



Convatec Moldable Technology™ Clinical Compendium

Proven to help patients break
the cycle of leakage and skin damage
creating a healthy bond

Stoma Challenges

People with a stoma often have persistent peristomal skin problems. In fact, peristomal skin problems are the most commonly experienced physical complication following ostomy surgery and often are caused by leakage or a poorly fitting skin barrier. Learning to navigate life with a stoma is an adjustment, but can bring new hope to patients. However, if skin problems are an ongoing issue, a patient's quality of life can be impacted. Studies show that eight out of ten people living with a stoma also have peristomal skin issues,¹ and as many as 76% endure complications that last up to three months.² In some less severe or moderate cases, patients may not recognize they have skin complications and fail to seek professional medical care until the problems have worsened.²

The underlying cause of most of the skin complications are leaks from the stoma onto the surrounding skin.³ These leaks can cause discomfort, soreness, and embarrassment for the stoma patients.

To date, the various ways to address leakage problems around a stoma have not adequately solved the problem. Cut-to-fit skin barriers are challenging for both healthcare professionals and stoma patients, who each have a unique body type and area where the stoma is located.

Convatec offers a solution to the leakage and skin problems cycle: Convatec Moldable Skin Barriers™. Our uniquely moldable skin products **fit better** and are **easier to use**, thereby breaking the cycle of **leakage** and **skin damage**, giving people with a stoma the **security and confidence** to live their lives.⁴

1. Fellows J, et al. Multinational survey on living with an ostomy: prevalence and impact of peristomal skin complications. *Br J Nurs* 2021; 30: S22–30.

2. Herlufsen P, et al. Study of peristomal skin disorders in patients with permanent stomas. *Br J Nurs* 2006; 15: 854–62.

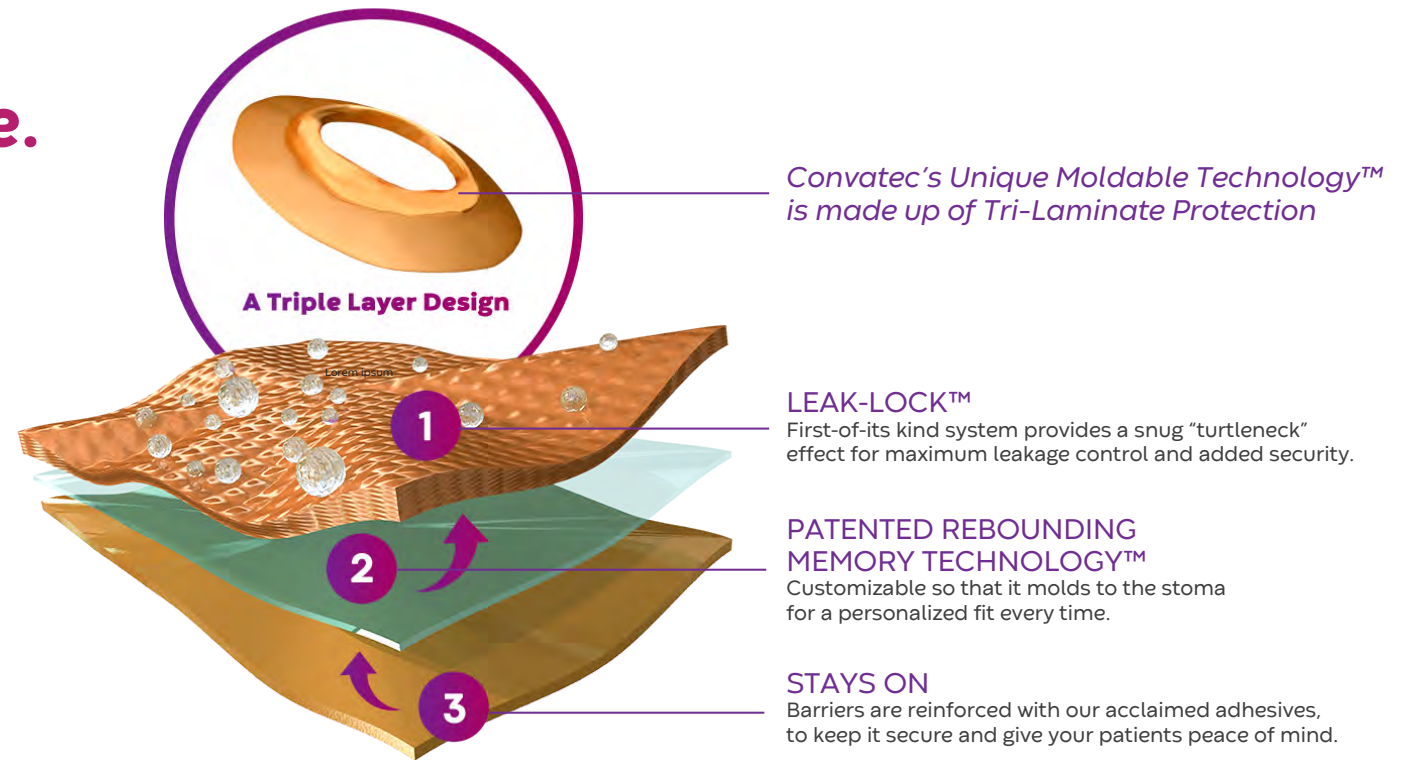
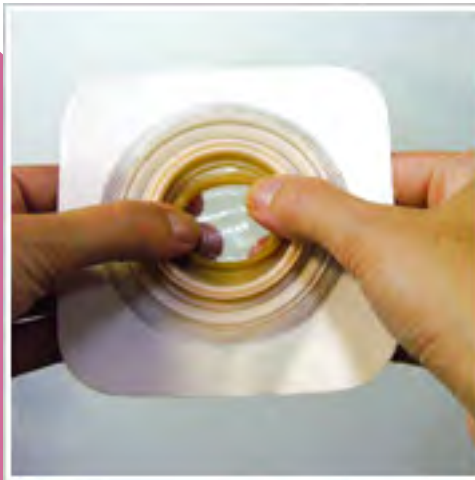
3. Voegeli D, et al. Factors influencing the incidence of peristomal skin complications: evidence from a multinational survey on living with a stoma. *Gastrointestinal Nursing* 2020; 18(suppl 4): S31–38.

4. Clinical Summary: Osmose Study, Multinational Evaluation of the Peristomal Condition in New Ostomates Using Moldable Skin Barriers. Maria Teresa Szewczyk, MD, PhD; Grazyna Majewska, RN, ETN; Mary V. Cabral, MS, FNP-BC, CWO-CN-AP; and Karin Hölzel-Piontek, RN; The Effects of Using a Moldable Skin Barrier on Peristomal Skin Condition in Persons with an Ostomy: Results of a Prospective, Observational, Multinational Study, *Ostomy Wound Management* 2014;60(12):16–26.

Convatec Moldable Technology™

**Works like nothing else,
because it is like nothing else.**

“The leading moldable barrier that new patients wear leaving the hospital, helping to break the cycle of leakage and skin damage”¹



1. Clinical Summary: Osmose Study, Multinational Evaluation of the Peristomal Condition in New Ostomates Using Moldable Skin Barriers. Maria Teresa Szewczyk, MD, PhD; Grazyna Majewska, RN, ETN; Mary V. Cabral, MS, FNP-BC, CWOCN- AP; and Karin Hölzel-Piontek, RN; The Effects of Using a Moldable Skin Barrier on Peristomal Skin Condition in Persons with an Ostomy: Results of a Prospective, Observational, Multinational Study, *Ostomy Wound Management* 2014;60(12):16–26.

