ANALYSIS OF THE IMPROVEMENT TO DAMAGED PERISTOMAL SKIN SEEN WITH THE USE OF POUCHES WITH MANUKA HONEY INCORPORATED INTO THE HYDROCOLLOID FLANGE

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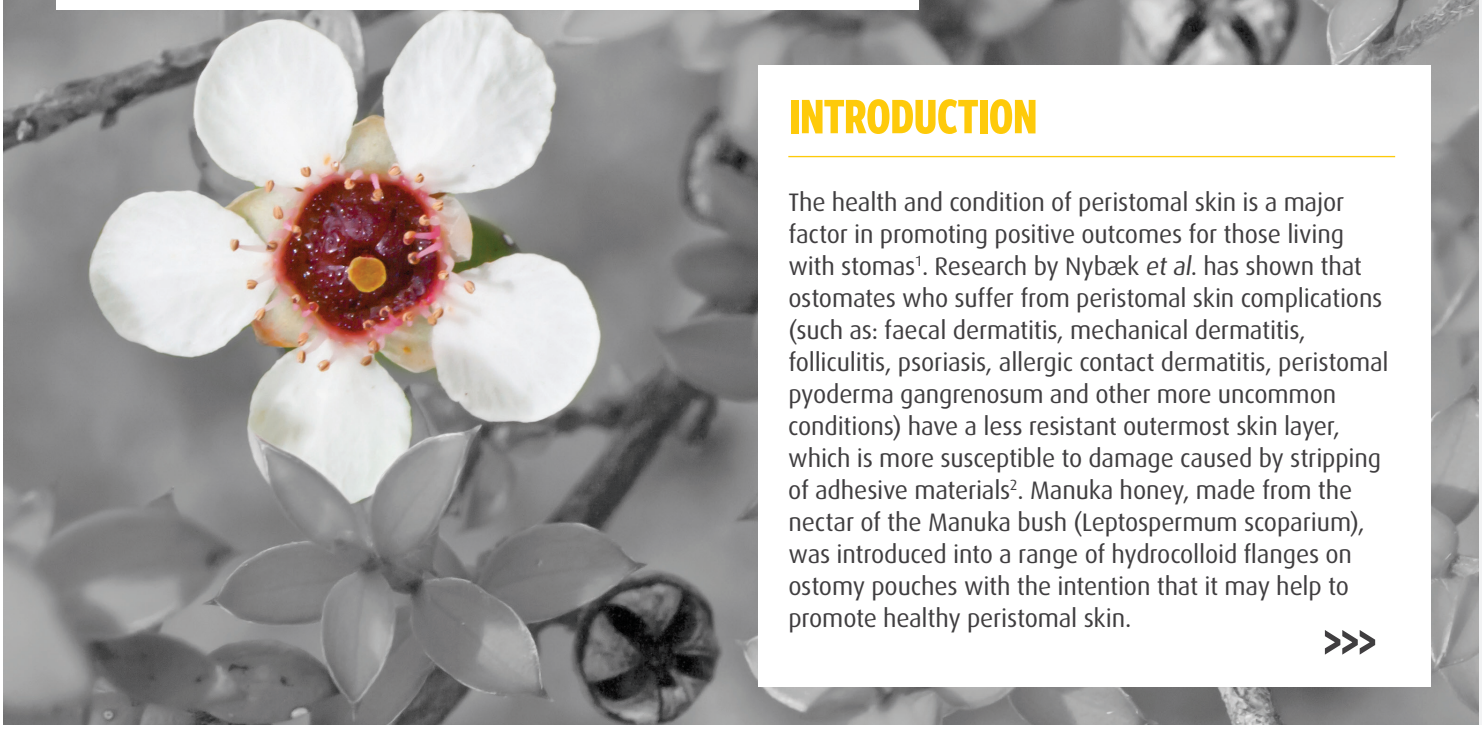

INTRODUCTION

The health and condition of peristomal skin is a major factor in promoting positive outcomes for those living with stomas[1]. Research by Nybæk *et al.* has shown that ostomates who suffer from peristomal skin complications (such as: faecal dermatitis, mechanical dermatitis, folliculitis, psoriasis, allergic contact dermatitis, peristomal pyoderma gangrenosum and other more uncommon conditions) have a less resistant outermost skin layer, which is more susceptible to damage caused by stripping of adhesive materials[2]. Manuka honey, made from the nectar of the Manuka bush (Leptospermum scoparium), was introduced into a range of hydrocolloid flanges on ostomy pouches with the intention that it may help to promote healthy peristomal skin.

