The Journal of Stomal Therapy Australia

Reprint from Volume 39 Number 2 June 2019

Comparing the skin stripping effects of three ostomy skin barriers infused with ceramide, honey or aloe

Thom Nichols (retired), Hollister Incorporated, Libertyville, IL, United States of America*
Email mequontnichols@gmail.com

Tim Houser, cyberDERM, Inc., Broomall, PA, United States of America

Gary Grove, cyberDERM, Inc., Broomall, PA, United States of America

Additional contributors: Gary Inglese contributed to development of manuscript.
Medical writing assistance provided by Ginger Salvadalena, 2000 Hollister Drive, Libertyville, IL 60048, United States of America Email ginger.salvadalena@hollister.com

**Corresponding author*

Keywords Transepidermal water loss, ostomy skin barrier, peristomal skin, randomised clinical study, ceramide.

For referencing Nichols T *et al.* Comparing the skin stripping effects of three ostomy skin barriers infused with ceramide, honey or aloe. Journal of Stomal Therapy Australia 2019; 39(2):14-18.

DOI https://doi.org/10.33235/jsta.39.2.14-18

ABSTRACT

Use of an ostomy skin barrier can place the skin at risk of injury due to mechanical, chemical and biological factors. Repeated application and removal of the ostomy skin barrier can be associated with skin stripping and damage to the skin barrier function. Measurement of transepidermal water loss (TEWL) is a way to assess the effect of ostomy barrier use on the skin. The objective of this study was to determine the effect of a ceramide-infused ostomy skin barrier compared to other infused skin barriers when changed once daily. The study was a randomised, prospective, repeated measures trial involving healthy volunteers. Twenty-four subjects were randomised to wear a ceramide-infused ostomy barrier and either Manuka honey barrier or aloe-infused barrier for five subsequent days. Barriers were changed daily and the skin was evaluated by visual examination and measurement of TEWL. We found the ceramide ostomy barrier minimised the effects of skin stripping when compared with aloe or Manuka honey skin barrier. Ceramide-infused skin barriers should be considered as part of an overall peristomal skin care strategy aimed at preserving peristomal skin integrity.

INTRODUCTION

One of the potential complications of living with a stoma is the development of skin problems such as peristomal moisture-associated skin damage (PMASD) or peristomal medical adhesive-related injury (PMARSI). Peristomal skin complications affect over 60% of individuals with a stoma[1,2] and these complications negatively impact body image, quality of life, and health utility[3-6]. Occurrence of peristomal skin complications has been associated with higher total health care costs in the first four months after stoma creation[7,8].

Peristomal skin is broadly defined as the abdominal skin surrounding the stoma, generally confined within the footprint of the ostomy skin barrier. Contact with the ostomy skin barrier may place the skin at risk of injury due to mechanical, chemical and biological factors. Removal of layers of the stratum corneum, described as skin stripping, can occur due to repeated application and removal of the ostomy skin barrier. Stripping can deteriorate skin barrier function; the extent of which may be measured as transepidermal water loss (TEWL)[9]. TEWL is the diffusion of water through the epidermal layers; a natural process that can be intensified by skin injuries such as stripping.

To help mitigate potential negative effects on peristomal skin health, ostomy product manufacturers have developed skin barriers infused with ingredients thought to benefit peristomal skin, such as ostomy skin barriers formulated with ceramide, Aloe vera, and Manuka honey[10-12]. Ceramide is a main component of the stratum corneum of the epidermis layer of human skin, and together with cholesterol and saturated fatty acids prevent excessive water loss and provide support as a barrier against the entry of microorganisms[13,14]. Ceramide is widely used in cosmetics and as an ingredient in some ostomy skin barriers and barrier rings/seals. Aloe is a succulent plant found in tropical climates and widely cultivated as a source of Aloe vera, best known for treating skin injuries. Although commonly used in skin lotions, cosmetics and ointments, a search of the published literature finds little scientific evidence of the effectiveness or safety of aloe for use in wound care[15].

