Original article

A prospective multicenter evaluation of a novel soft convex skin barrier

ABSTRACT

Aims Recent expert consensus supports the safe use of convexity at all stages post-ostomy, including immediately after surgery. Finite element analysis predicted interactions between geometric shapes in new soft convex technology and simulated stoma sites. This evaluation compared the clinical performance and user satisfaction of the novel soft convex ostomy system with existing products.

Methods A prospective convenience sample of patients with an ostomy in acute care or outpatient clinics across four US advanced specialty hospitals was evaluated between January 16 and June 14, 2024. Data were collected from wound ostomy continence nurse practitioners and registered nurses through an online survey managed by a certified research organisation, which also performed blinded data analysis.

Results Ninety evaluations were completed across four institutions. Most respondents were board certified wound ostomy continence nurses (99%), with 79% evaluating patients in acute care and 21% evaluating outpatients. The technology was assessed across a diverse patient population, with 49% ileostomies, 34% colostomies, and 17% urostomies. Most patients were in the immediate post-operative phase (57%), and 69% had complex peristomal skin contours. Clinical performance was rated highly: 96% reported wear time as "as expected" or "longer than expected," and 89% strongly agreed that it created an effective seal. Flexibility and comfort were noted by 92%, while 91% agreed the convex design met clinical needs. Overall, 100% of respondents rated the product experience as good or excellent.

Conclusions The novel soft convex technology was found to be safe, effective and improved wear time in challenging clinical scenarios.

Keywords convexity, peristomal, leaking, pouching system, soft convex.

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INTRODUCTION

Achieving an ideal fit between the ostomy product and the individual with an ostomy is the bedrock of clinical care to prevent leakage and ensure confidence in the selected pouching system. It has been reported that 76% of individuals with an ostomy experience leaking under the skin barrier,[1] with close to half (43%) of individuals with an ostomy reporting frequent pouching system changes.[2] Leaking presents not only a risk to peristomal skin health but also impacts individuals with an ostomy adjustment after surgery, their behavioral health and quality of life. In a 2019 survey of over 5000 individuals with an ostomy, Jeppesen and colleagues[2] reported that 92% of respondents were worried about leaking: of these, 40% worried about leaking to a "high or very high" degree. Moreover, a literature review of 18 studies assessing psychosocial impact of having an ostomy identified that 48% of patients had a higher prevalence of anxiety than normal and the pooled prevalence of depression was reported to be 39%.[3] While having a stoma alone may impact psychosocial challenges such as body image, sexual dysfunction and appropriate adaptation after surgery, living in constant fear of leaking may exacerbate these concerns.

The first step in achieving an ideal fit of any ostomy appliance is to carry out a thorough clinical assessment of the patient. This includes, but is not limited to, a holistic approach and typically

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involves several key components, including: a complete medical history and physical examination; a review of current medications; a nutritional evaluation; and an assessment of the abdomen and stoma. It also includes evaluating the condition of the peristomal skin, the patient's ability to manage their own care and their overall functional status.[4]

Each of the above assessments may help identify the risk of and/or reason for active leaking under or around the ostomy appliance. While these holistic assessments are best performed by a certified ostomy nurse, the most basic assessment should include abdominal, stomal and peristomal skin assessments.[5] These assessments are crucial in identifying common reasons for leaking, such as the presence of a flush or retracted stoma, skin creases and folds, irregular peristomal plane, stoma changes by patient positions, effluent and inappropriate pouch selection and sizing, among others. For these situations, convex pouching systems are often beneficial.[6]

Historically, the use of convexity after surgery was suggested to be controversial due to the risk of complications, such as mucocutaneous junction (MCJ) separation and peristomal pressure injury. For example, the recent Italian clinical guidelines indicate that convex appliances should be avoided in the "first post-operative days" secondary to the risk of increased tension on the MCJ separation.[7] However, there are multiple intrinsic and extrinsic risk factors that may lead to a complication like a MCJ separation that is not related to convexity.[8-10] Often, mucocutaneous separation (MCS) is associated with conditions that increase the tension on the stoma, such as the use of a stoma support rod, or that hinder the healing process. Specifically, intrinsic risk factors, such as diabetes, smoking, cancer, obesity, poor nutritional state and advanced age may impair appropriate mucocutaneous incisional healing.[11] For example, the use of immunosuppressive agents or biologics, such as vedolizumab in the treatment of inflammatory bowel disease, may increase the risk six-fold[12] Moreover, surgical technique has been described to influence the risk of complications such as MCS,[13] with Ohara and colleagues identifying that suturing techniques impact the risk and severity of MCS when comparing all dermal layer techniques to a seroerdermal approach.[9,14] In the immediate postoperative period, appropriate assessment and selection of the pouching system are therefore essential, with clinicians needing to match the findings of the physical assessment to the characteristics of convexity required to achieve an effective seal.[15] Recently, a group of ostomy experts reached consensus that convexity can be used safely at any point throughout any stage of an individual's journey with an ostomy, including immediately after surgery, where the primary goal for any individuals with an ostomy is to prevent leaking and its associated complications.[6] Moreover, each convex appliance's interaction with the skin and its effects on the abdominal wall, and the peristomal plane will be different based on its unique construction relative to the five characteristics of convexity (depth, compressibility, flexibility, tension location and slope).[15] In the immediate post-operative period, soft convexity is often selected but should also be considered the preferred choice when patients need a convex appliance but would benefit from improved flexibility, compression and fit to match the abdominal contours.