Key Evidence

Better Fit

Durnal A. Clinical comparison of a moldable skin barrier versus a shape-to-fit. 45th Annual WOCN Conference, Seattle, WA, USA; June 22–26, 2013.

Haas S, Reider, K. The road to independence: successful use of moldable ostomy skin barriers to improve patient outcomes. 43rd Annual WOCN Conference, New Orleans, LA. June 4–8, 2011 (5137).

Ison R, Hadley G. Moldable technology simplifies pouching over rods. WOCN/WCET Joint Conference, Phoenix, AZ, USA; June 2010.

Easier to Use

Geriach MA. Doing away with scissors and patterns using a new technology of ostomy skin barriers. 40th Annual WOCN Conference, Orlando, FL, USA; June 21–35, 2008.

Philbin S, Rochette J. A new moldable barrier provides solutions for people with ostomies and dexterity challenges. 40th Annual WOCN Conference, Orlando, FL, USA; June 21–25, 2008.

Stallings B. The perfect fit: the use of flat moldable skin barriers in home care. 43rd Annual WOCN Conference, New Orleans, LA, USA; June 408, 2011.

Tomlinson L. Teaching older ostomy patients—moldable technology eases the fear factor. 41st Annual WOCN Conference, St Louis, MO, USA; June 6–10, 2009 (3354).

Fewer Leaks

Durnal A. Clinical comparison of a moldable skin barrier versus a shape-to-fit. 45th Annual WOCN Conference, Seattle, WA, USA; June 22–26, 2013.

Clinical Summary: Osmose Study, Multinational Evaluation of the Peristomal Condition in New Ostomates Using Moldable Skin Barriers. Maria Teresa Szewczyk, MD, PhD; Grazyna Majewska, RN, ETN; Mary V. Cabral, MS, FNP-BC, CWOCN-AP; and Karin Hölzel-Piontek, RN; The Effects of Using a Moldable Skin Barrier on Peristomal Skin Condition in Persons with an Ostomy: Results of a Prospective, Observational, Multinational Study, *Ostomy Wound Management* 2014;60(12):16–26.

Watanabe M, et al. Evaluation of stoma pouch with moldable skin barrier for early postoperative outcomes after stoma construction. *J Japan Coll Surgeons* 2013; 38: 765–70 (in Japanese).

Wolfe L. A new tool in the Canadian ET toolbox. WOCN/WCET Joint Conference, Phoenix, AZ, USA; June 12–16, 2010.

Skin Health

Erbe JM. Skin Barrier selection in an outpatient ostomy clinic. *J Wound Ostomy Continence Nursing* 2011; 38:S47.

Liu G, et al. The application of a moldable skin barrier in the self-care of elderly ostomy patients. *Gastroenterol Nursing* 2017; 40:117–20.

Marescalco K. Improving patient outcomes by increasing consistency of ostomy care. WOCN/ WCET Joining Conference, Phoenix, AZ, USA; June 12–16, 2010.

Scott V, et al. Prospective assessment and classification of stoma-related skin disorders. 41st WOCN Annual Conference, St Louis, MO, USA; June 6–10, 2009.

Clinical Summary: Osmose Study, Multinational Evaluation of the Peristomal Condition in New Ostomates Using Moldable Skin Barriers. Maria Teresa Szewczyk, MD, PhD; Grazyna Majewska, RN, ETN; Mary V. Cabral, MS, FNP-BC, CWOCN- AP; and Karin Hölzel-Piontek, RN; The Effects of Using a Moldable Skin Barrier on Peristomal Skin Condition in Persons with an Ostomy: Results of a Prospective, Observational, Multinational Study, *Ostomy Wound Management* 2014;60(12):16–26.

Watanabe M, et al. Evaluation of stoma pouch with moldable skin barrier for early postoperative outcomes after stoma construction. *J Japan Coll Surgeons* 2013; 38: 765–70 (in Japanese).

Satisfaction

Hoeflok J, et al. A prospective multicenter evaluation of a moldable stoma skin barrier. *Ostomy Wound Management* 2009; 55:62–69.

Huang HI, et al. Moldable skin barriers as a clinical option for patients following ileostomy. *J Soc Colon Rectal Surgeon* (Taiwan) 2020; 31: 204–12.

Clinical Summary: Osmose Study, Multinational Evaluation of the Peristomal Condition in New Ostomates Using Moldable Skin Barriers. Maria Teresa Szewczyk, MD, PhD; Grazyna Majewska, RN, ETN; Mary V. Cabral, MS, FNP-BC, CWOCN- AP; and Karin Hölzel-Piontek, RN; The Effects of Using a Moldable Skin Barrier on Peristomal Skin Condition in Persons with an Ostomy: Results of a Prospective, Observational, Multinational Study, *Ostomy Wound Management* 2014;60(12):16–26.

Better Fit

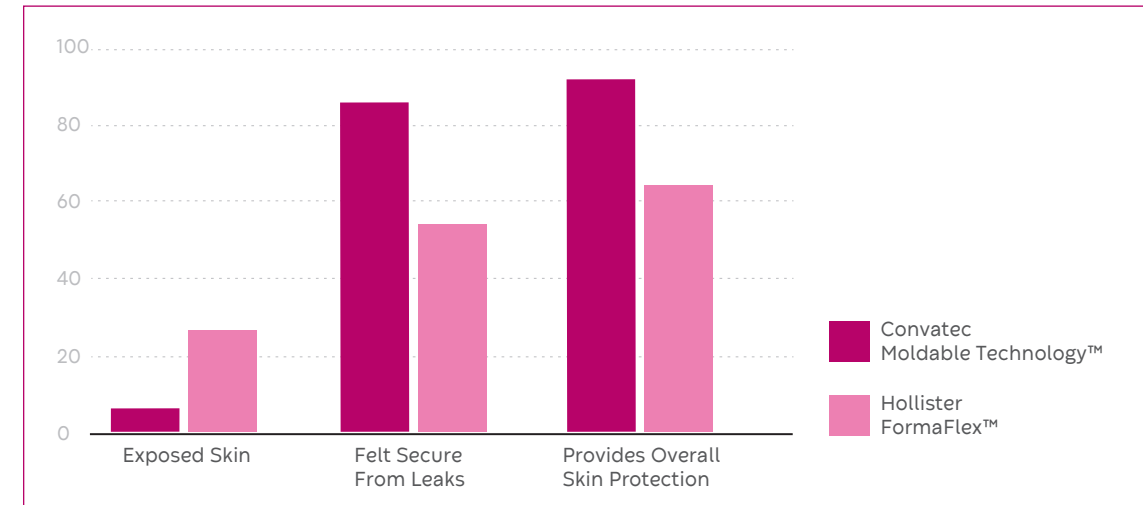
- Maintains a snug fit
- Works across a range of stoma shapes
- Challenging post-operative stomas

Maintains a snug fit

Moldable technology demonstrated superior results in maintaining a secure fit and reducing leaks



Durnal A. Clinical comparison of a moldable skin barrier versus a shape-to-fit. 45th Annual WOCN Conference, Seattle, WA, USA; June 22–26, 2013.