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The health and condition of peristomal skin has a significant impact on the effectiveness of ostomy products. Nybæk *et al.* explain that "the peristomal skin plays an important role in the functioning of the whole pouching system, by providing the surface to which it adheres, and skin complications often reduce the base-plates' ability to attach to the skin; thus the quality of peristomal skin is important"[3]. Any damage to the skin surrounding the site of a stoma could reduce the security of an ostomy product and increase the likelihood of leakage. A study by Woo *et al.*[4] proposed that, of those ostomates diagnosed with a peristomal skin disorder, 77% could be linked to contact with the stoma's output but Nybæk *et al.* put the figure at around 50%[3]. While the exact figures vary, the connection between leakage and peristomal skin health is clearly established in existing literature. Meisner *et al.* argue that peristomal skin complications can create a cycle where they cause the adhesive of ostomy products to fail, causing leakage, leading to further skin problems[5].

Peristomal skin complications can cause a wide range of signs and symptoms, which can lead to discomfort, pain, poor self-image, social isolation and impaired quality of life[6]. The World Health Organisation defines quality of life as "a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs"[7]. Meisner *et al.* argue that the frequency and severity of peristomal skin complications has a major effect on a patient's quality of life and daily living[5]. Boyles and Hunt support this, stating that complications such as sore skin have a direct negative impact on how ostomates view themselves and live their lives[1].

This study sets out to assess how significant the introduction of Manuka honey into hydrocolloid flanges of ostomy pouches can be with regard to both peristomal skin health and an ostomate's quality of life.

OBJECTIVES

The aim of this study is to verify improvements observed in the peristomal skin condition with the use of pouches containing Manuka honey in the hydrocolloid flange compared to participants' usual pouches and the effect the use of these pouches has on their quality of life. If a correlation is drawn between the use of pouches with Manuka honey and an improvement in peristomal skin health, these results may provide potential recommendations for improving the health of damaged peristomal skin. Additionally, if improvements in quality of life can be correlated with the introduction of Manuka honey, this study could help to develop recommendations which may improve the quality of life of ostomates affected by damaged peristomal skin.

MATERIALS AND METHODS

Historical records of honey being used to treat human skin conditions date back to the earliest civilisations[8]. Manuka honey is made only from the nectar of the Manuka flower in New Zealand and is known to exhibit strong antibacterial properties[8]. Research has shown active Manuka honey to have characteristics that may help to kill bacteria, suppress inflammation, and stimulate the growth of cells, which may aid the healing process. The Manuka honey used in the manufacturing of the trial pouches was certified by the Unique Manuka Factor Honey Association (UMFHA), the group responsible for the Unique Manuka Factor Quality Mark (UMF). This ensures that the Manuka honey used is genuine Manuka honey and meets the standards required by the UMFHA, certifying purity and consistency. All Manuka honey used in the trial pouches had a grade of UMF 16+.

A total of 336 patients took part in the study: 118 of these (35.12%) had colostomies, 96 (28.57%) had ileostomies, 111 (33.04%) had urostomies, 10 (2.98%) had nephrostomies and 1 (0.3%) had both a colostomy and a urostomy. This study, therefore, incorporated a wide range of 1-piece ostomy pouch types with Manuka honey incorporated into the hydrocolloid flange.

