

A new approach with a novel silicone adhesive stoma bag: a clinical study on peristomal skin and quality of life

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Good skin integrity is vital to good health. It acts as a barrier to microbes and toxins, and any breaches in the skin can have a negative impact on the overall health of patients, as well as cause pain and discomfort (Payne, 2020).

The vulnerability of the skin surrounding a person's stoma (peristomal skin) presents a major challenge for people living with a stoma, as well as stoma care nurses (SCNs).

Healthy peristomal skin is intact and does not cause distress, nor impair the quality of life (QoL) of the person living with the stoma (Burch et al, 2021). However, the peristomal skin is highly vulnerable to damage and this is reflected by the fact that more than 80% of ostomates have skin problems around their stoma within 2 years of surgery (LeBlanc et al, 2019).

Some examples of peristomal skin complications that ostomates may experience include medical adhesive-related skin injuries/skin stripping (MARSI), moisture-associated skin damage (MASD) and contact dermatitis (Burch et al, 2021). Such complications are often a result of leakage (Voegeli et al, 2020), as well as ostomates' limited choice of stoma bags, with a hydrocolloid adhesive flange/baseplate, potentially leading to detrimental effects on their peristomal skin (Lager and Loxdale, 2021).

The study

This article presents a study examining the use of the first stoma bag to be developed with a silicone adhesive. Genii™ stoma bag (Trio Healthcare) is described as the first ever stoma bag in the world that uses the unique Sil2 Breathable Silicone Technology® in the flange. This means it sticks with a unique silicone adhesive that flows in and around skin cells, allowing stronger adhesion and less risk of leaks. It is designed to seal perfectly to protect the skin from harmful bodily waste, bacteria and moisture and, because the silicone flange moves with the patient's body, it is described as feeling 'like it is not even there' (Trio Healthcare, 2022) (Figure 1).

Sixty-four colostomates were initially recruited for the study; however, two dropped out before the trial began and one withdrew at week 4 as they did not have time to complete the study. Therefore, the study was conducted with 61 colostomates living in the UK over 6 weeks, the primary objective of which was to investigate the effects of the Genii flat one-

ABSTRACT

The care of peristomal skin is a major challenge for people living with a stoma, as well as stoma care nurses. Peristomal skin complications include medical adhesive-related skin injuries/skin stripping, moisture-associated skin damage and contact dermatitis. There is also a limited choice of hydrocolloid adhesive stoma bags. This article reports on the introduction of Genii™, a new stoma bag that sticks with a unique breathable silicone adhesive. The study investigated the experiences of 61 colostomates over a 6-week period, examining the effect on their peristomal skin and their quality of life, in terms of sleep, self-image, social confidence and exercise, and overall product performance. The majority of study participants reported a positive experience when using the stoma bag.

Key words: Peristomal skin ■ Moisture-associated skin damage ■ Silicone stoma bag ■ Ostomy patients ■ Medical adhesive-related skin injury

piece closed stoma bag on colostomates' peristomal skin. The secondary objectives of this study were to look at whether use of the Genii stoma bag improved aspects of colostomates' quality of life (QoL) and to investigate the performance of the bag, specifically looking at how acceptable it was to the colostomates in terms of comfort, adherence and security.

Methods

Colostomates recruited into the clinical study must not have used Genii stoma bags before and had to be able to use a Genii one-piece midi closed stoma bag. Suitability criteria included the following. Participants:

- Must currently use a closed stoma bag that is either flat or soft convex
- Must have a protruding stoma (a stoma that sticks outside the stomach 4 mm and does not retract)
- Must not have a stoma bigger than 60 mm
- Must not have broken or bleeding skin
- Must have had a stoma for more than 9 months

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Figure 1. Genii stoma bag range with Sil2 Breathable Silicone Technology

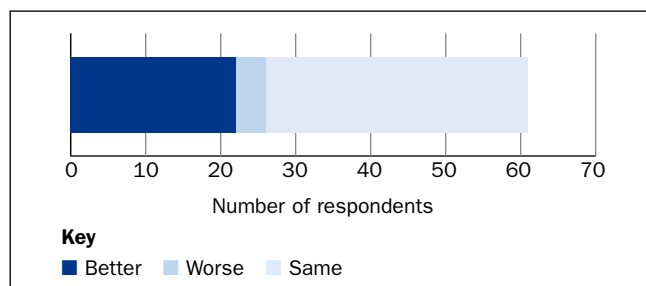


Figure 2. Participants' assessment of their peristomal skin at the end of the study

■ Must be self-caring.