Overview

An estimated 75-77% of peristomal skin breakdown is a result of contact with stoma effluent, driving a reported 94% of patients with an ostomy to change the type of pouching system within the first 12 months following surgery: 76% change due to peristomal skin irritations and 62% due to leakage.

Multicenter study comparing the performance of Convatec Moldable Technology™ to Hollister FormaFlex™ in the following categories:

- Ease of application
- Protection from leaks
- Maintenance of skin integrity

N=60

Participants were instructed to refrain from using any accessory products during the study system across three investigational centers in the USA.

* FormaFlex™ is a trademark of Hollister, Inc.

Results

Patients in the study rated Convatec Moldable Technology™ as superior to Hollister's FormaFlex™ in the following categories:


- Ease of removal
- Security from leaks
- Peristomal skin health and overall skin protection

Conclusion

As compared to Hollister FormaFlex™, Convatec Moldable Technology™ skin barriers were shown to have a better fit which reduced the possibility of leaks and ultimately peristomal skin breakdown, making Convatec Moldable Technology™ an excellent choice for resolving these issues in numerous stoma patients.

An ostomate's road to independence

With no cutting or sizing, patients are able to obtain a secure stoma fit



"A method that has helped our clients to travel down the road to 'independence' again while learning how to change their ostomy appliance is to use the moldable wafers. Clients have quickly felt successful in the mastering of this skill."



Haas S, Reider, K. The road to independence: successful use of moldable ostomy skin barriers to improve patient outcomes. 43rd Annual WOCN Conference, New Orleans, LA. June 4–8, 2011 (5137).

Overview

Single center case series: three stoma patients with individual challenges in learning to self-care for their ostomy appliance during the post-operative period were highlighted. Challenges ranged from limited mental capacity to anxiety around cutting the appropriate size of the wafer. It's important that the wafer is cut to fit closely to reduce leakage, but can be challenging for patients with limited dexterity or a complicated or irregular-shaped stoma.

All three patients returned post-op with regular leakage, which was impacting their quality of life. One patient was experiencing pretty serious skin issues including maceration and denuded skin.

Results

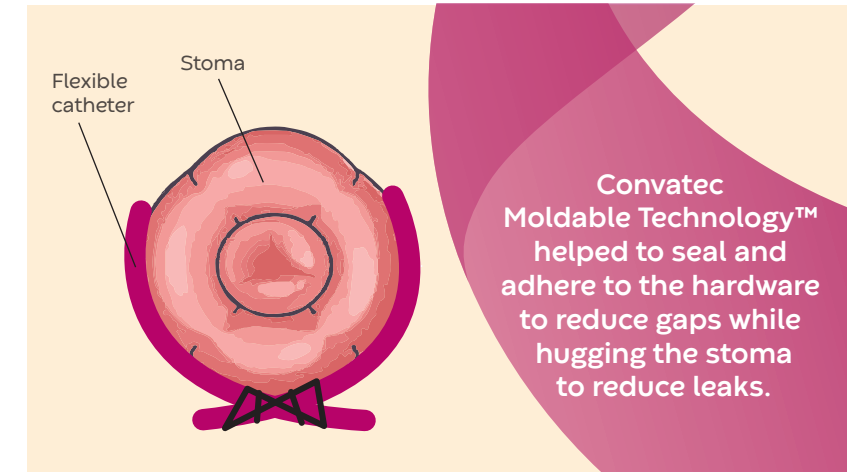
The patients in this study all converted from cut-to-fit and pre-sized barriers to Convatec Moldable Technology™. Patients found they were able to easily mold the product to create a secure seal, and prevent peristomal skin issues.

Conclusion

Convatec Moldable Technology™ skin barriers can help patients with dexterity challenges by increasing their abilities for self-care with ease of implementation, improved fit, and ultimately create a better quality seal for them to remain independent and free of peristomal skin issues.

Convatec Moldable Technology™ helped to simplify pouching in challenging cases

Including accommodating protruding hardware



Ison R, Hadley G. Moldable technology simplifies pouching over rods. WOCN/WCET Joint Conference, Phoenix, AZ, USA; June 2010.

Overview

A single center case series of three different highly challenging surgical techniques utilizing hardware to create temporary loop ostomies to prevent retraction of and protect the stoma. The cases include the use of a 1. flexible rubber catheter connected in an “O” ring configuration; 2. soft end of Jackson Pratt Drain with wooden end of the cotton tip applicator inserted into center; and 3. a commercially manufactured loop ostomy rod. The challenge was to find a skin barrier that could accommodate the protruding hardware while providing patient comfort, extended barrier wear time, and leak prevention, thereby reducing the nursing time for better readability usually required for these complicated cases.

Results

In all three cases, Convatec Moldable Technology™ helped to seal and adhere to the hardware to reduce gaps while hugging the stoma to reduce leaks. As a result, the facility was able to achieve a 3-5 day wear time in all the cases.

Conclusion

Surgical technique can vary greatly depending on the patient's needs. These variations can often contribute to an increased likelihood of post-surgical complications, making it challenging for nurses to find a skin barrier that prevents complications, while providing comfort and extended wear time. Convatec Moldable Technology™ skin barrier has been shown to be an effective solution in these challenging cases, providing the best fit around protruding hardware, to prevent leaks and provide extended wear time, thereby increasing patient comfort.

Easier to Use

- Simplifies ostomy care
- Reduces accessories and associated costs
- Benefits across a range of patient needs
- Easier for patients to use
- Easier to use and teach for healthcare professionals

Simplifying ostomy care for patients and hospitals

Convatec Moldable Technology™ simplifies application and reduces the number of accessory/ostomy products this hospital carries



Geriach MA. Doing away with scissors and patterns using a new technology of ostomy skin barriers. 40th Annual WOCN Conference, Orlando, FL, USA; June 21-35, 2008.



"After surgery, I dealt with my cut-to-fit wafers cutting into my stoma - literally cutting it, causing it to bleed. I also dealt with horrid bag leaks. Thankfully my stoma nurse introduced me to Convatec Moldable Technology™ and I've never gone back!"

Overview

Single center case series to determine if Convatec Moldable Technology™:

- Provides adequate wear time and skin protection in a variety of applications
- Can be used in a wide range of patients
- Increases application convenience for patients and staff

Results

Results of the product evaluation demonstrated that Convatec Moldable Technology™:

1. Was easier to apply compared to cut-to-fit and pre-sized barriers
2. Met or exceeded WOCN acceptable wear time for ostomy skin barriers
3. Protected peristomal skin, even for less than ideally constructed stomas

Conclusion

Convatec Moldable Technology™ simplifies ostomy application for patients, caregivers and health care providers by avoiding the use of scissors. In addition, Convatec Moldable™ skin barriers provide adequate wear time all while protecting the peristomal skin from further irritation, even with stomas that fall below the ideal in construction. Based on the study results, this center decided to convert their primary ostomy supply line to Convatec Moldable Technology™ skin barrier.