The observational examination of the use of these pouches was executed across 21 different Italian stoma centres from May until December 2015. During the study enrolment, the 336 participants were informed about their involvement and their clinical conditions, the features of their usual pouches and their quality of life was evaluated. The attending nurses assessed the health of the participants' peristomal skin, recording a classification of the skin's health as well as the type and location of any lesions present. After two weeks of using the trial pouches, the participants' quality of life scores were recalculated and their clinical conditions and the health of their peristomal skin were reassessed by the nurses. Each participant's quality of life was evaluated through a stoma quality of life questionnaire which was completed at the point of enrolment and then completed again after the two-week trial period.

Exclusion criteria were established so as to ensure that patients whose skin conditions required treatment beyond that which could be provided by an ostomy pouch and patients whose skin conditions would have been altered by external factors or ongoing medical treatments were not included. >>>

Those undergoing chemotherapy or radiotherapy were excluded as were those who were taking medication for their skin because these treatments could alter the condition of the peristomal skin during the trial.

All of the participants involved in this study were either suffering from skin problems at the start of the trial or had a clinical history of skin problems affecting their peristomal skin area which was linked to the use of stoma care products. At the start of the trial, 85% of participants had acute episodes of these problems ongoing. The area surrounding the stoma was broken up into four quadrants to help record the location and size of peristomal skin complications. Of the respondents, 55.63% recorded that their problem skin was in all four quadrants surrounding their stoma. This could suggest that the issues they have been experiencing with their skin were related to the flange of the pouch they had been regularly using before the trial began.

RESULTS

Response Rate

Overall, 336 participants were involved in this study but not all participants provided an answer to every question put to them. Therefore, the number of complete and valid responses to each question (n) varies and the percentages calculated and included in this report are based on the number of valid responses received for each question.

Peristomal Skin

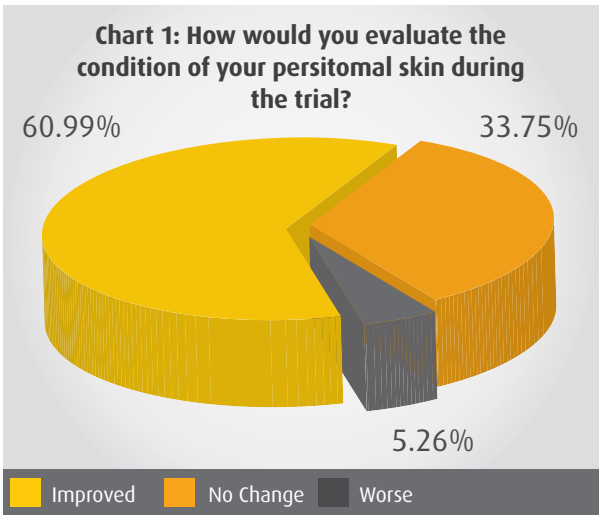
Participants were asked to assess how they felt the condition of their peristomal skin had changed while wearing the trial pouch and were given the options of improved, no change and worsened. Of the participants, 60.99% (n=323) said that the condition of their peristomal skin had improved while they took part in the trial, 33.75% felt that there was no change and the remaining 5.26% felt that it had become worse (Chart 1). Of this 5.26%, 35.29% saw an increase in the quality of life score after the trial had concluded, 11.76% had a quality of life score equal to the score given before the trial and 50% said that the flange was comfortable during the trial. However, 64.71% of those who felt that the condition of their peristomal skin had worsened felt that their overall situation had also worsened. Of the 60.99% who felt that the condition of their peristomal skin had improved, 93.4% of respondents described their overall condition as either healed or improved, 92.89% felt that the hydrocolloid flange was either secure or very secure and 68.37% saw an increase in their quality of life score.