Recently, finite element analysis was used to predict the specific interaction of different geometric shapes in a new soft convex technology, demonstrating its interaction with a novel abdominal wall stoma model.[16] In order to test these theories in clinical practice, a prospective, multicenter product evaluation was performed at four US institutions. The purpose of this evaluation was to determine product performance and user satisfaction with the novel soft convex line in a variety of patient populations and geographic regions.

METHODS

A prospective, convenience sample of individuals with an ostomy admitted to acute care or being treated at outpatient ostomy clinics from four US quaternary institutions was obtained via an online survey conducted from 16 January, 2024 to 14 June 2024. The four institutions were selected based upon their volume of surgeries resulting in ostomy creation, representation of large, diverse populations, provision of cancer care services and a representative of large trauma surgery practices. These facilities, therefore, represented a diverse population of geographies and reasons for ostomy surgery. The goal of the study was to evaluate the clinical performance of a new soft convex technology (EsteemBody® with Leak Defense™, Convatec Technology Center, Lexington, MA). The survey was designed by Dr Brindle and focused data collection in three areas: patient demographics (which did not include any protected health information), stoma characteristics and complications and user feedback. The target respondents were certified wound ostomy continence (WOC) nurses, nurse practitioners and registered nurses caring for individuals with an ostomy who had used Convatec EsteemBody™ in their respective institutions. There was no defined protocol for care as the nurses were asked to consider the evaluation of Convatec EsteemBody™ based on their clinical assessments, and level of expertise. The WOC nurses or nursing respondents chose how long to trial the product, performed all clinical assessments and determined discharge and ongoing care needs. This approach was taken due to a lack of a standardised, evidence-based approach to post-operative ostomy care in the US. Facility protocols for post-operative ostomy care vary, leading to differences in intraoperative pouch selection, change frequency given the need for removals based on need for patient education and teaching, and so on. Therefore, the performance of the product in the opinion of the nurses was based on their respective facility standards of care.

INCLUSION AND EXCLUSION CRITERIA

The inclusion criteria included any patient admitted to the hospital with a urostomy, ileostomy or colostomy. The exclusion criteria included patients with open, full thickness

wounds within the pouching surface area or those individuals with an ostomy who had peristomal varices.

ETHICAL APPROVAL AND CONSENT TO PARTICIPATE IN THIS STUDY

The EsteemBody™ study was a product evaluation assessing nurses' experiences of a novel soft convex skin barrier rather than a formal research study; therefore, ethics committee approval and informed consent were not required.

EVALUATION FORMS

Healthcare professionals (HCPs) were asked to identify their title, practice setting, and specify the manufacturer(s) of the soft convex products they typically utilised in daily practice for comparison. Non-personal health-related patient information included ages <18 years; 18–35; 36–45; 46–60; >60 years old), gender (male, female, non-binary), length of stay and surgery type (colostomy, ileostomy, urostomy). Stoma characteristics included duration of the stoma (Intraoperative/day 0; 1–8 days; 9–30 days; 31 days–6 months; >6 months), stoma shape (round, oval or irregular), stoma characteristics: os/stoma opening location (central, 12 o'clock, 3 o'clock, 6 o'clock, 9 o'clock); shape (round, oval, irregular), abdominal turgor (soft; normal; firm), peristomal plane (flat; creases; skin fold shallow; skin fold deep; incision in pouching area) and stoma complications (none, hernia, prolapse, retraction, mucocutaneous separation, other). Convatec EsteemBody™ product feedback included performance attributes including wear time, ability to achieve an intact seal around stoma, appearance of pouch sagging and pouch bulge compared to usual products and pouch material. Ten specific performance features were additionally collected for HCPs to compare Convatec EsteemBody™ performance with their usual choices of soft convex products, using a 5-point Likert scale (strongly agree, agree, neutral, disagree, strongly disagree). Key features studied included flexibility, characteristics of the baseplate meeting clinical needs, ease of application and removal, ability to manage emptying, softness, accommodation of unique patient needs, and improvement of seal compared to usual products. Overall clinician experience was evaluated, including HCP perception of Convatec EsteemBody's™ ability to improve wear time compared to other pouch manufacturers' products and the likelihood of recommending Convatec EsteemBody™ to other HCPs.