Convatec Moldable Technology™ provides a solution for ostomates with dexterity problems

Allowing patients to remain independent and improve quality of life



Philbin S, Rochette J. A new moldable barrier provides solutions for people with ostomies and dexterity challenges. 40th Annual WOCN Conference, Orlando, FL, USA; June 21–25, 2008.



“For patients with dexterity issues, moldable decreased the number of outpatient follow-up visits and cost.”

Overview

Patients in this one center study had dexterity problems and experienced difficult challenges with the preparation and application process of traditional cut-to-fit products, including a poor fit and subsequent complications around leakage and skin irritation.

Two patients had multiple sclerosis, two had arthritis, and a fifth patient had very large fingers and hands which made cutting with scissors very challenging. All the patients needed to involve family members and friends to assist with cutting wafers and trying to properly fit them.

Results

All patients were transitioned from traditional cut-to-fit barriers to a flat moldable barrier to increase ease of application and effective wear time.

Patients' independence measurably improved using the flat moldable barrier. All reported increased comfort, simplicity of use, and a better overall satisfaction with application with the Convatec Moldable Technology™. The number of outpatient ostomy visits and peristomal skin breakdown decreased for all five patients.

Conclusion

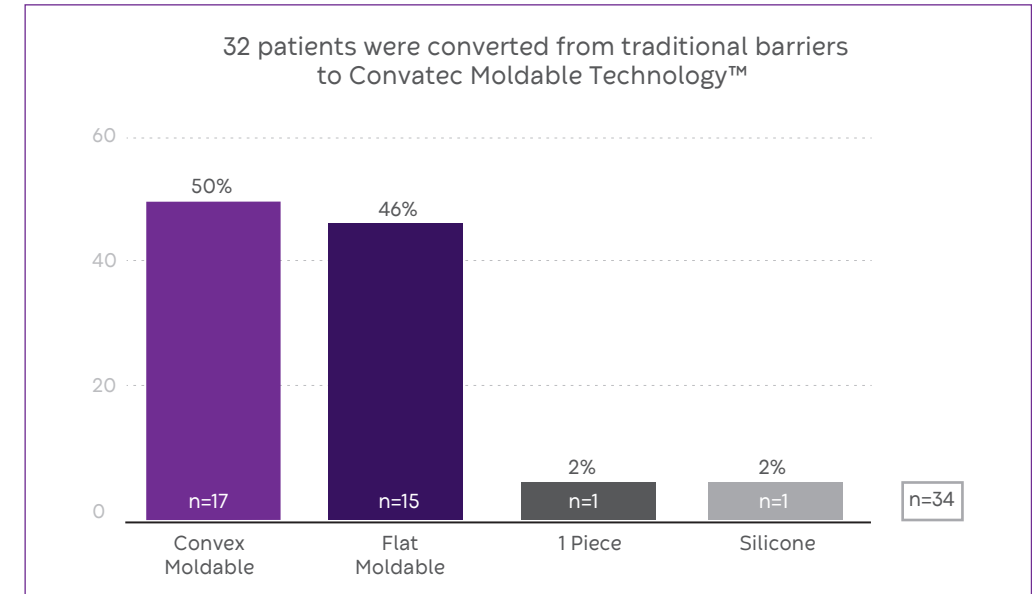
Ostomy patients with dexterity issues benefit from Convatec Moldable Technology™ skin barriers in measurable quality of life ways, such as satisfaction with self-care and newfound independence. In addition, patients using a moldable technology skin barrier need less outside help and have less trips for outpatient follow-up. This saves cost for both the patient and the clinic.

Convatec Moldable Technology™ was easier for nurses to use and apply

Creating better seals, reduced leakage and accessories use



Stallings B. The perfect fit: the use of flat moldable skin barriers in home care. 43rd Annual WOCN Conference, New Orleans, LA, USA; June 408, 2011.



Overview

A large home health care system with more than 200 agencies, serving 100-700 patients, incorporated Convatec Moldable Technology™ into their agency with the objectives of better management of irregular stomas and ease of learning and use for nurses.

Results

Since the addition of Convatec Moldable Technology™ to the formulary, 50% of patients were placed in a convex moldable product, 46% were placed in flat moldable, 2% in a 1-piece system, and the last 2% placed in an off-formulary, non-adhesive silicone product.

- Both patient and nurse feedback reported high ease of use
- Increased wear time was achieved
- Moldable was found effective for irregular stomas
- "No cutting required" was viewed as a positive asset
- In many cases, no stoma paste was required

Conclusion

Overall, fewer accessory products were purchased, decreasing agency costs and simplifying patient care routines, which led to reduced budget spend across the board.

Convatec Moldable Technology™ was easier for elderly patients to use than traditional barriers

Elderly patients were able to remain in the home longer and reduce complications



Tomlinson L. Teaching older ostomy patients—moldable technology eases the fear factor. 41st Annual WOCN Conference, St Louis, MO, USA; June 6–10, 2009 (3354).

"Moldable Technology™ and its ease of use gives the new users (patients) the confidence and hope that they can be independent with ostomy care at home."

Overview

Study conducted in a New Jersey (US) enclave where the adult population over age 65 is 23%, and there are over 91 adult communities where the elderly are taking on the care responsibilities of themselves and their neighbors.

Convatec Moldable Technology™ was introduced to elderly patients as an easier-to-use solution with the hopes of allowing them to remain in their homes.

Results

This clinical approach showed Convatec Moldable Technology™ skin barrier products are easier for patients to understand and learn to use, thereby decreasing fears over their abilities to care for themselves and increasing confidence in living a higher quality of life with a stoma than they previously thought possible.

As an example, one elderly couple in the study was highlighted as being able to remain at home together instead of one being transferred to a nursing home because of the wife's colostomy. Even with less dexterity, the 86-year-old husband, who was to be his wife's caregiver, felt more comfortable with the Convatec Moldable Technology™ skin barrier product in managing any changing of dressings of the stoma.

Conclusion

With Convatec Moldable Technology™, the skin barrier has a much better fit and is easier to learn for an elderly patient or caregiver than a cut-to-fit product. This is helpful because it allows for seniors to continue their quality of life and to age in home longer than they may be able to if unable to self-manage their ostomy care.



Fewer Leaks

- Reduces leaks vs shape-to-fit barriers
- Reduces leaks vs cut-to-fit barriers
- Improves wear time

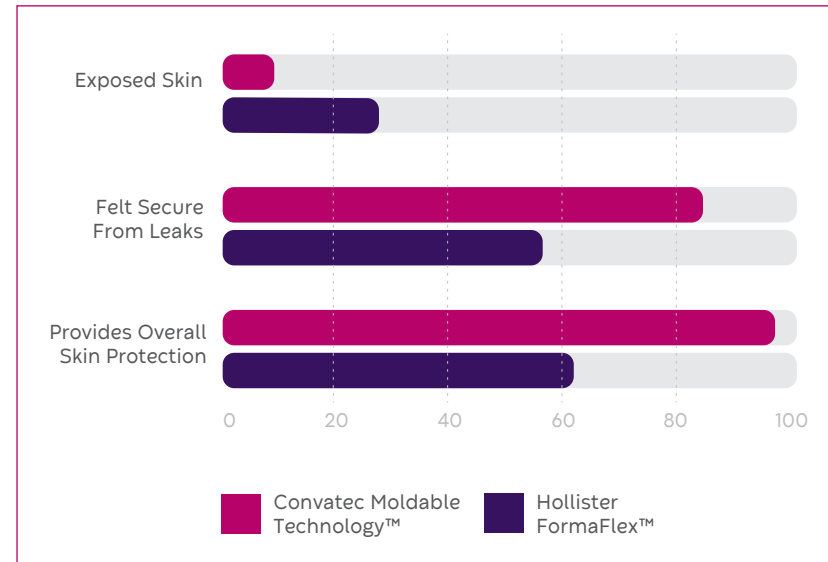


Comparison of two leading barrier products in ostomy patients

Convatec Moldable Technology™ demonstrated better leak control and patient satisfaction



Durnal A. Clinical comparison of a moldable skin barrier versus a shape-to-fit. 45th Annual WOCN Conference. Seattle, WA, USA. June 22-26, 2013.



