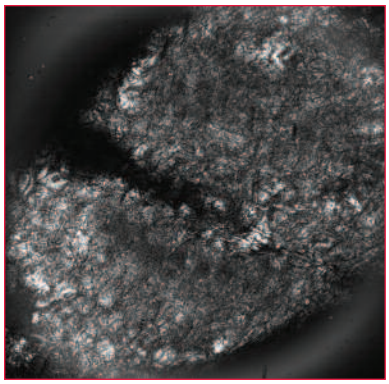

Figure 5 The above captured image of the stratum corneum in an area of "normal skin" shows a smooth layer of corneocytes that are indistinguishable from one another.

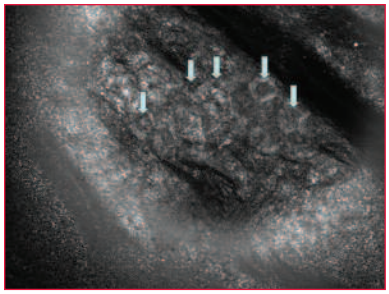

Figure 6 The above image was captured of the stratum corneum in the peristomal area of skin. Parakeratosis is the incomplete keratinization of epidermal cells characterized by retention of nuclei in the cells reaching the level of the stratum corneum. Cell nuclei are not present in healthy corneocytes. Parakeratotic cells (arrows) in the stratum corneum have nuclei that appear large and dark.

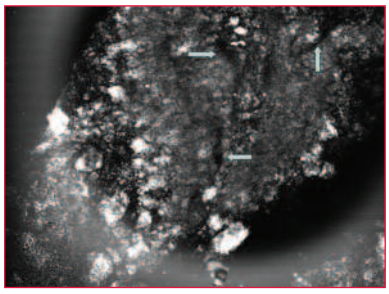

Figure 7 Disruption of the stratum corneum is characterized by detached corneocytes at the surface of the stratum corneum and fissures or cracks (arrows) in the surface of the stratum corneum.

Conclusions

The results of this study provide further evidence of the feasibility of obtaining non-invasive biophysical measurements of the peristomal skin. The difference in peel force between the peristomal and adjacent normal skin appears to be a real, long-term change, and may be due to decreased loosely adherent stratum corneum cells, changes in skin texture, alteration of biochemistry, or some combination.

- The difference of the adhesion level for peristomal skin does call into question the use of adhesion testing on normal skin to predict performance of ostomy skin barriers.
- These studies will be extended to a broader range of adhesive types to determine how widely these observations can be generalized.
- Issues encountered in this study suggest that there is still opportunity for further improvement in the test methods.

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Hollister Incorporated
2000 Hollister Drive
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1.800.263.7400

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