Once a colostomate was evaluated as suitable for the trial and their consent was gained, participants were asked to complete a form either online or over the telephone. The pre-trial form captured the patient's contact details, demographics, stoma details, including surgery date, size and profile of their stoma, skin condition, current stoma bag and accessories used (ie adhesive remover spray, barrier wipes, seals, flange extenders, odour sachets, stoma paste), whether or not they had any contact with their stoma nurse, GP, surgeon, oncologist or other health professional, as well as effects on their QoL.

The participants in the study were asked about the condition of their skin before starting the study and weekly thereafter for 6 weeks. Participants completed evaluation forms weekly (either online or over the telephone) and participants were also asked to provide photographs of their stomas, including the peristomal skin, to monitor any changes over the trial. Trio advisers supported participants and collected data throughout the study, either via phone or email (depending upon which option was most convenient for each individual) and a weekend telephone support line was set up to provide assistance if needed.

Both quantitative and qualitative data were gathered to help evaluate the performance of the Genii stoma bag. The colostomates were asked to carry on with their stoma-care regimen as normal and not change it unless they felt it was

necessary during the trial. At the end of the 6-week trial, participants were asked for a final assessment of the Genii stoma bag, the condition of their peristomal skin and if they experienced any improvements to their QoL (ie sleep, self-image, social aspects, exercise routines and intimacy).

Results

The youngest age range in the current study was 36–45 years ($n=6$), followed by ages 46–55 years ($n=12$), over 55 years ($n=15$), those aged over 65 being the most common ($n=20$) and over 75s ($n=8$). Patients' stomas ranged from 25 mm to 60 mm in size, over 41% of which were also accompanied by a hernia ($n=25$).

Preliminary data showed that peristomal skin was improved in 36% of the study participants ($n=22$). This could have been a result of the product's performance, with a majority of the participants highlighting that there was no pain upon removal and no residue left when the product was removed.

Peristomal skin

One of the most significant challenges for ostomates is maintaining the health and integrity of the skin surrounding their stoma (Burch et al, 2021). Peristomal skin complications are relatively common, with a recent survey reporting an incidence of 73% in 4235 ostomates across 13 countries in the previous 6 months (Voegeli et al, 2020).

However, this incidence is thought to be potentially higher, considering ostomates do not always recognise complications or seek help for them (Burch et al, 2021). In fact, in the present study, two participants had a clear peristomal skin complications, including recurring granulomas and MARSI, but did not realise it or report it at the start of the study and it was not noticed until it was seen on the photographs taken and collected as part of the study data. Unreported peristomal skin conditions could have been more prevalent as only 39% of participants ($n=24$) provided photographs throughout the study.

At baseline, 30 patients reported their skin condition as being 'normal', 23 as having 'normal-to-mild' soreness, 5 as 'mild', 3 as 'mild-to-severe' and none as 'severe'. By the end of the 6 weeks, 36% of participants experienced an improvement in their peristomal skin condition ($n=22$) (Figure 2), while 57% reported that their skin remained the same ($n=35$), with only 6% of people reporting a worsening of their skin condition ($n=4$).

The greatest improvement in peristomal skin condition occurred in week 1 of the trial, with 63% of participants reporting this improvement within the first week of using the Genii stoma bag. This was followed by an 11% improvement in week 2, 16% in week 3, 5% in week 4, and the remaining 5% seen in week 5 of the trial.

Furthermore, 49% of participants reported having a normal peristomal skin condition at the start of the trial ($n=30$). This improved by 20% to 69% by the end of the 6 weeks using the Genii stoma bag ($n=42$).

Patients also made comments reflecting these improvements such as 'skin has improved' and 'there has been minimal

irritation to my skin since using the bag’.

Contact with a stoma nurse

The majority of colostomates had not had contact with their stoma nurse within the last 12 months. This could be due to a number of factors including COVID-19 restrictions and the fact that they may seek help or advice from an SCN only if severe problems occur (see *Figure 3*).