Over 80%
of study participants strongly agreed that the moldable product provided high security from leaks

Overview

Multicenter US study comparing Convatec Moldable Technology™ barrier vs Hollister FormaFlex™ skin barrier in patients with colostomies, ileostomies, and urostomies. Sixty (60) patients were enrolled in the study. Patients had a median age of 59.2 years. The primary reasons why patients cited for changing their barrier was routine need to change and leaks.

Results

There was a significant difference between Convatec Moldable Technology™ and FormaFlex™ with regard to exposed skin, security from leaks, and overall skin protection. More than 80% of study participants strongly agreed that Convatec Moldable Technology™ provided high security from leaks.

Conclusion

According to ratings by study participants, Convatec Moldable Technology™ exceeded expectations for security from leaks with nearly 80% of participants strongly agreeing that the moldable product provided the best security from leaks.

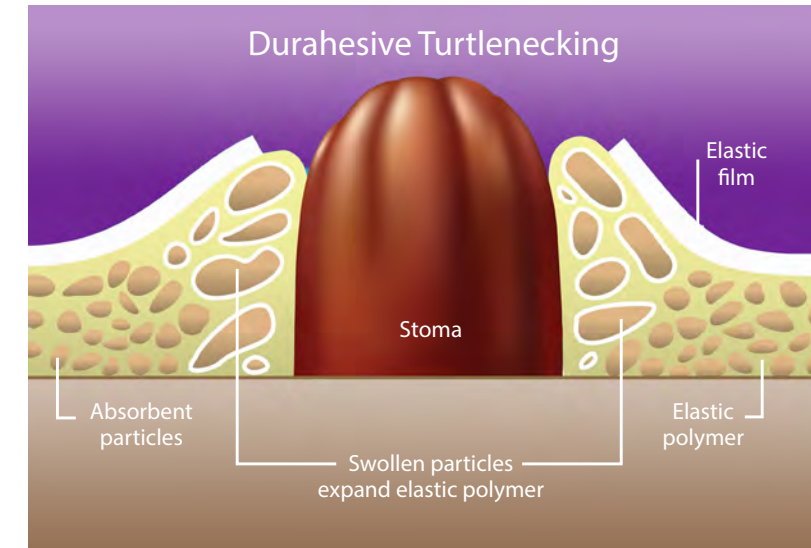
* FormaFlex™ is a trademark of Hollister, Inc.

Convatec Moldable Technology™ turtlenecking feature helped reduce leaks

Convatec Moldable Technology™ significantly reduced leakage across stoma types vs conventional skin barriers



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Overview

A prospective, observational, multinational study in people with colostomy, ileostomy, or urostomy assessing the incidence of peristomal lesions and level of patient satisfaction with Convatec Moldable Technology™ skin barriers. The study was initiated at 90 centers: 48 in Poland, 28 in Germany, and 14 in the USA. The study evaluated 277 patients new stoma patients with intact skin.

Results

The results of this study found that 95.6% of new ostomates who start with Convatec Moldable Technology™ maintain peristomal skin integrity.

Conclusion

The Convatec Moldable Technology™ skin barriers were shown to be effective in preventing skin complications and were rated as Good or Excellent by the vast majority of patients.

Reduces leaks vs shape-to-fit skin barriers

Convatec Moldable Technology™ significantly reduced leakage across stoma types



Watanabe M, et al. Evaluation of stoma pouch with moldable skin barrier for early postoperative outcomes after stoma construction. *J Japan Coll Surgeons* 2013; 38: 765–70 (in Japanese).

Postoperative Outcome

		Convatec Moldable Technology™ (n=32)	POSPACK® (n=32)
The initial replacement date of a stoma (POD)*		3 (1-5)	2 (1-3)
Stoma edema at the time of initial replacement	+ -	23 9	30 2
Contamination under the skin barrier at the time of initial replacement	+ -	8 4	16 16
Skin complication scores at the time of initial replacement*		0 (0-0)	0 (0-2)
Skin problems during hospital stay (%)		43.7% (14/32)	68.7% (22/32)
Skin complication score at the time of discharge*		0 (0-2)	2 (0-40)

*Values are median (range)

Overview

64-patient prospective study to evaluate the efficacy of Convatec Moldable Technology™ in the prevention of leaks and peristomal skin damage as compared to POSPAC® (ALCARE Co) post-operatively.

Results

The post-operative outcomes showed that:

- Stoma edema was observed in 71.9% of the Convatec Moldable Technology™ patients vs. 93.8% of the POSPAC® Barrier.
- Contamination under the face plate was observed in 25% of the Convatec Moldable Technology™ group and 50% of the POS group.
- Skin disorder incident rate was significantly lower with Convatec Moldable Technology™ (43.7% vs. 68.7%: p = 0.019, 0 vs 2: p = 0.033).

Convatec Moldable Technology™ had significantly less contamination under its base plate which translates into less leaks and better skin health.

Conclusion

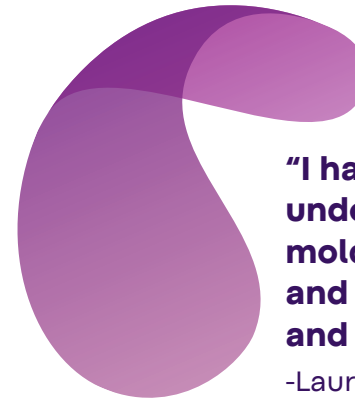
When patients experience less leakage, they also experience less chance for infection or skin complications around the stoma area, as well as less need to change the dressing. This translates to more comfort for the patient, less complications, and ultimately provides a health economic benefit as well.

Reducing leaks and expanding wear time

One Canadian healthcare provider's experience with Moldable Technology™ skin barriers



Wolfe L. A new tool in the Canadian ET toolbox.
WOCN/WCET Joint Conference, Phoenix, AZ, USA;
June 12–16, 2010.



"I have found that once patients understand that all they need to do is mold/stretch the opening of the skin barrier and press down gently, they find it much easier and less preparation versus cut-to-fit barriers."

-Lauren Wolfe, RN, BSN, CWOCN



Overview

Case series demonstrating the use of a moldable barrier in various challenging patient types where patients were previously using cut-to-fit barriers. They include:

1. 80 year-old frail and shaky male with a total ileostomy which is round, raised, red and 38mm.
2. 28 year-old female with an ileostomy post total colectomy. Stoma is oval, raised and red.
3. 68-year-old female post-radical cystectomy with ileal conduit. Stoma was raised, oval and ischemic but viable below the level of the skin.