DATA COLLECTION AND DATA ANALYSIS

IQVIA MedTech (Chesapeake, VA), a certified research organisation, digitised the data collection tool, created a secure and encrypted site for nurses to access and perform anonymous evaluations and provided quality control. Nurses accessed the secured site via mobile phone or computer following the patient encounter. IQVIA managed all data collected during the study and performed data analysis (which was blinded to the researchers) and the collective results were blinded to the site team members respectively. The study was open for six weeks or to the point when 90 total evaluations were completed. The study was based on the number of evaluations and not number of patients, and therefore, it was possible for a single patient to be evaluated twice by different HCPs. For example, if they were evaluated as an inpatient by more than one clinician after surgery and/or on return to the outpatient clinic. Mean scores were calculated across responses from different hospital settings and provider type. While data was collected, descriptive statistics were performed on the survey data including mean, standard deviation and minimum/maximums for continuous variables, and frequencies for categorical variables. A bivariate comparison of study site results was conducted using one-way ANOVA at 95% confidence interval (CI) and 90% CI respectively.

Given the heterogeneity in practice norms and patient populations at the respective institutions, these comparisons were not intended to suggest superior/inferior performance or level of care differences between institutions, but instead to evaluate a real-world assessment of performance based on these geographical, institutional and population-based differences. When applicable, significant statistical differences between sites were reported with context from the specific site study leads to capture qualitative experiential data to guide interpretation of the data and why there may have different outcomes.

RESULTS

The evaluation was concluded upon notification from IQVIA that a total of N=90 evaluations had been reached across all institutional sites (Massachusetts General Hospital [MGH, 21%; Brigham & Women's Hospital [BWH], 21%; University of Louisville, [UL], 18%; Memorial Sloane Kettering [MSK], 40%). The primary respondents were WOC nurses (99%), with 79% of HCPs evaluating patients in acute care and 21% in outpatient clinics. In these settings, respondents reported a wide range of soft convexity use across four major manufacturers including: Convatec 42%, Hollister© (Hollister Incorporated, Libertyville, IL) 37%, Coloplast® (Coloplast US Headquarters, North Minneapolis, MN) 18% and Marlen© (Marlen Manufacturing & Development Co, Bedford, Ohio) 3%. The commonly used products for each institution in comparison to Convatec EsteemBody™ are listed in Figure 1.

DEMOGRAPHIC AND FACILITY DATA

Patient demographics included the percentage distribution across age ranges at the four facilities as >60 years old (43%), 46–60 years old (24%), 36–45 years old (20%) and 18–35 year olds (12%). There were no patients under the age of 18 evaluated in this study. Almost half of the patients in the study were over the age of 60 which may be representative of one facility being a large cancer institution (MSK) and each facility having a cancer facility. MGH houses a large cancer center; however, many patients under the age of 60 still develop colorectal cancer and require an ostomy. In a cohort of 29 patients at MGH, 10 were diagnosed with cancer, while other common diagnoses included diverticulitis, bowel perforations and inflammatory bowel disease. Of interest,

the proportion of patients 18–35 years old at one facility (UL) (31%) was statistically different than MGH and MSK at the 95% CI. Study HCP respondents indicated that this may be related to a substantial percentage of trauma patients at UL, as they are one of only two trauma hospitals in the state and manage patients with the need of emergency ostomy surgery. There were no differences in gender across the sites with the mean scores of 58% female and 44% males evaluated. One facility, MGH, reported 5% of respondents selected non-binary.

The mean length of stay (LOS) for patients evaluated in the study was 8 days, however, there were significant differences between BWHs (reporting 3 days LOS) and all other sites (MGH 10; MSK 7; UL 11). All facility respondents were surprised by the reported LOS and indicated this may have been due to variation of reporting from actual LOS to number of days in the Convatec EsteemBody™ product during admission. Additionally, in some cases at MGH, their patient conditions were reported being of higher acuity. One participant already had an ostomy and was admitted for an unrelated issue that took a long time to resolve, leading to an extended hospital stay. Others experienced complications, such as post-operative ileus, infections or fistulas, which also prolonged their length of stay. At BWH, the shorter length of stay is likely attributable to the hospital's use of Enhanced Recovery After Surgery (ERAS) protocols.[17] For example, in a meta-analysis of randomised clinical trials (RCT)s including 73 RCTs of 9076 patients, both length of stay and overall complications rates were lower with the use of ERAS guided surgical procedures. A few cases experienced longer stays, typically due to post-operative complications, such as ileal or anastomotic leaks. The breakdown of ostomies during the evaluation was 49% ileostomy, 34% colostomy and 17% urostomy. Of note, the rates of colostomy were higher at UL (50%) and MGH (53%), which were both statistically different at a 95% CI compared to BWH and MSK at a 90% CI. One facility (MGH) reported no urostomy patients evaluated, while BWH (37%) had the highest frequency, which was statistically different from UL at a 90% CI. Among the patients evaluated at MGH, 47% were placed in the Convatec EsteemBody™ category in post-operative days 1-8. However, urologists often require a two-piece system for patients with stents to allow for easier access. An additional 37% of patients were seen between days 9–30 post-operatively. At this stage of recovery, if a patient was initially started on a specific manufacturer's system (such as a two-piece system), any necessary changes are typically made within the same brand family whenever possible. This approach ensures continuity of care, particularly for older patients, as transitioning to an entirely new system, including a different spout, connection,or pouch type may be overwhelming. When adjustments are needed, clinicians may opt to incorporate soft or firm convexity or add a belt rather than switching to a different manufacturer.