Manuka honey is a variety of honey produced by bees from flowers of the Manuka tree found in New Zealand. In laboratory studies, honey has been shown to have antibacterial properties[16]. Research conducted on Manuka honey indicates that it is effective against a variety of human pathogens, to include *Escherichia coli*, *Enterobacter aerogenes*, *Salmonella typhimurium*, and *Staphylococcus aureus*[17].

While ostomy manufacturers of skin barriers formulated with various infusates (aloe, honey or ceramide) suggest they are of benefit to the peristomal skin of the ostomate, to date there have been no comparative studies of skin barriers formulated with these components to suggest that any one may have benefit over the others.

The purpose of this study was to explore how skin changes over time with repeated use of infused ostomy skin barriers. Specifically, the intent was to determine the effect of a ceramide-infused ostomy skin barrier compared to other infused skin barriers when changed once daily.

METHODS

The study was a randomised, prospective, repeated measures trial involving healthy volunteers. The study included three ostomy skin barriers infused with ceramide, aloe or honey as part of an overall investigation into ostomy barriers conducted in January 2017. It took place at a single study site in the US (cyberDERM Inc., Broomall, PA), and the study was conducted in accordance with Good Clinical Practices (GCP) and in compliance with ICH guidelines. The study was reviewed and approved by an Independent Review Board (Allendale Investigational Review Board of RTA Incorporated); all subjects completed informed consent prior to the start of study procedures.

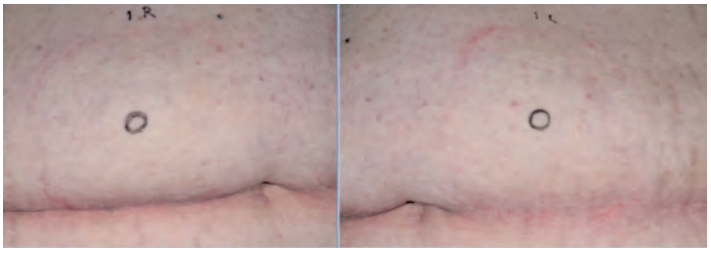

Figure 1

PARTICIPANTS

Twenty-four healthy volunteers without stomas served as study participants. They were randomised to wear two types of adhesive ostomy barriers (one product on each side of the abdomen, as shown in Figure 1). Study participants were recruited from a database of healthy volunteer candidates maintained by the research site. The inclusion and exclusion criteria are shown in Table 1.

MATERIALS

The study products in this analysis were marketed ostomy skin barriers containing ceramide, Aloe vera, or Manuka honey, as listed in Table 2. Each product was used for a total of five applications and removals during the five-day study period. This wear schedule was selected to reflect that commonly followed for the frequency of ostomy skin barrier change in Australia and several other countries.

Table 1: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Age 18–65	Pregnant or nursing mother
Caucasian	Menopausal with hot flashes
Fitzpatrick skin type I, II, or III	Allergic to adhesives or test products
Does not use anti-inflammatory medications	Clinically significant skin disease or damaged skin around test sites
Sufficient abdominal size to fit two test products	Immunological disorders
Agrees to refrain from swimming and soaking in hot bath during study	Cancer treatment within six months
	Uses topical drugs on the abdomen

Table 2: Study products

Product	Number	Description
CeraPlus skin barrier	15102	Flat skin barrier, tapeless
Salts Harmony Duo with Flexifit® and Aloe	FHD 1332	Flat skin barrier
Welland Aurum® 2	2MH2F413	Flat flange

DESIGN

This study was a prospective, randomised, repeated measures evaluation. The expert graders evaluating the visual appearance of the skin and the technicians taking TEWL measurements were blinded to the identity of the products being used.

PROCEDURE

Ostomy barriers were applied and removed by a technician who removed the release liner, placed the barrier on the skin and held it in place with their hand for 30 seconds. To remove the barrier, the technician gently peeled back the barrier at a 90° angle. Skin observations were completed by a single trained observer and TEWL measurements were completed in a temperature- and humidity-controlled room by a separate technician 25 minutes following barrier removal.