Quality of life

Living with sore skin has a direct negative impact on patient outcomes, leading to pain, suffering, leaks, malodour and a compromised QoL (Burch et al, 2021). The current study results indicate that the Genii stoma bag can help to improve all aspects of QoL to varying degrees, depending on the individual, with the most notable improvements seen in sleep, self-image and social confidence. Results are presented in *Figure 4*.

It should be noted that some ostomates who have lived with a stoma for many years may not realise or become accustomed to how it can effect their QoL. When asked at the beginning of the study, some participants reported that their stoma did not affect any aspect of their QoL, however, at the end of the study those same participants noted an improvement.

Sleep

Just over half of the participants ($n=31$; 51%) felt that living with a stoma affected the quality of their sleep at the start of the trial; 14 of these indicated these effects to be ‘moderate’ or ‘quite a lot’. By the end of the 6-week period, improved sleep was reported by 41% of the colostomates ($n=25$) and more than half of this improvement was noted to be ‘moderate’, ‘quite a lot’ or ‘very much’ (as opposed to ‘a little’). One patient noted that the bag was secure, discreet and allowed her to sleep on her side, which she was previously unable to do. Another patient found that the bag gave her more freedom in terms of how she could sleep:

‘[It’s] comfortable, feels more secure, better fit, can sleep in all positions, don’t have to worry.’

Self-image

At the start of the trial, 59% of the colostomates ($n=36$) felt that living with a stoma affected their self-image such as their confidence, and 22 of the participants felt that the impact was ‘moderate’, ‘quite a lot’ or ‘very much’. However, improvements in self-image were experienced by close to half (49%; $n=30$) of colostomates in the trial, with some participants specifically noting a reduction in self-consciousness or an increase in confidence since using the Genii stoma bag:

‘Skin has improved, less self-conscious, ballooning was an issue, cut smaller since, not aware of pouch.’

‘The look and feel, can shower with it staying dry, I’m so confident with it. Has built my confidence massively with my stoma.’

Social confidence

At the beginning of the trial, 35 participants (57%) indicated

Case studies

Participant 1

A 61-year-old female had undergone surgery to treat a perforated bowel where a stoma was created more than 5 years ago. She assessed her skin condition as being ‘mild-to-severe’ sore skin at the beginning of the trial. By the end of the trial, however, her skin had noticeably improved (*Figure A*) to the point that she decided to make a permanent switch to the Genii stoma bag. Her comment was: ‘I would recommend it. Trial has been great and have now switched to Genii. Genii is definitely for me.’



Peristomal skin at week 1 of using the Genii stoma bag



Peristomal skin after using the Genii stoma bag for 6 weeks

Figure A. Change in 61-year-old female participant’s skin condition after 6 weeks

Participant 2

A 37-year-old female colostomate who has had a stoma for more than 2 years, initially assessed the skin around her stoma as ‘normal-to-mild’ but saw a noticeable improvement in its condition by the end of the trial (*Figure B*) and commented on the more discreet nature of the Genii stoma bag, as well as the reduced need to change her bag so frequently. She commented: ‘At first I had a few hiccups with bags not sticking but we resolved that very early on in the trial. Glad we did as I’m loving these bags as [they] suit me a lot better with how quiet they are and definitely a lot less bag changes for me in the day now. Would definitely recommend others try these and have a good experience like me.’



Peristomal skin before using the Genii stoma bag



Peristomal skin after using the Genii stoma bag for 5 weeks

Figure B. Change in 37-year-old female participant’s skin condition after 5 weeks

that their stoma affected them socially, such as in terms of their willingness to go out and socialise or the nature of the activities they participate in. Of these, 24 participants felt that living with a stoma affected their social life ‘moderately’, ‘quite a lot’ or ‘very much’. In fact, one participant made the following comment:

‘Affects my life a lot, I don’t want to go out in case of a leak; also affects [my] husband.’