Results

1. After 4 weeks using 1-piece cut-to-fit products with unsatisfactory results, the 80-year-old male patient switched to Convatec Moldable Technology™. He found it much easier to use and achieved a solid seal vs. cut-to-fit.
2. After switching to Convatec Moldable Technology™, the 28-year-old female was able to achieve wear time of 4-5 days and reduce skin complications.
3. The 68-year-old female patient found Convatec Moldable Technology™ worked well and was easier-to-use. As a result, she was able to achieve a 3-4 day wear time.

Conclusion

Overall, patients in these case studies found that Convatec Moldable Technology™ skin barrier provided:

- The ability to hug irregular-shaped stomas
- Improved wear time due to providing a better seal and preventing leakage
- Less need for accessory products
- Overall ease of use due to the lack of cutting required
- Improved comfort

Skin Health

- Prevents and improves skin condition vs conventional
- Better protection vs shape-to-fit
- Fewer peristomal problems (post-operative)

Convatec Moldable Technology™ reduced skin complications

Eliminating the need to cut resulted in a secure fit and ultimately a reduction in peristomal skin complications



Erbe JM. Skin Barrier selection in an outpatient ostomy clinic. *J Wound Ostomy Continence Nur* 2011; 38:S47.



"Convatec Moldable Technology™ is better able to manage patient concerns related to leakage and/or skin irritation."

Overview

Results from a 6-month product evaluation at a single US center of 70 patients with new and existing ostomies seen, 25% were successfully placed on Convatec Moldable Technology™.

Results

For the 25% of patients who were placed on the Convatec Moldable Technology™, no longer having to cut skin barriers helped to obtain a more secure fit, which was found to decrease the chance of leakage and trauma to the stoma. The hydrocolloid tape border on the moldable skin barrier reportedly helped resolve irritation from acrylic sensitivities in some patients.

Conclusion

"For our patient population, moldable skin barriers have improved our clinical outcomes such as wear time and peristomal skin problems. This product is better able to manage patient concerns related to leakage and/or skin irritation."

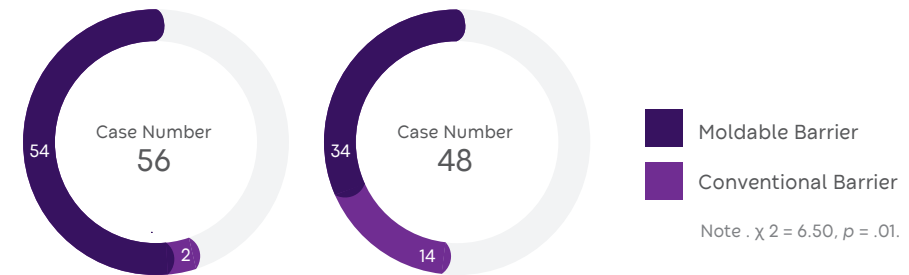
Convatec Moldable Technology™ reduced peristomal skin irritation

Elderly patients in this study had fewer peristomal skin complications while also finding moldable easy to apply



Liu G, et al. The application of a moldable skin barrier in the self-care of elderly ostomy patients. *Gastroenterol Nursing* 2017; 40:117-20.

Comparison of Peristomal Skin Disorder Between Two Groups



Comparison of Self-Care Satisfaction Between Groups

Groups	Case Number	Very Satisfied	Satisfied	Not Satisfied
Moldable Barrier	56	32	24	0
Conventional Barrier	48	16	22	10

Note . $\chi^2 = 7.45, p = .02$.

Overview

Prospective, randomized, controlled study evaluating the efficacy of moldable skin barrier compared to conventional skin barriers in post-surgical colostomy patients.

Study details include:

- n=104
- Fifty-six (56) patients received moldable barriers
- Forty-eight (48) patients received conventional, cut-to-fit barriers
- Information on peristomal irritation, satisfaction with self-care, and related costs were collected 1 month after discharge from hospital

Results

The overall incidence of irritant dermatitis was significantly lower, the self-care satisfaction score was significantly higher, and the cost for leakage-proof cream was significantly lower in the experimental moldable group than in the cut-to-fit control group. In contrast, no significant differences in the cost of ostomy equipment and the barrier replacement interval were observed.

Conclusion

In elderly stoma patients, a moldable skin barrier can reduce the incidence of irritant dermatitis, reduce the cost of leakage-proof cream, and improve their overall self-care satisfaction when compared with the conventional stoma skin barrier.

Use of Convatec Moldable Technology™ eliminated hospital-acquired peristomal skin complications

Convatec Moldable Technology™ was easy to use and easy to teach



Marescalco K. Improving patient outcomes by increasing consistency of ostomy care. WOCN/WCET Joining Conference, Phoenix, AZ, USA: June 12-16, 2010.



100% of the nurses at the facility, including first-year nursing students, learned to effectively apply a moldable skin barrier with ease.

Overview

A training and product implementation program at a US hospital had the goal of decreasing the number of hospital-acquired peristomal skin complications. Ostomy product selection was standardized to a moldable skin barrier over multiple cut-to-fit styles available. Facility-wide educational program for nurses included a 15-minute educational program with a short video and a hands-on demo of product application using stoma model.

Results

100% of the nurses at the facility, including first-year nursing students, learned to effectively apply a moldable skin barrier with ease. Following implementation of the new program, the incidence of hospital-acquired peristomal skin breakdown was zero.

Conclusion

Standardizing product selection to a moldable skin barrier for ostomy patients in a US hospital combined with educational programs for nurses lowered incidence of peristomal skin complications to zero, thereby improving patient outcomes.

Fewer peristomal skin complications post-operatively using Convatec Moldable Technology™ vs cut-to-fit

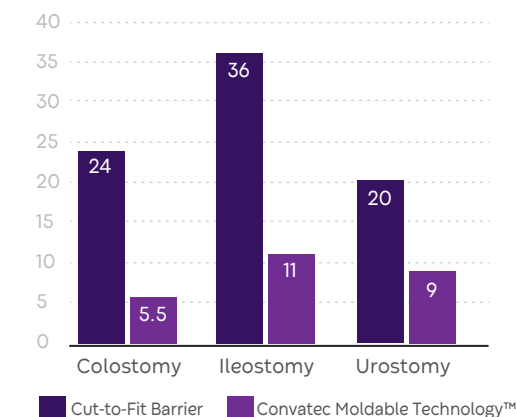
Large prospective, post-surgical observational study



Scott V, et al. Prospective assessment and classification of stoma-related skin disorders. 41st WOCN Annual Conference, St Louis, MO, USA; June 6–10, 2009.

	Cut-to-Fit Results		Moldable Results		Variance
	Number (N)	% Skin Lesions	Number (N)	% Skin Lesions	Reduction in Lesions
Ileostomy	209	36%	230	11%	69%
Colostomy	105	24%	164	5.5%	77%
Urostomy	91	20%	77	9%	55%

Number of Peristomal Lesions Identified



Overview

A prospective, observational study to assess peristomal skin complications in patients following ileostomy, colostomy or urostomy surgery when using cut-to-fit vs moldable barriers. 405 patients were assessed using cut-to-fit and 471 patients were assessed using moldable.

