

# Introducing a Novel Product for the Protection of Peristomal Skin of Ileostomates

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As presented at ECET 2007 Salzburg, Austria.

## abstract

The objective of the study was to clinically evaluate the efficacy of a novel skin-care product for use by ostomates. The product was evaluated in terms of performance compared with currently available stoma pastes, user experience and changes in skin condition.

## introduction

Skin protection is an important consideration in caring for a patient with an enterocutaneous fistula or stoma and peristomal skin problems are common. Irritation reactions such as dermatitis (Figure 1), lesions, inflammatory acanthomatous reaction and overgranulation at the mucocutaneous junction have all been reported (Lyon *et al.*, 2000).

Additional problems associated with pouching stomas and fistulae include:

- Proper attachment of the pouch around high output or irregular fistulae or stomas;
- Difficulty with attaching adhesive onto wet excoriated skin;
- Irritation of damaged skin by alcohol in stoma pastes; and
- Allergic reaction to ostomy accessories.

To address the current problems in stomacare, Cohesive® Paste has been developed as a **paste with a difference**, as Figure 2 illustrates.



**Figure 1:** Chronic faecal dermatitis surrounding a colostomy.

## materials & methods

### Clinical Trial

- Conducted at the Royal Victoria Hospital, Belfast, UK.
- 20 patients, who do not currently use paste, used Cohesive® Paste for a 2-week period.

### IA User Trial

- In conjunction with the Ileostomy Association of Northern Ireland.
- 59 ostomates, who normally use stoma pastes as part of their stoma care routine, participated and evaluated the paste for a 2-week period.

Typical Stoma Pastes	Cohesive PASTE
An emulsion of solids & adhesive polymers in alcohol.	Formulation based on Cohesive® which <b>protects peristomal skin</b> .
Alcohol causes stinging & discomfort to the patient when applied to damaged skin.	<b>No alcohol - therefore no stinging.</b> Cohesive® Paste can be used directly on excoriated skin.
Typical pastes must 'dry' before fitting the pouch - pouching is more difficult & time-consuming especially for the elderly.	Cohesive® Paste requires <b>no drying time</b> , as it does not dry out.
Typical paste residue can be difficult & painful to remove.	Cohesive® Paste is <b>easy to remove</b> .

**Figure 2:** Comparison of Cohesive® Paste to Typical Stoma Pastes

## clinical trial results

The clinical trial involved participants who had **never used paste before**.

Figure 3 shows the clinical trial results which indicate that 85% of participants found Cohesive® Paste **comfortable to apply and remove**. 84% experienced **no stinging sensation** on application. As Cohesive® Paste does not require any **drying time**, quicker application can be achieved.

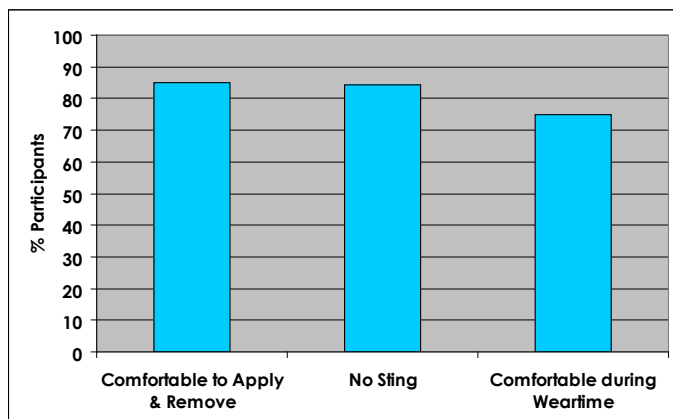


Figure 3: Clinical Trial Results

When patients were asked to describe the condition of the skin under Cohesive® Paste, the response was positive:

- '...skin ulcers have now healed...'
- 'skin healthier whilst using paste'
- 'paste felt comfortable on application'
- '[skin condition] improved – less red'.

## user trial results

The user trial involved participants who use stoma pastes as part of a settled pouching regime.

Figure 4 illustrates the findings of this trial. **100%** of participants experienced **no stinging** on application of Cohesive® Paste. 89% found Cohesive® Paste to be **more comfortable** or as comfortable as their existing paste. 90% found Cohesive® Paste allowed the pouch to be **removed easier** or as easy as with their existing paste.

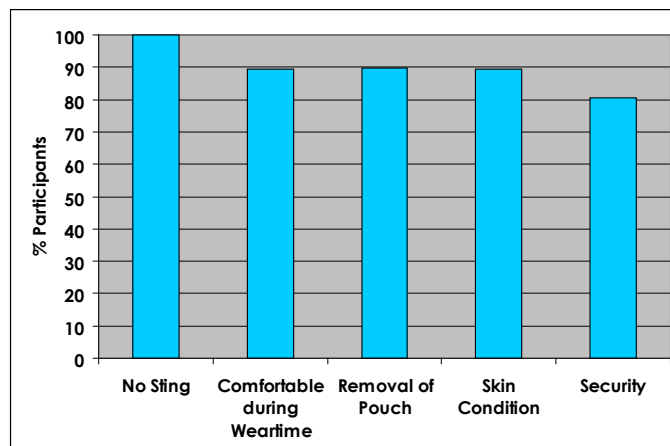


Figure 4: User Trial Results

**Skin condition** was found to be **improved** or the same among **89%** of participants. And finally 81% of participants felt that their pouches were **more secure** or as secure with Cohesive® Paste as with their existing paste.

## conclusion

Cohesive® Paste was comprehensively evaluated by way of a clinical and user trial. The new product provided significant improvement in performance in a number of areas, including:

- **Enhanced pouch security;**
- **Prevention of leaks;**
- **Increased wear time;**
- **Improvement in skin condition;**
- **Comfort during application, wear time and removal;**
- **Reduction in residue;**
- **Ease of pouch and residue removal.**

Finally, because Cohesive® contains **no alcohol** there is **no sting on application**.

## acknowledgements

TG Eakin Limited would like to thank Marie McGrogan and Prof. Brendan McCormack from Royal Victoria Hospitals Trust, Belfast, for conducting the clinical trial. Thanks also to the N. Ireland branch of the Ileostomy Association for their help with the user trial.

## references

Lyon *et al.*, 2000, The spectrum of skin disorders in abdominal stoma patients. *British Journal of Dermatology* **143**: 1248 – 1260.