A calibrated cyberDERM RG1 Evaporimeter System (Broomall, PA) with TEWL probes manufactured by Cortex Technology (Hadsund, Denmark) was used to obtain TEWL measurements. Water loss is expressed in gm/m^{2}hr. At each session, duplicate water loss readings were taken from the designated zone within the medial area of each site (Figure 1). Additional measurements were made in other zones or edges of a given test site if either the skin was compromised, denuded, eroded or had other signs of irritation that resulted in an early termination. Technicians performing skin measurements were blinded to the identification of the study barriers and did not see the application or removal of the products. Digital images were taken of participants' skin following discontinuation or completion of the study.

Table 3: Scoring system used for visual observation of skin irritation

	Erythema
0	None
1	Mild, slight irritation
2	Moderate erythema
3	Marked erythema, slight oedema
4	Marked erythema, oedema, possible erosion
Denudation	
0	No sign of denudation
1	Trace amount of denudation (slight glazed appearance)
2	Partial thickness denudation (moist or wet surface)
3	Full thickness denudations (exudates present on test site)
4	Full thickness denudations in combination with extreme erythema/oedema

Edge irritation
0 = None
1 = Mild
2 = Moderate
3 = Marked
4 = Severe with erosion

One blinded expert grader made all skin assessments in this study. The assessments were made prior to the first application of the ostomy skin barriers at baseline and approximately 30 minutes post-removal of ostomy skin barriers on days 2–5. The skin grader was blinded as to product applications and was not allowed to compare any previous scores. In order to qualify for the study, all assessments at baseline must have been zero. If any of the barriers were partially adhered or had fallen off at subsequent study visits, it was recorded and assessments were still made and the barriers were reapplied on schedule.

All subjects were visually evaluated using the five-point ordinal scales for erythema, denudation (skin stripping) and edge irritation. These methods are described in further detail in a previous publication, describing the measurement zones and method of summing scores[18]. The scale ranges from 0 (none) to 4 (severe), with intermediate scores of 1, 2 and 3 representing mild, moderate and marked conditions respectively. Half grades were allowed so that finer distinctions could be made.

If any test site zone reached a grade 3 or greater for erythema, 2 or greater for denudation or 4 or greater for edge irritation during the study, treatment on that site was discontinued. Once a site was discontinued, all product application and study assessments were discontinued for both sites, the last recorded observations for the comparisons were carried forward in the data, and adverse event information was captured until the irritation was resolved. Statistical analysis of the data consisted of regression analysis with comparisons of slopes, and paired comparisons (paired t-tests) of repeated measures (adjusted for multiple comparisons per the Bonferroni/Holm adjustment)[19] between the ceramide and aloe skin barriers, and the ceramide and Manuka honey barriers. Analysis was performed using SAS v9.4 (SAS Institute, Cary NC).

RESULTS

A total of 12 participants were randomised to wear ceramide and aloe, and 12 were randomised to ceramide and Manuka honey. The mean age was 47.8 (range 18–63) and most (20 out of 24) were female. One participant from group 2 (honey) withdrew from the study on day 4 due to subjective discomfort and the remaining 23 subjects completed the study. There were no serious adverse events. There were no discontinuations related to the ceramide ostomy barrier. On the other hand, three participants were discontinued from the study at day 4 due to skin problems occurring on the sites where the honey ostomy barrier was used and five were discontinued due to skin problems occurring under the aloe ostomy barrier (one at day 3 and four at day 4).

At baseline, no statistically significant differences were noted in TEWL for the two sides of the subjects' abdomens. With subsequent measurements (following ostomy barrier removals) TEWL increased for all barrier types as the days progressed. For days 2–5, the TEWL at the sites associated with the ceramide skin barriers was significantly lower than that associated with the aloe and the honey skin barriers.

Specifically for the aloe versus ceramide: Figure 2 displays the mean of the daily TEWL measurements for participants wearing ceramide and aloe. For days 2–5, the skin sites with ceramide skin barriers demonstrated statistically significantly lower TEWL than the aloe skin locations. The linear increase in TEWL per day of wear was lower for the ceramide barrier than the aloe barrier (3.33 gm/m^2/hr vs. 8.71 gm/m^2/hr; p<0.0001). The means for the scores for each type of visual observation of the skin (erythema, skin stripping, and edge irritation) were also lower for the areas with ceramide barrier than the aloe barrier.

