PRELIMINARY STUDIES ON THE SKIN BIOPHYSICS AND OSTOMY SKIN BARRIERS

Part 2–Feasibility of Measuring Peel Force and Skin Properties Comparing Peristomal to Normal Surrounding Skin

Richard I. Murahata, Ph.D.[1], Michael G. Taylor, Ph.D.[1], Jonn Damia[2], Charles R. Zerweck, Ph.D.[2], and Gary L. Grove, Ph.D.[2]

(1) Hollister Incorporated, Libertyville, Illinois USA (2) cyberDERM, Inc., Broomall, Pennsylvania USA

INTRODUCTION

While the ideal situation may be to have the peristomal skin be "normal," it is likely that continuous wear of even the most gentle of barriers in combination with repeated barrier removal and occasional exposure to feces or urine can result in skin that may be far from normal. Although the clinical condition of the peristomal skin has often been described, most recently by Herlufsen *et al.* (1), there is little information on the underlying biophysical and biochemical changes that may contribute to the clinical condition. Physiological measurements were reported to have been obtained in a large survey (2), but the data have yet to be published. An early report by Tazawa and Yasuda attempted to relate biophysical measurements of the peristomal skin to the desired properties of the barrier (3). Mortensen used several standard, noninvasive techniques to assess peristomal skin changes during the first 6 months post-operation (4). Results of that study showed barrier function as measured by transepidermal water loss (TEWL) decreased and skin roughness increased. No significant changes in capacitance (moisture content) or pH were observed.

Leung and Nichols (5-6) and, more recently, Nielsen *et al.* used (7) repeated barrier application on normal skin to demonstrate differential effects of various products over a relatively short time. Both groups reported that TEWL rapidly increased following repeated application and removal of barriers. Recent work by Tokumura *et al.* (8) explored the possible influence of microtopography on adhesion to normal skin.

Since the skin condition directly affects barrier adhesion and directly or indirectly affects other aspects of the patient's condition, there is a need to better characterize the differences between peristomal skin and the surrounding normal skin on which testing has commonly been performed. The feasibility of measuring the differential adhesion of a single commercially available barrier formulation to the peristomal and surrounding normal skin was examined in this study. In addition, biophysical characterization of the skin was accomplished using a battery of well-established noninvasive methods, including TEWL, conductance, ultrasound and skin surface photography.

MATERIALS AND METHODS

Peel Force

The key component is the cyberDERM Peel Tester, which is interfaced to a bench-top PC and as such provides a means for measuring the loads that are generated as the adhesive resists being peeled away from the skin (Figure 1). This improvement on the device originally used incorporates an integral restraint to hold the skin taut during the peel force test. This replaces the straps

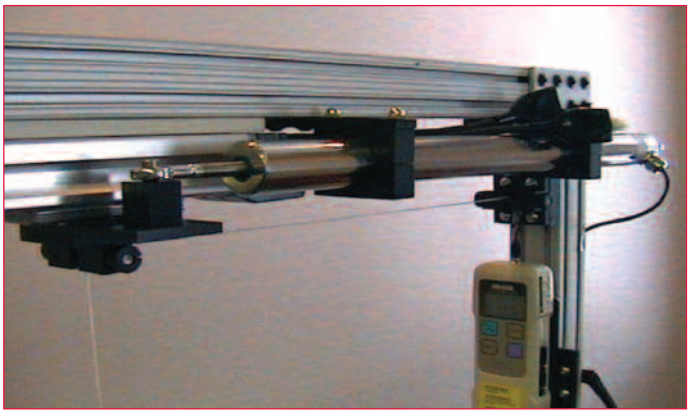


Figure 1. cyberDERM PEEL tester

used in the earlier study (see Figure 2 for placement of adhesive strip and restraint). Based on consumer observation, a 90 degree peel angle was utilized. The peel angle was kept constant by using a novel pulley system which is affixed to a sliding block on the lead screw that moves the pull point. The geometry ensures that the forces generated as the adhesive tape resists being peeled away from the skin are pulling on the load cell in the same orientation regardless of the location of the pulley. The peel rate was 150 mm/minute.

The protocol received IRB approval, and all subjects provided informed consent prior to enrollment into the study. The intention was to enroll up to six subjects in this feasibility study. The normal and peristomal skin was characterized using a battery of well-established noninvasive biophysical measurement. A 1″ x 4″ strip of barrier material was applied to their abdomen starting on normal skin and ending on the peristomal skin. The strip was removed after four hours.

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).