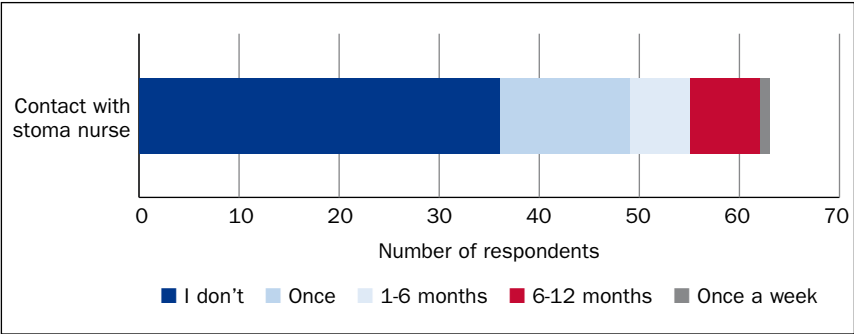


Figure 3. Participants' contact with a stoma care nurse

However, by the end of the 6 weeks, 33% of participants ($n=20$) said they had experienced a positive impact on their social life as a result of using the Genii stoma bag.

Intimacy

Another important and, unfortunately, often-overlooked area of a person's life that can be impacted by living with a stoma is in intimacy or a romantic relationships. In the present study, 42% of participants ($n=24$) felt, at the start of the trial, that their stoma affected their relationship with their partner (four participants indicated that they preferred not to disclose this information).

Of those who said it affected their relationship, most ($n=18$) highlighted that it affected their relationship 'moderately', 'quite a lot' or 'very much'. Some ostomates who have lived with a stoma for many years may not realise how much it

has affected their QoL, or may have become accustomed to a restricted life with a stoma. Some participants, when asked about QoL at the beginning of the study reported that their stoma did not affect any aspect of their QoL. However, at the end of the study many of them had noted an improvement.

By the end of the 6-week trial, 84% of participants ($n=49$) reported that they did not feel it affected their intimacy at all. Of the remaining 16% participants ($n=9$) who felt it still had an impact, four specified that it affected their relationship 'a little' (down from six at the beginning); one said it affected it 'moderately' (down from five at the start of the trial); four said it affected it 'quite a lot' (no change); and none selected the response that it affected their relationship 'very much' (down from nine at the start of the trial). The remainder preferred not to disclose this information. This is an area that requires further research.

Exercise

At the beginning of the trial, 33% of participants ($n=20$) reported that their stoma affected their exercise routine, for example having to do less or change the exercise they do as a result of having a stoma. For 13 (65%) of these 20 participants, their stoma affected their exercise routine 'moderately', 'quite a lot' or 'very much'. By the end of the trial, 36% of all 61 participants ($n=22$) reported improvements in their experience of physical exercise. However, in relation to those who saw no change, it must be remembered that 67% of participants did not feel that their stoma affected their exercise at the beginning of the trial—a sentiment that was up to 79% by