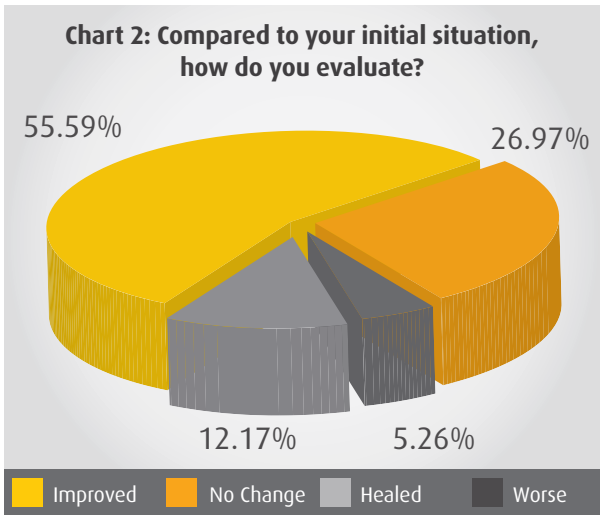
Leakage

A significant influence on the health of peristomal skin is the risk of leakage; 49.8% (n=255) experienced leakage with their existing products. In the two-week trial period this was reduced to 18.64% (n=295). A total of 84 participants of this study provided valid responses to both questions on leakage, which showed that they experienced problems with leakage with their normal pouches but did not with the trial pouch. Of these, 79.52% of respondents described their overall condition as either healed or improved, 82.14% of respondents felt that the condition of their peristomal skin had improved and 73.49% of respondents saw an increase in their quality of life score.

Perception of Overall Condition

At the end of the two-week trial period participants were asked how they would assess the overall status of their stoma and general condition. The options they were given to select were worsened, not changed, improved and healed. A total of 304 participants provided valid responses, 12.17% of these described their condition as "healed", 55.59% described it as "improved", 26.97% described it as not changed and 5.26% described it as "worsened" (Chart 2).



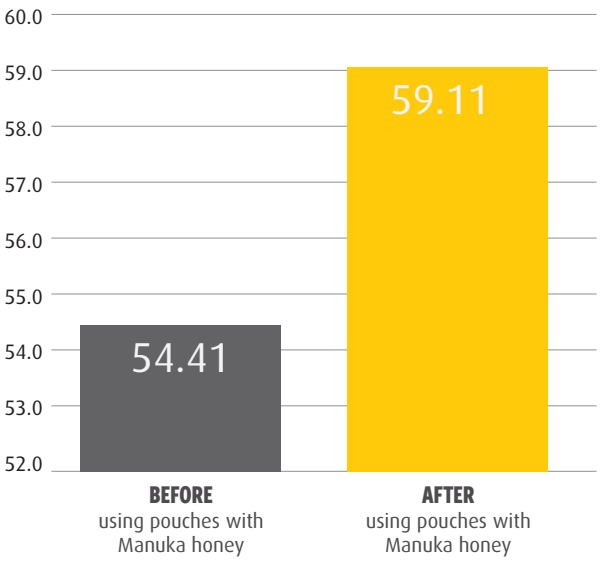


QUALITY OF LIFE

The quality of life of participants was assessed and scored through the completion of a validated stoma quality of life questionnaire (Stoma-QOL – Italian version[9]). This comprises 20 statements which were put to each participant and they were asked how frequently in their lives they felt each statement was true (Table 1)*. All the statements were phrased so as to highlight potential negative aspects of having a stoma; some linked directly to the pouch and stoma, such as worrying about odour, noise or security of the adhesive, and some focused on potential negative influences of having a stoma, such as poor sleeping habits, restricting choices of clothing or reducing perceptions of one's own sexual attractiveness. The possible responses were: always (1), sometimes (2), rarely (3) and never (4). The scores linked to each response were tallied and the resulting figure gives an idea of each participant's overall quality of life in relation to their stoma at that particular time. The higher the final score, the less a participant feels these negatives are affecting their daily life.

Participants completed the same stoma quality of life questionnaire twice, once before the trial began and then again after the two weeks had come to an end. A total of 286 participants fully completed both quality of life questionnaires. The average total quality of life score for this group before the trial began was 54.41; after the two-week trial this increased to 59.11 (Chart 3). Comparing the total scores before and after the trial for each of these participants shows that 26.32% saw their quality of life scores increase after completing the trial, 62.46% did not change and for 11.23% their score decreased.