TEWL

Water loss measurements were taken following a 15-30 minute acclimation period in a controlled environment with the relative humidity maintained at less than 50% and temperature maintained at 68±2°F/20±1°C. Damage to skin barrier function as indicated by increased TEWL was assessed using a cyberDERM RG1 Evaporimeter with TEWL probes that were manufactured by Cortex Technology and utilizing well-described methodology (9-10).

Skin Thickness

Noninvasive measurements of skin thickness over each test site were made baseline using a DermaScan C (Cortex Technology, Hadsund, Denmark). Average thickness measurements were made using a total image boundary threshold method.

Skin Moisture

As has been shown, most notably by Obata and Tagami (11), the ability of an alternating current to flow through the stratum corneum is an indirect measure of its water content. In this study, an IBS Skicon-200 Conductance Meter equipped with a Measurement Technologies probe was utilized to measure skin surface hydration.

RESULTS

This pilot study was conducted on three volunteer subjects, two with a colostomy and one with an ileostomy. The time post-surgery ranged from 3-12 years. All three subjects successfully completed the study, and there were no adverse events.

The test barrier strip adhered to the peristomal skin more tightly than to the normal skin, and the demarcation was quite sharp in two of the three subjects. (Data from all subjects are summarized in Table 1. Peel Test Result from Subject #1 is shown in Figure 3).

	Peel Force	
Subject #	**Normal**	**Peristomal**
1	1.07	2.01
2	1.41	2.09
3	1.18	1.86
Mean	**1.22**	**1.99**
SD	**0.17**	**0.12**

Table 1. Average peel force of adhesive removal from normal and adjacent peristomal skin. Measurements are expressed in Newtons.

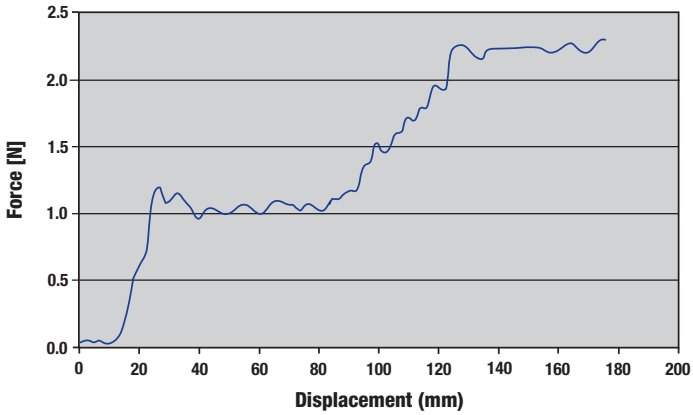


Figure 3. Peel Test Results–Subject #1

Differences in TEWL between the normal skin and peristomal skin were small (Table 2). There was a decrease in skin surface moisture in two of three subjects (Table 3), and a slight thinning of the skin observed by ultrasound (Figure 4 and Table 4). On a macroscopic level, skin texture seemed to reflect the texture of the adhesive and/or backing rather than a change in the underlying skin biology.

	TEWL	
Subject #	**Normal**	**Peristomal**
1	7.5	4.7
2	6.1	4.9
3	8.5	5.5
Mean	**7.36**	**5.03**
SD	**1.23**	**0.42**

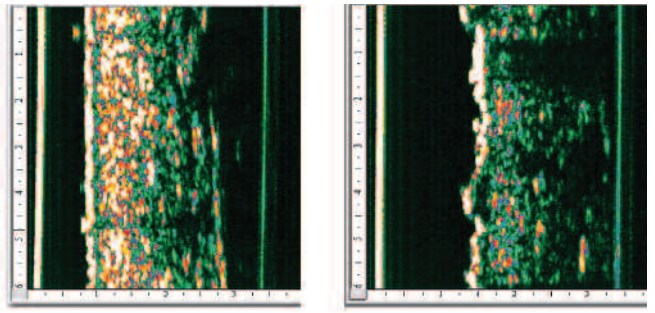
Table 2. TEWL Measurement. All water loss measurements were taken following a 15-30 minute acclimation period in a controlled environment with the relative humidity maintained at less than 50% and temperature maintained at 70±2°F/21±1°C. Duplicate TEWL readings were taken from each site and an average reading calculated. Measurements are expressed in grams/square meter/hour.

	Skicon 200	
Subject #	**Normal**	**Peristomal**
1	585.0	274.2
2	169.2	134.4
3	179.8	356.6
Mean	**311.3**	**255.1**
SD	**237.1**	**112.3**

Table 3. Skin Surface Moisture from Skicon Measurements. Five conductance measurements were taken from each test site and the average value was computed. Measurements are expressed in microSiemens.