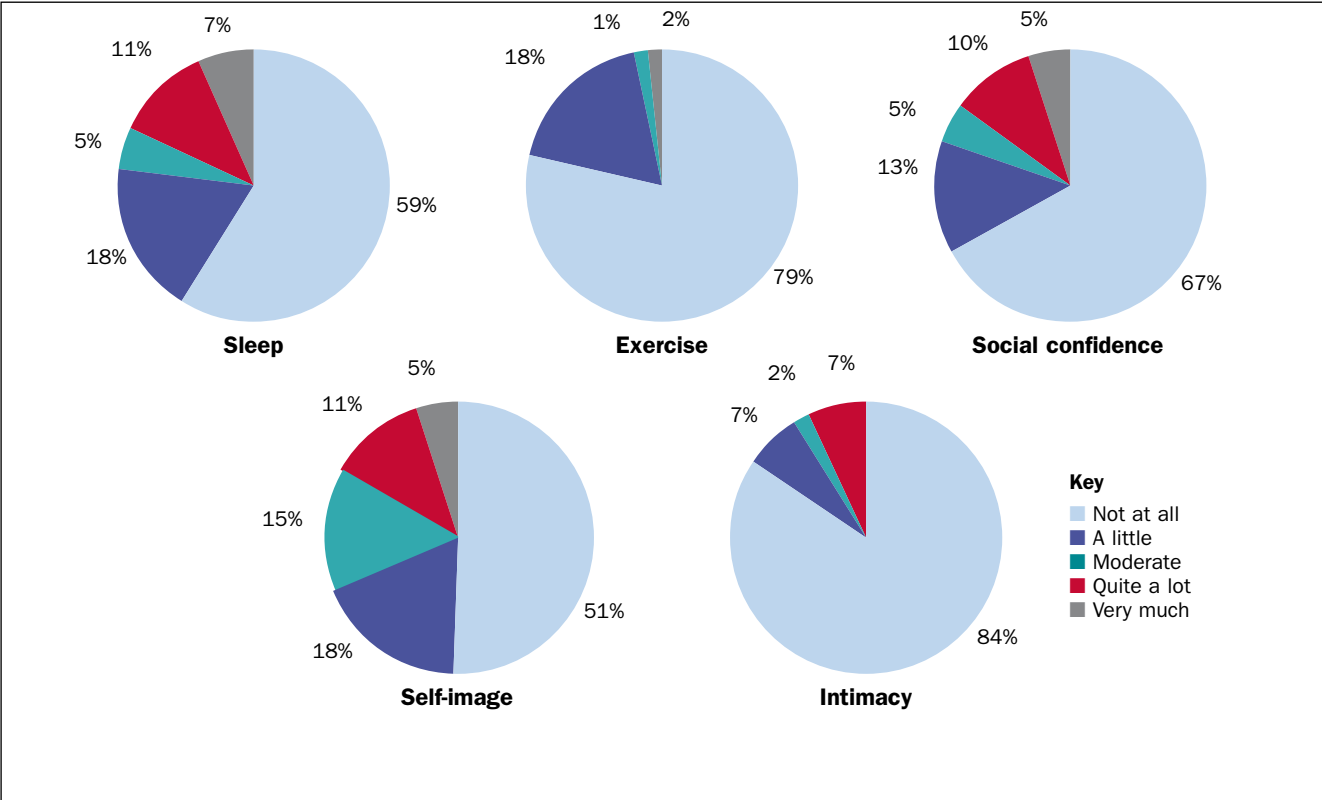


Figure 4. Effect of using the Genii stoma bag on different aspects of participants' health-related quality of life

the end of the trial. Furthermore, when asked how secure the bag was when worn during physical activity, patients rated it 87% on average (Table 1). One participant commented that, as a result of the comfort and security of the stoma bag, she would not have to worry if physically active while out. Another patient also commented that he felt so confident that he no longer needed to take any emergency supplies with him when exercising.

Product performance

Participants were also asked to rate the performance of the Genii stoma bag every week from 1 to 10 in relation to several different factors, such as how well the bag adhered to their skin, effectiveness against pancaking and ballooning, comfort, pain on removal and residue on the skin. Their average ratings indicate positive results overall (Table 1). Overall, the majority of participants were happy to continue using the stoma bag and to recommend it to others (Figure 5)

In particular, participants awarded a high rating to the stoma bag in terms of comfort level (92%) compared with their usual stoma bag, security while sleeping (90%) and ease of removal/lack of residue (94%). Some of the comments made by colostomates were as follows:

‘Overall, the soft adhesion disc fitted very well over my hernia and felt very comfortable.’

‘The bag is more comfortable and easy to wear, apply and remove. There has also been minimal irritation to my skin since using the bag.’

‘I’ve loved using the bag. The flange is soft, the filter works to prevent pancaking and it’s made me think less about my bag and what it’s up to!’

Many colostomates who participated in the current study reported they would be happy to continue using the Genii stoma bag after the trial (66%), with some having already switched or ordered their new prescription. Most also reported that they would be happy to recommend the Genii stoma bag to other ostomates (93%). Some participants commented on their experience of participating in the trial and the likelihood they would recommend the Genii stoma bag to others:

‘Bags are brilliant, trial went great and recommend bags to others. Happy with the service, been 100%.’

‘[I have] thoroughly enjoyed taking part in the trial. Has been good, like everything about them.’

‘Trial has been a joy, very impressed with silicone adhesive, so easy to wear.’

‘Would recommend to anyone.’

