Laboratory Measurements and User Appreciation of a Novel Ostomy Barrier Ring with Improved Wear Characteristics

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Abstract

Ostomy barrier rings are used by many patients as an accessory device to improve the seal around the stoma and to protect peristomal skin from effluent. The barrier ring material must be flexible to allow molding of the ring into new shapes to follow skin contours around the stoma and have excellent cohesive strength when wet to provide superior durability in the presence of high fluid output. A new barrier ring incorporating a novel skin barrier formulation has been developed. It provides the required flexibility with high cohesive wet strength.

Benefits

The benefits of the barrier rings made using this new formulation were demonstrated in controlled laboratory test methods and these observations were validated by data collected from people with ostomies who trialed the product. Laboratory testing showed excellent cohesive strength for this new barrier formulation even when challenged by long-term exposure to liquid. The benefit of this high cohesive strength was demonstrated in a randomized, controlled study of the effectiveness and acceptance of the new barrier rings compared to a well accepted product in the marketplace. The overall performance of the new rings was highly rated and most importantly, the new rings showed a significantly enhanced resistance to erosion.

Conclusion

In conclusion, the user feedback confirms the laboratory predictions that this product has superior resistance to fluid erosion and provides an effective seal around the stoma.

Introduction

Ostomy Barrier Rings

- Accessories widely used to improve skin barrier performance
- Often used by patients with irregular stomas to fill in uneven skin surfaces
- Provide extra fluid handling capacity for patients with high fluid output

Performance Requirements for Ostomy Barrier Rings

- Must be easy to mold into new shapes to conform to the stoma shape and irregularities in the skin
- Must be flexible enough to follow changes in skin contours even as the patient moves
- Must be able to absorb high fluid output
- Must be durable enough to resist erosion from fluid and maintain integrity over time

The Challenge:

- Meet all these requirements in a single product

The Solution:

- A novel barrier formulation used in a new barrier ring product*
- Rings that:
  - Are easy to mold by stretching or compressing
  - Maintain their new shape after molding
  - Have high cohesive strength to resist fluid erosion

*Adapt Barrier Rings with Flextend M Skin Barrier

Adhesive and Cohesive Strength

- Ostomy barrier ring products must have both adhesive and cohesive strength
- Adhesive strength allows the ring to stick well to surfaces, e.g. the skin and the skin barrier on the pouch
- Cohesive strength holds the barrier material itself together – it is the internal strength of the barrier

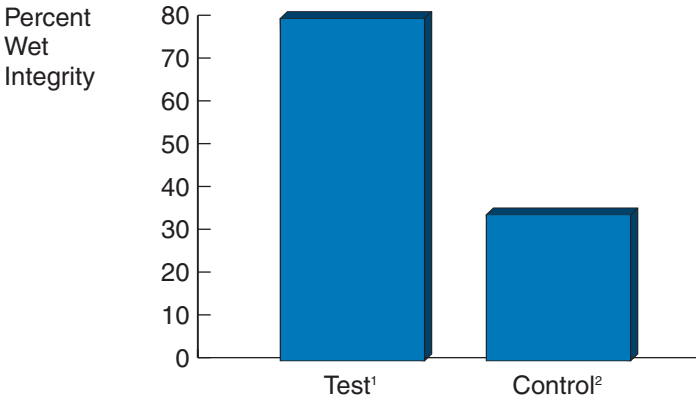
Importance of Cohesive Strength

- Barrier rings must have cohesive strength in the dry state so they can be stretched easily without breaking the ring
- Wet cohesive strength is very important for a barrier ring since they are often used for high fluid output challenges
- Wet cohesive strength allows the barrier to resist erosion as it absorbs fluid
  - Helps prevent exposure of the skin to corrosive output from the stoma
  - Reduces the chance of leaving adhesive residue on the skin when the product is removed