Specific to the honey versus ceramide comparisons, again at baseline no statistically significant differences were noted between sites for the two products. As shown in Figure 3, for days 2–5, the skin sites with ceramide barriers demonstrated statistically significantly lower TEWL than the honey skin barrier locations. The linear increase in TEWL per day of wear was lower for the ceramide barrier than the honey barrier (2.69 gm/m^2/hr vs. 9.72 gm/m^2/hr; p<0.0001). The visual scores for erythema, skin stripping and edge irritation were lower for the ceramide areas than the honey barrier. Figure 4 displays the visual scores in the two comparison groups.

DISCUSSION

Since the early years of the 20th century, those manufacturing ostomy products have been aware of peristomal skin problems primarily caused by industrial adhesives (as opposed to contemporary products) used to secure steel or hard rubber and plastic 'face plates' to the abdomen of the person that has undergone ostomy surgery. In more modern times there have been considerable improvements. In the 1960s, the use of karaya as a skin barrier greatly improved peristomal skin health, as did the advent of hydrocolloid barriers in the 1970s. As the ostomy industry evolved, it mirrored and in part was directed by the emergence of the development of the stoma care nurse specialty. Their exacting perspective on ostomy products held that products must complement the care their profession provides.

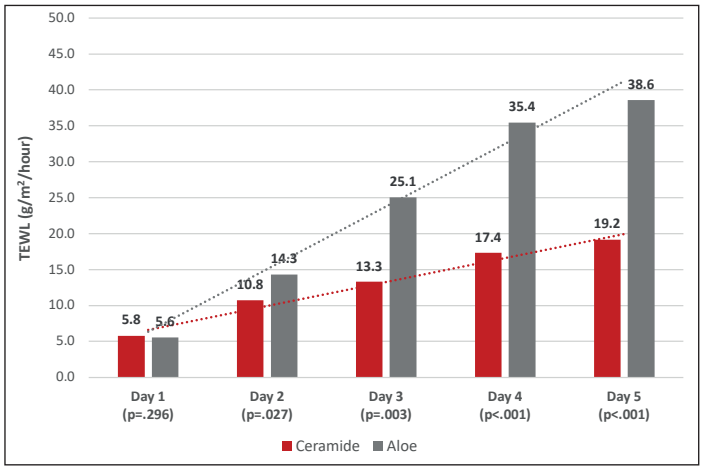

Figure 2: TEWL by day between ceramide and aloe skin barrier

Maintaining the health of peristomal skin is a key interest of stoma care nurses and their patients. Thus, quantitative data from studies comparing ostomy skin barriers for their performance qualities provides evidence to inform decision making and product selection. TEWL is an objective way to measure the skin stripping effects of repeated removal of adhesive products and it has been used extensively in comparisons of tapes. In tape studies, the inner arm is often used, while in this study we chose to apply the test products to the skin of the abdomen. This location was chosen to better represent the site of application of ostomy products. As expected, the skin showed evidence of