Chart 3: Average quality of life score



CONCLUSIONS

The results of this study show that the majority of participants, 60.99% (n=323), have seen an improvement in the health and condition of their peristomal skin after using the trial pouch for two weeks. The quality of life score generated by the stoma quality of life questionnaire increased for 26.32% of respondents (n=286) and that the average score rose from 54.41 to 59.11 out of a maximum of 80. This would suggest that the use of an ostomy pouch with Manuka honey incorporated in the hydrocolloid flange over this two-week trial had a positive effect on the health of these participants' peristomal skin and had a positive effect on the quality of life score generated by the questionnaire selected.

BEFORE

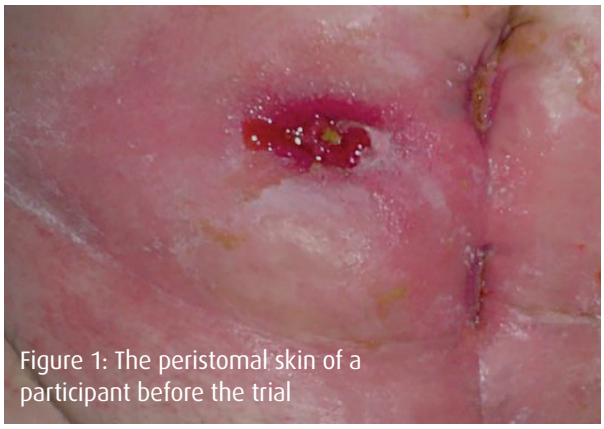


Figure 1: The peristomal skin of a participant before the trial

AFTER

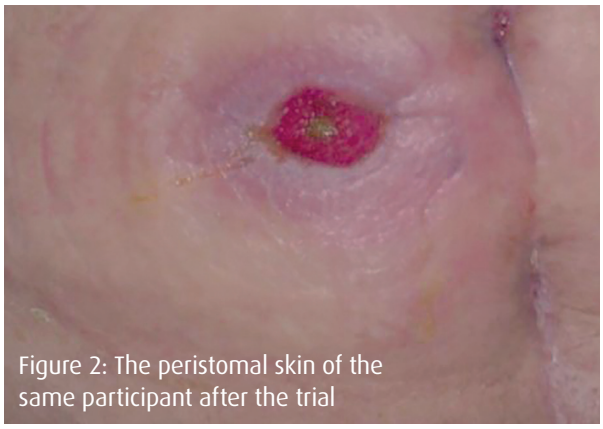


Figure 2: The peristomal skin of the same participant after the trial

*See last page

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Table 1.

S-QOL1	I become anxious when the pouch Is full
S-QOL2	I worry the pouch will loosen
S-QOL3	I feel the need to know where the nearest toilet is
S-QOL4	I worry that the pouch may smell
S-QOL5	I worry about the noise from the stoma
S-QOL6	I need rest during the day
S-QOL7	My stoma pouch limits the choice of clothes that I can wear
S-QOL8	I feel tired during the day
S-QOL9	My stoma makes me feel sexually unattractive
S-QOL10	I sleep badly during the night
S-QOL11	I worry that the pouch rustles
S-QOL12	I feel embarrassed about my body because of my stoma
S-QOL13	It would be difficult for me to stay away from home overnight
S-QOL14	It Is difficult to hide the fact that I wear a pouch
S-QOL15	I worry that my condition is a burden to people close to me
S-QOL16	I avoid close physical contact with my friends
S-QOL17	My stoma makes it difficult for me to be with other people
S-QOL18	I am afraid of meeting new people
S-QOL19	I feel lonely even when I am with other people
S-QOL20	I worry that my family feel awkward around me

The 20 statements presented to participants which make up the Stoma-QOL (translated from italian). Participants were asked how frequently they feel each of these statements are true, with the passible responses being: always (1), sometimes (2), rarely (3) and never (4).

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