Lab Evaluation of Wet Cohesive Strength

- The wet cohesive strength of a barrier ring can be assessed in a simple lab test:
  - Pre-weighed samples of barrier ring materials are suspended in tubes half-filled with deionized water
  - The tubes are gently shaken using a laboratory shaker for eight hours
  - Intact barrier material is recovered from the tube (if the barrier breaks up during the test, the largest intact piece of the sample is used)
  - The recovered samples are dried overnight and weighed
  - The % Integrity value is calculated from the ratio of the weight after the test to the starting weight for each sample
  - Higher values indicate a barrier material with higher wet cohesive strength
- Barrier ring samples from Test[1] and Control[2] products were compared in this with the results shown below:

Demonstration of Wet Cohesive Strength



1. Adapt Barrier Ring
2. Eakin Cohesive Seal

Clinical Trial

The safety and performance of the new barrier ring was demonstrated in a multi-site clinical study. This test was a controlled, non-blinded study using volunteers with ostomies who were current users of the control product. All test materials passed biomaterials safety assessment, the study received IRB approval, and all subjects provided informed consent prior to being enrolled in the study. Subjects used a total of three rings (2 test and 1 control) according to their normal habit and assessed their performance via a written questionnaire. The overall assessment was an unweighted index of the individual performance assessments.

- Primary assessment attributes:
  - Peristomal skin irritation
  - Resistance to erosion
- Secondary assessment attributes:
  - Freedom from leakage
  - Wear time
  - Functional conformability (flexibility, moldability, and ability to stretch without breaking)
  - Shape memory (reduced “spring back”)
  - Comfort (ease of removal and comfort upon removal)
  - Ease of use

Results

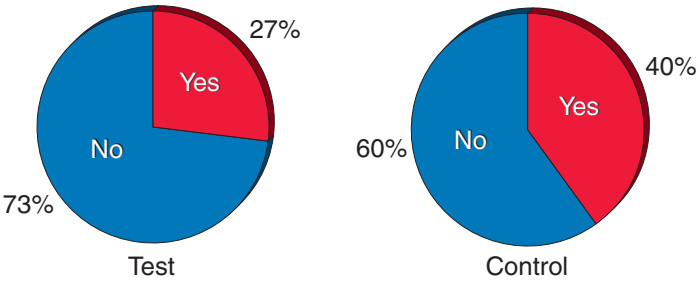
A total of seventy-three (73) subjects were enrolled, and all completed the study. Three adverse events were reported. All were related to irritation due to leakage. All resolved promptly, and did not affect the subject's ability or willingness to complete the study.

Subject Profile

- Age: mean 57.6 years (SD 14.7)
- Height: mean 65.9 inches (SD 4.0)
- Weight: mean 173.4 lbs (SD 44.3)
- Gender: 27 males (37%) and 46 females (63%)
- Stoma diameter: 1.12 inches (SD 0.25)
- Median reported time since original surgery was 40 months
- Ostomy type: colostomy 54.8%; ileostomy 27.4%; urostomy 17.8%
- Stoma profile: protruding 66.2%; flush 22.5%; recessed 11.3%
- Usual usage of rings: 2-3 per week 69.1%; 1 per week 25.0%
- Duration of current product usage: more than 5 years 17.8%; 1-5 years 42.5%; less than 1 year 39.7%

The overall objectives of the study were met. There was no significant difference between the test group and the control group with respect to the change in reported skin condition before and after product use, indicating an acceptable level of biocompatibility during product use.

Proportion Reporting Erosion or Melting



Notably, the subjects were less likely to report erosion while wearing the test ring as compared to using the control ring, and this difference was statistically significant ($p < 0.05$, chi-square test).

The test ring was uniformly highly rated for all of the secondary performance attributes, leakage, wear time, conformability, shape memory, comfort, and ease of use.

Attribute	% Positive Response
Easy to remove liner	86.9
Easy to mold	93.1
Did not break when stretched	100.0
Kept shape	93.0
Easy to apply	93.2
Easy to remove	90.3
Comfortable to remove	87.0
Overall	95.9

Conclusions

- Results from the clinical trial indicate that the new ring product is safe and efficacious and will be well accepted by patients
- Laboratory testing of the wet cohesive strength of barrier materials predicts ability to resist fluid erosion during use

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