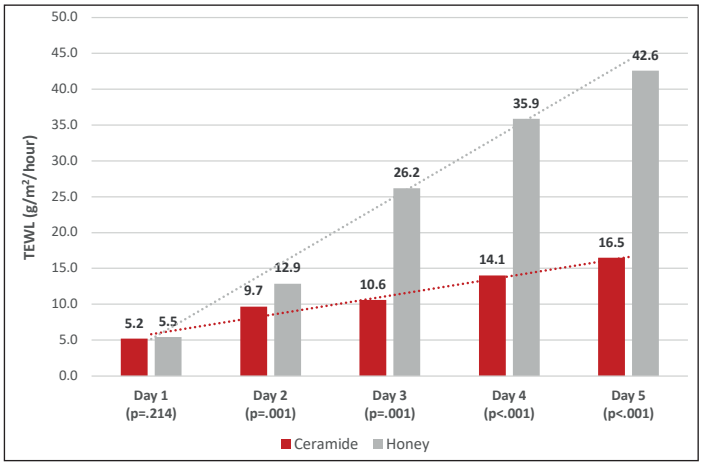

Figure 3: TEWL by day between ceramide and honey skin barrier

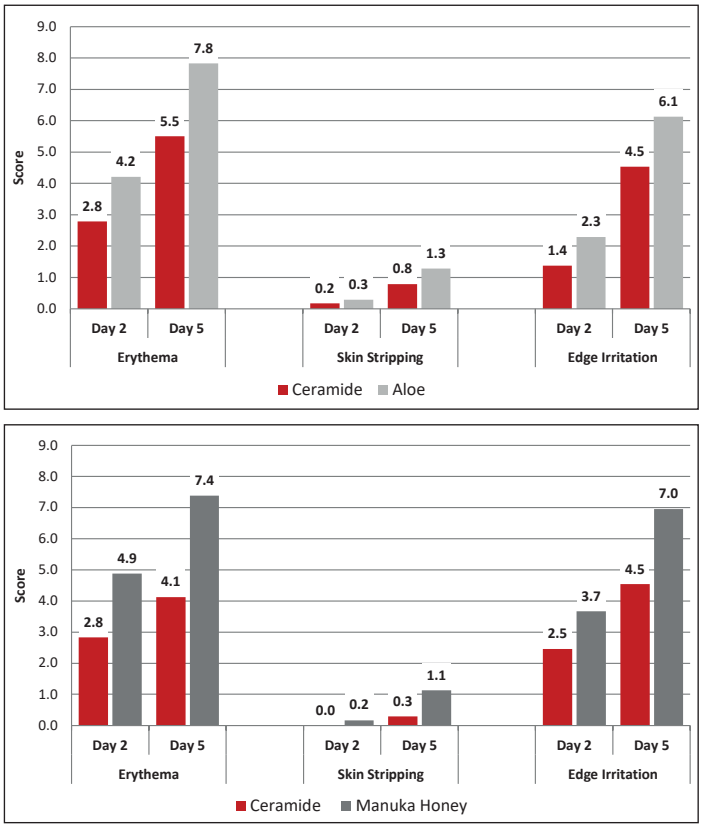

Figure 4: Summed visual scores on days 2 and 5 for the two comparison groups

barrier disruption, which increased over time with repeated ostomy product removal. As the number of days progressed, differences in the effect of product types became more evident.

This study addressed the issue of infused barrier performance in regard to the effects of skin stripping, which is a contributor to PMARSI[20]. The use of TEWL as a method of measuring the skin-stripping effects of ostomy barrier removal was effective at detecting differences between test products. Additionally, expert observer subjective comparisons were included in this study as part of a dimensional analysis requiring the observer to choose numerical ratings (scores) to assess erythema, skin stripping, and edge irritation changes in the abdomen of study participants. The data from this healthy volunteer study suggest that a ceramide-infused skin barrier may reduce the effects of skin stripping from repeated application and removal of adhesive skin barriers when compared with barriers containing extract of Aloe vera or Manuka honey.

STUDY LIMITATIONS

A limitation of the study is that the study did not include people with stomas. As such, it is not known what the effect would be on existing peristomal skin, that is, peristomal skin that has been subject to long durations of repeated application and removal of skin barriers such as that experienced by most ostomates. Ostomy skin barriers were changed daily in this study; it is unclear whether similar results would be obtained if the barrier were changed less often. Manufacturing of ostomy barriers makes it difficult to blind studies involving use of ostomy skin barriers. In this study, neither the technicians nor the expert grader ever saw the products in use or being placed on the skin; this helped to reduce bias in the measurements.

CONCLUSIONS

These data suggest that ceramide-infused skin barriers reduce the effects of skin stripping as a result of repeated application and removal of adhesive skin barriers when compared with an aloe and honey-containing ostomy skin barriers. Ceramide-infused skin barriers should be considered as part of an overall peristomal skin care strategy aimed at maintaining skin integrity.