Results


- Over about 9 months, 405 patients with surgically placed stomas received care by a WOCN. There were 209 ileostomies, 105 colostomies and 91 urostomies. Of these, skin complications were noted in 36% of ileostomies, 24% of colostomies and 20% of urostomies.
- The following three months, this facility converted from a cut-to-fit skin barrier to moldable skin barrier as the standard post-operative product. There were 230 ileostomies, 164 colostomies and 77 urostomies. Of these, skin complications were noted in 11% of ileostomies, 5.5% of colostomies and 9% of urostomies.

Conclusion

The conversion to Convatec Moldable Technology™ resulted in a significant reduction in peristomal lesions versus cut-to-fit. Ileostomy patients reduced lesions by 69%, colostomy by 77% and urostomy by 55%, indicating that moldable provided greater leak protection and ultimately better skin health.

Better Skin Health

Convatec Moldable Technology™ was shown to prevent peristomal skin complications in the majority of patients

 Clinical Summary: Osmose Study, Multinational Evaluation of the Peristomal Condition in New Ostomates Using Moldable Skin Barriers. Maria Teresa Szewczyk, MD, PhD; Grazyna Majewska, RN, ETN; Mary V. Cabral, MS, FNP-BC, CWOCN- AP; and Karin Hölzel-Piontek, RN; The Effects of Using a Moldable Skin Barrier on Peristomal Skin Condition in Persons with an Ostomy: Results of a Prospective, Observational, Multinational Study, *Ostomy Wound Management* 2014;60(12):16–26.

"I never realized how important maintaining the skin under my ostomy was until I started becoming more active and experiencing issues."



Overview

Prospective, multicenter, multicountry, observational evaluation of persons with a colostomy, ileostomy, or urostomy was conducted to assess the incidence of peristomal lesions and level of patient satisfaction with moldable skin barriers. Peristomal skin was assessed using the Studio Alterazoni Cutanee Stomale (SACS™) scale, and patients were asked to rate barrier application and usage variables.

Results

During a period of 12 months, 277 new stoma patients who had a colostomy (174), ileostomy (72), or urostomy (10) were evaluated; All patients were assessed at baseline and after 1 and 2 months.


In the patients with a new stoma, 225 (90.4%) had intact skin at baseline, 239 (95.6%) had intact skin after 2 months, and 98% rated overall satisfaction with the barrier as Good or Excellent.

Conclusion

The Convatec Moldable Technology™ skin barriers evaluated were effective in preventing leaks and as a result, reducing peristomal skin complications. Moldable was rated as Good or Excellent by the vast majority of patients.

Better protection vs cut-to-fit, fewer peristomal problems

Convatec Moldable Technology™ delivers better post-surgical outcomes vs cut-to-fit

 Watanabe M, et al. Evaluation of stoma pouch with moldable skin barrier for early postoperative outcomes after stoma construction. *J Japan Coll Surgeons* 2013; 38: 765–70 (in Japanese).



Convatec Moldable Technology™ skin barrier had no skin complications at the time of discharge.

Overview

A single center evaluation of whether use of Convatec Moldable Technology™ skin barrier is beneficial for preventing and ameliorating early postoperative outcomes after stoma construction vs cut-to-fit barriers. Thirty-two (32) patients were given cut-to-fit barriers (POSPACK-K®) and 32 patients were given moldable barriers (NATURA™ Moldable Technology). Post-operative outcomes with two groups, including patient background and stoma-related early complications were compared.

Results

Compared with conventional cut-to-fit barriers, Convatec Moldable Technology™ is proven to deliver:

- Better skin health during hospital stays and at discharge: Patients using moldable skin barriers had significantly fewer skin problems during their hospital stay (43.7% vs 68.7%, $p=0.019$) and at discharge (0 vs 2; $p=0.033$) than those given cut-to-fit barriers.
- Less stoma edema: Fewer patients given moldable skin barriers had stoma edema at the time of first stoma replacement vs those given cut-to-fit barriers (71.9% vs 93.8%; $p=0.020$).
- Fewer skin problems in moldable patients at discharge: 0 vs. 2 ($p=0.033$).

Conclusion


The patient group using Convatec Moldable Technology™ had significantly fewer challenges post-operatively with stoma edema, contamination under the skin barrier and moldable was found to be useful against early complications after stoma construction, particularly against stoma-related skin problems.

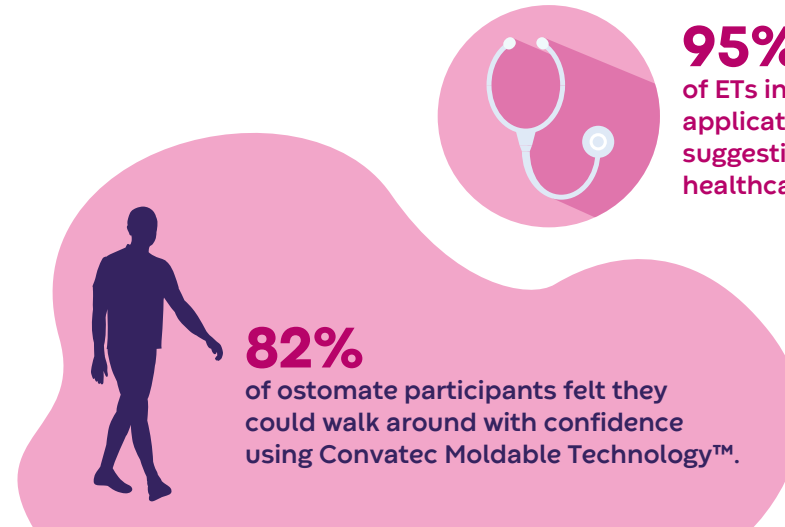
Satisfaction

- Higher satisfaction among new patients
- Patients and nurses highly satisfied
- Made most patients feel secure
- High satisfaction among elderly patients
- Improved confidence / reduced anxiety

Patients and nurses (across stoma types)

A multicenter evaluation to assess the satisfaction of Ostomates and Enterostomal Therapy (ET) nurses with a new Convatec Moldable Technology™ skin barrier

 Hoeflok J, et al. A prospective multicenter evaluation of a moldable stoma skin barrier. *Ostomy Wound Management* 2009; 55:62-69.



Overview

A multicenter evaluation to assess the satisfaction of Ostomates and Enterostomal Therapy (ET) nurses with a new moldable skin barrier. At baseline, skin irritation was noted in 41% of ET evaluations and by 46% of participants with a stoma and cited as a reason to discontinue product usage in 11 ET reports (6.4%) and by seven users (3.6%).

Ostomates: n=172, the majority (116) had ostomy surgery >90 days before the evaluation.

Enterostomal Therapy Nurses: n=49, complete 195 evaluations.

Results

The percentage of Very good or Excellent ratings from ostomates was 84.2% for colostomies, 85.4% for ileostomies, and 92.5% for urostomies. Overall, for all ostomy surgery types combined, 82% of participants felt they could walk around with confidence and 83.7% of participants would recommend the product.


For ET evaluations, the percentage of Very good or Excellent ratings for all evaluation criteria was 89.0% for colostomies, 92.7% for ileostomies, and 92.7% for urostomies and 87% of ETs noted that teaching product usage was easy.