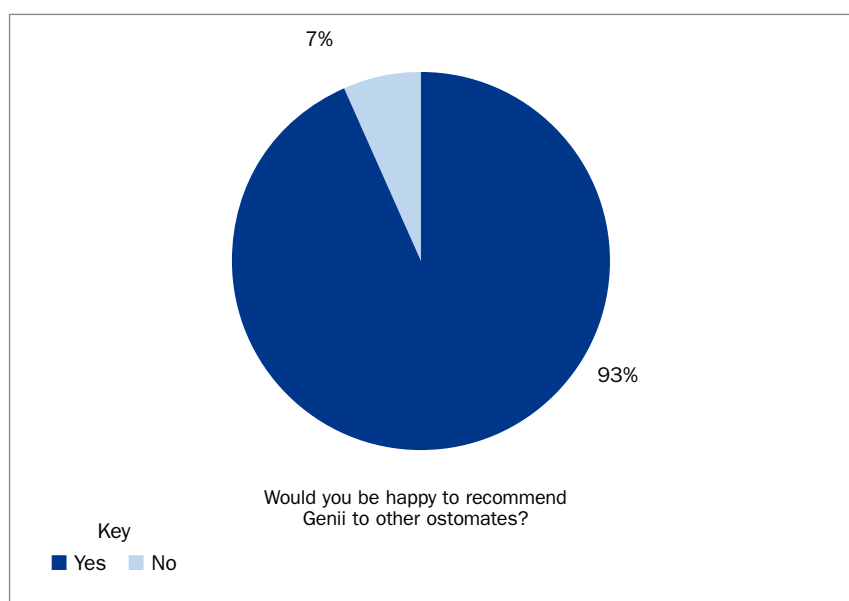


Figure 5. Participants' satisfaction with the Genii stoma bag

Table 1. Participants' average rating of the Genii stoma bag's effectiveness	
Factor being rated/question posed	Average rating
How well did the Genii bag stick to the skin?	9/10 (1 = poor, 10 = excellent)
When removing the Genii, how did it feel compared with your usual bag?	9.2/10 (92%) (1=more pain/10=no pain)
How secure did you find the Genii stoma bag during the night/while sleeping?	9/10 (90%) (1=poor/10=excellent)
If you took part in exercise while wearing the Genii stoma bag, please rate the bag's security	8.7/10 (87%) (1=poor/10=excellent)
How did you find the Genii stoma bag during bathing/showering?	8.7/10 (87%) (1=poor/10=excellent)
How comfortable was the Genii stoma bag compared with your usual bag?	9.2/10 (92%) (1=very uncomfortable/10=very comfortable)
When the Genii stoma bag was removed, did it leave any residue on the skin?	9.4/10 (94%) (1=excessive/10=none)

Conclusion

Both quantitative results and qualitative responses given by participants reflected an overall positive experience by the majority of colostomates who used the Genii stoma bag over a 6-week period. Most participants found the pouch to be comfortable, secure and noted improvements in terms of their peristomal skin condition and their QoL. Although not all comments were included in the present article, several comments gathered in the data indicated that the bag was preferable to their usual stoma bag. The Genii stoma bag offers a broader range of choice to ostomates, helps to improve skin damage caused by traditional hydrocolloid materials while preventing further damage, and has the potential to improve overall ostomate

KEY POINTS

- Peristomal skin complications are just one of a range of challenges faced by individuals with a stoma
- Living with a stoma can have a major impact on a person’s quality of life
- In a trial of a new silicone stoma bag, participants reported its effect on their peristomal skin, quality of life and overall performance
- In the current trial, participants reported on quality-of-life factors such as sleep, self-image, social confidence, intimacy and exercise
- The majority of participants were satisfied with the overall performance of the pouch, noting it to be comfortable and secure, with improvements observed in both their peristomal skin and quality of life

wellbeing, particularly in the areas of self-image, sleep, social confidence and intimacy. **BJN**
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CPD reflective questions

- To what degree do you feel that choice of appropriate products such as a stoma bag can affect the peristomal skin of a person living with a stoma?
- How might living with a stoma impact an individual’s quality of life, and how comfortable are you broaching personal topics such as confidence, exercise and intimacy with your patients?
- How involved are you in ensuring that your patient’s stoma bag is meeting their individual needs and how might you become more proactive in this regard?