ACKNOWLEDGEMENTS

Gary Inglese contributed to the development of this manuscript. Medical writing assistance was provided by Ginger Salvadalena, Hollister Incorporated.

FUNDING INFORMATION

Hollister Incorporated.

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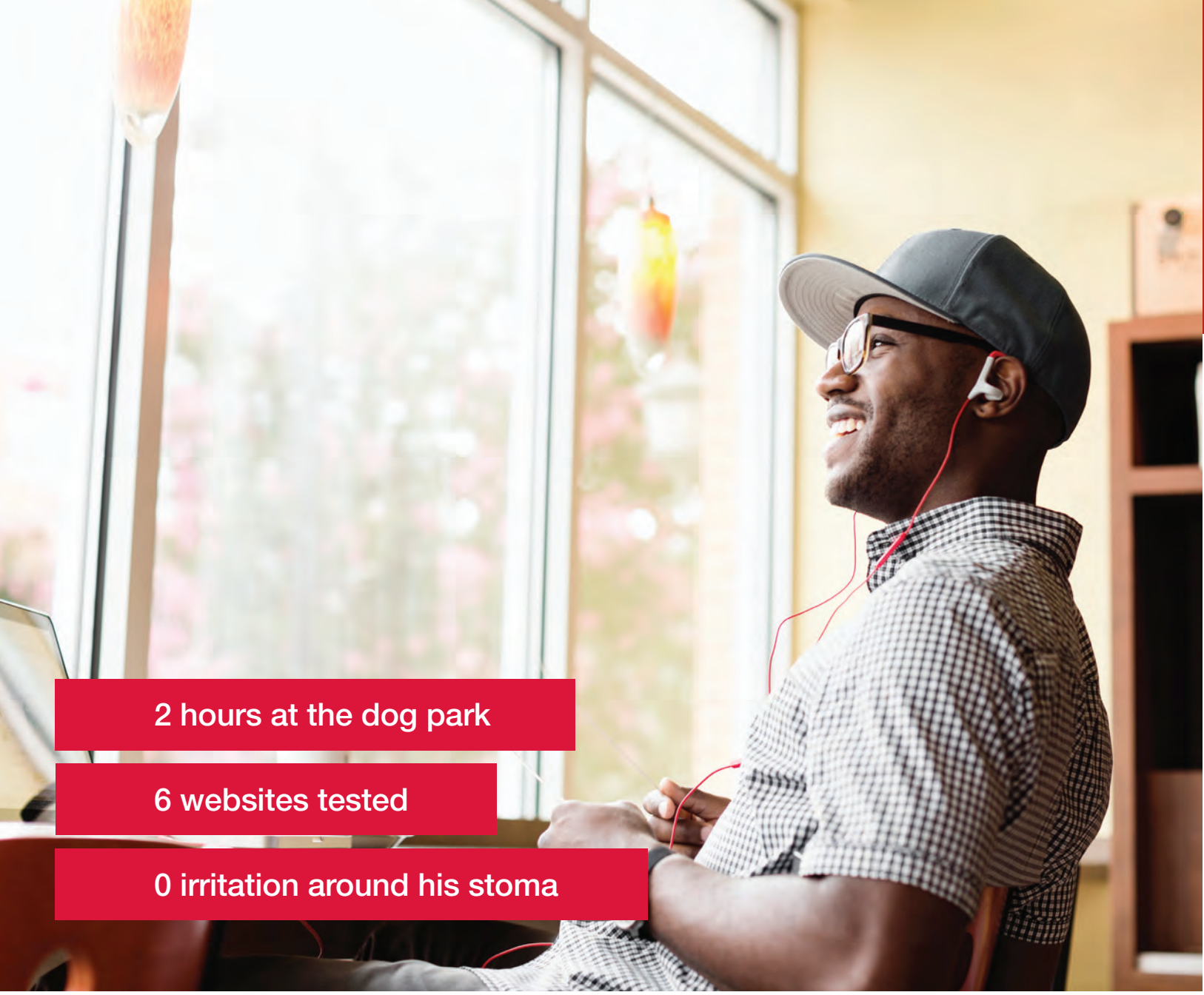

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