Conclusion

The results show very high levels of satisfaction with the moldable skin barrier, regardless of the type of ostomy surgery. Participants with a stoma and ETs overwhelmingly rated the product easy to use, easy to learn to use, and easy to teach. It provided effective skin protection regardless of the type of ostomy surgery and/or regardless of baseline skin condition and very few skin irritation concerns were reported. All these benefits have potentially significant implications for ETs and people living with an ostomy who require viable options in ostomy care.

Convatec Moldable Technology™ has a higher patient satisfaction for ileostomy patients

Suggesting it is a preferred option following ileostomy surgery

 Huang HI, et al. Moldable skin barriers as a clinical option for patients following ileostomy. *J Soc Colon Rectal Surgeon (Taiwan)* 2020; 31: 204–12.

Evaluation of Skin Barrier Performance

Evaluation Criteria	Rating	Cut-to-fit (n=19)	Moldable (n=41)	p-value
Effective skin protection	Good/Excellent	2 (10.53)	23 (56.10)	0.0031
	Not bad	13 (68.42)	12 (29.27)	
	Poor	4 (21.05)	6 (14.63)	
Stable sealing effect around the stoma to prevent leakage	Good/Excellent	3 (15.79)	25 (60.98)	0.0049
	Not bad	12 (63.16)	12 (29.27)	
	Poor	4 (21.50)	4 (9.76)	
Ease of application	Good/Excellent	5 (26.32)	31 (75.61)	0.0006
	Not bad	12 (63.16)	9 (21.95)	
	Poor	2 (10.53)	1 (2.44)	

Overview

Data suggests that skin complications for ileostomy patients with cut-to-fit barriers is high, leading to high dissatisfaction with choice of product.

A prospective study evaluating post-surgical satisfaction of ileostomy patients comparing cut-to-fit skin barrier and Convatec Moldable Technology™ barrier. One hundred twenty (120) patients were initially enrolled in the study:

Group A: 60 patients using cut-to-fit barrier were enrolled

Group B: 60 patients using moldable barrier were enrolled

Patients were asked to rate the performance of their product in the following areas: 1. Effective skin protection, 2. Stable sealing effect and 3. Ease of application.

The three response options were Good/Excellent, Not bad, and Poor.

Results

Number of patients completing the study were as follows:

Group A: 19 patients using cut-to-fit barrier

Group B: 41 patients using moldable barrier

Patients were observed at the following post-surgical intervals: 7-10 days, one and two months.


- 56% of the Convatec Moldable Technology™ and 11% of the cut-to-fit patients ranked their product as “Good/Excellent” in the category of “Effective Skin Protection”
- 61% of Convatec Moldable Technology™ and 16% of cut-to-fit patients ranked their product as “Good/Excellent” in the category of “Stable sealing effect around the stoma to prevent leaks”
- 76% of Convatec Moldable Technology™ and 26% of cut-to-fit patients their products as “Good/Excellent” in the category of “Ease of application”

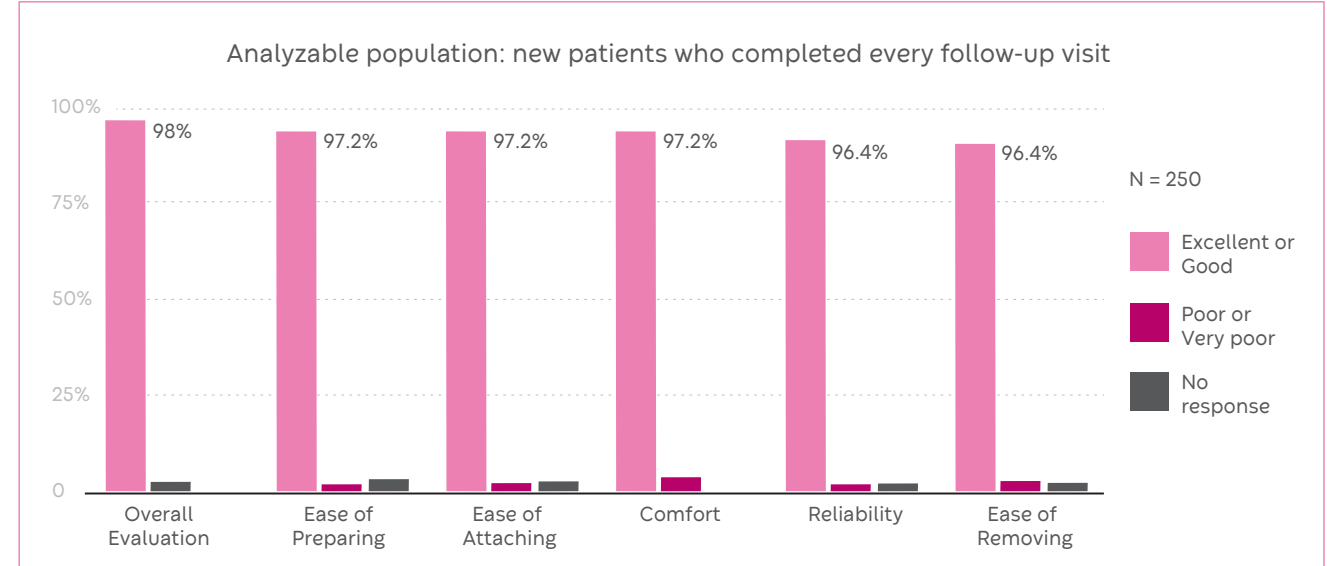
Conclusion

Convatec Moldable Technology™ was evaluated in this study against cut-to-fit barriers by ileostomy patients. Convatec Moldable Technology™ was found to have high patient satisfaction in its ease of application and ability to prevent leaks suggesting that moldable is a preferred choice for this patient group.

High patient satisfaction in a multisite and multinational moldable study

Demonstrating multiple benefits for new patients

 Clinical Summary: Osmose Study, Multinational Evaluation of the Peristomal Condition in New Ostomates Using Moldable Skin Barriers. Maria Teresa Szewczyk, MD, PhD; Grazyna Majewska, RN, ETN; Mary V. Cabral, MS, FNP-BC, CWOCN- AP; and Karin Hölzel-Piontek, RN; The Effects of Using a Moldable Skin Barrier on Peristomal Skin Condition in Persons with an Ostomy: Results of a Prospective, Observational, Multinational Study, *Ostomy Wound Management* 2014;60(12):16–26.



Overview

A prospective, observational, multinational study in people with colostomy, ileostomy, or urostomy assessing the incidence of peristomal lesions and level of patient satisfaction with moldable skin barriers.

- 277 patients used Convatec Moldable Technology™ post-surgical.
- All patients were assessed at baseline 8-15 day, 1 and 2 months.
- Patients assessed the comfort level, ease of preparing, ease of attaching, ease of removal, reliability, and overall perception of moldable skin barrier in a patient satisfaction questionnaire at all follow-up visits.

Results

In the patients with a new stoma, 98% rated overall satisfaction with the barrier as Good or Excellent.

Conclusion

Patients all ranked comfort, ease of preparation, application, removal, and reliability as about 95% in all categories for new patients, indicating Convatec Moldable Technology™ skin barrier may offer significant multiple benefits to new patients.



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