	Skin Thickness	
Subject #	**Normal**	**Peristomal**
1	1.87	1.60
2	1.89	1.82
3	2.08	1.83
Mean	**1.95**	**1.75**
SD	**0.12**	**0.13**

Table 4. Skin Thickness derived from Ultrasound Images. B-scan images were computed from 224 A-scan lines. Average thickness measurements were made utilizing a total image boundary threshold method. Measurements are expressed in mm.



Normal Skin *Peristomal Skin*

Figure 4. Ultrasound–Subject #1 Scale is in mm. Skin surface is to the left.

Discussion

The feasibility of obtaining biophysical measurements on peristomal skin was demonstrated in this limited study. It is particularly noteworthy that obtaining skin peel measurements across the normal/peristomal skin junction was possible. None of the subjects experienced leakage or discomfort during the test period. For the barriers used by the three subjects, there was sufficient area either under the tape border or hydrocolloid barrier to obtain measurements.

The difference in peel force between the peristomal and adjacent normal skin may be due to decreased loosely adherent stratum corneum cells, changes in skin texture, alteration of biochemistry or some combination. These possibilities will be explored further upon confirmation of these preliminary results. These results do call into question the direct application of data generated using normal skin as the test substrate.

Surprisingly, the difference in TEWL between the peristomal skin and adjacent normal skin was modest, and opposite of what may have been expected. This observation is particularly interesting since limited data in the published literature reported severe disruption of the barrier function similar to that seen in tape stripped normal skin. However, those studies were conducted within the first few months following surgery, and the skin may not have had time to "harden." There is a possibility that the result was due to interference by adhesive residue, but that is considered unlikely since the skin was rinsed prior to the measurement, and the amount of residue would need to be substantial to produce the observed effect.

FINANCIAL ASSISTANCE/DISCLOSURE

The support of Hollister Incorporated for this clinical presentation is gratefully acknowledged.

910286-408

REFERENCES

1. Herlufsen P, Olsen AG, Nybaek H, Karlsmark T, Laursen TN, Jemec GBE. Study of peristomal skin disorders in patients with permanent stomas. Brit J Nursing 15(16): 854-862, 2006.
2. Laursen TN, Knudsen DB. A study of peristomal skin. Helios 12:3-7, 2005.
3. Mortensen LL. Peristomal skin condition in colostomy patients. Ph.D. Thesis. Danish Academy of Technical Sciences & Faculty of Health Sciences, University of Copenhagen, 1997.
4. Tazawa K, Yasuda T. "Pharmacologic actions of skin barriers" in Skin Barriers for Stoma Care pp 56-68 (Eds, Tazawa K, Anazawa S, Ohmura Y, Yoshikawa R), ALCARE Co., Ltd, Tokyo 2001.
5. Nichols TR, Leung PT. Adhesive skin stripping and air space technology skin barriers. Poster presented at the 14th biennial Congress WCET, Florence, Italy 2002.
6. Nichols TR, Leung PT. Transepidermal water loss and air space technology barriers. Poster presented at the 14th biennial Congress WCET, Florence, Italy 2002.
7. Nielsen LF, Blume N, Romme T, Samuelsen P, Everland H, Ifversen P, Karlsmark T. Skin changes induced by a zinc oxide dressing compared with a hydrocolloid dressing in healthy individuals. Skin Res and Technology 11: 140-151, 2005.
8. Tokumura F, Homma T, Tomiya T, Kobayashi Y, Matsuda T. Properties of pressure-sensitive adhesive tapes with adhesives to human skin and their mechanism. Skin Res and Technology 13: 211-216, 2007.
9. Grove, G.L., M.J. Grove, C. Zerweck and E. Pierce: Comparative metrology of the evaporimeter and the DermaLab® TEWL probe. Skin Res. & Tech. 5:1-8, 1999.
10. Grove, G.L., M.J. Grove, C. Zerweck and E. Pierce: Computerized evaporimetry using the DermaLab® TEWL probe. Skin Res. & Tech. 5:9-13, 1999.
11. Obata, M. and Tagami, H. A rapid in vitro test to assess skin moisturizers. J. Soc. Cosmet. Chem., 41: 235-241, July/August, 1990.

As Presented at

17th World Council of Enterostomal Therapists (WCET) Congress

June 15-19, 2008

Ljubljana, Slovenia

Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048
1.888.740.8999

Distributed in Canada by
Hollister Limited
95 Mary Street
Aurora, Ontario L4G 1G3
1.800.263.7400

www.hollister.com