STOMA CHARACTERISTICS

Most patients in the evaluation were immediately post-operative with a new stoma (μ-57%) followed by stoma durations of 9–30 days (20%), 31 days–6 months (16%) and >6 months (8%) respectively. The presence of immediate post-operative patients was especially true at MSK (78%) while BWH had statistically significant differences in both 31 day–6 month patients (37%) and >6 months (28%) patients compared to MGH, MSK and UL.

On average, os/stoma opening locations were reported as central 61% of the time across institutions, while MSK reported the highest frequency of the os pointing to 12 o'clock (37%). However, in discussions with the facilities after the study, it is possible that HCPs considered "12 o'clock" and "central" as the same thing, as it was not always clear to the team. An os position pointing straight down, or at the 6 o'clock position, was reported on a range of 14–21% of the time across the facilities. Most facilities reported round "normal" stomas 71% of the time, with a range between 56–81%. The second most common reported stoma shape was oval (μ-27%) with few to no irregular or prolapsed stomas (5–6%).

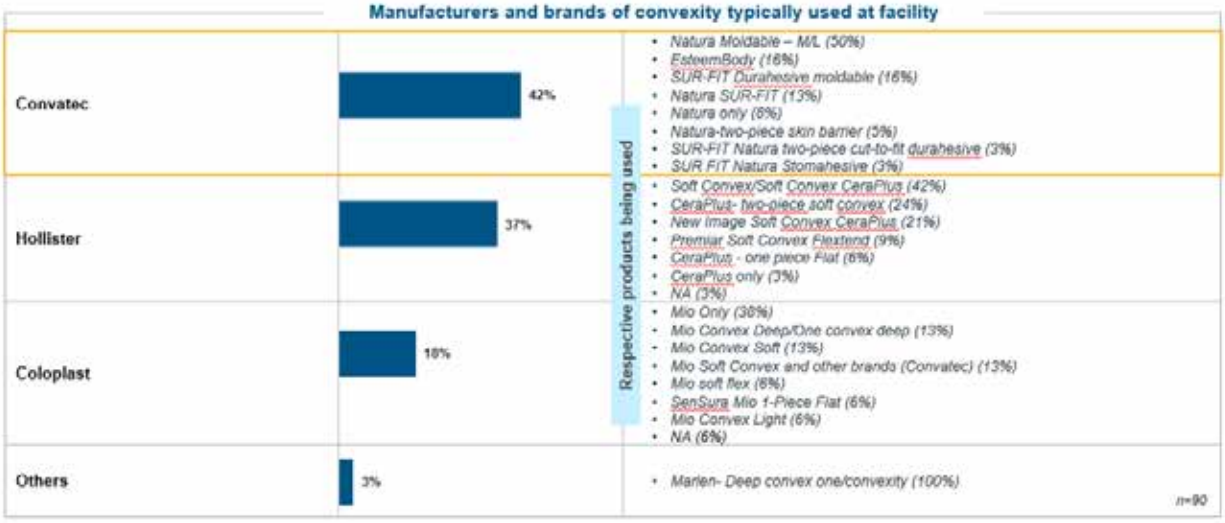

Figure 1. Manufacturers and brands of soft convex use for comparison to Convatec EsteemBody™
Results of product use by manufacturer and brand. Data may not add up to 100% as respondents could provide multiple answers.

Next, HCPs reported on abdominal and peristomal skin assessments with or without the presence of complications. Abdominal assessment (normal, soft, firm) showed a mean presence of soft abdomen (56%), firm (10%) and normal (34%) respectively. Convexity is often selected for soft abdomens where abdominal fat compression is necessary to achieve a seal, and firm abdomens often indicate a need to consider convexity characteristics of depth, compressibility and flexibility to ensure the selected convex product does not exert too much force with the counter pressure of a firm or edematous abdomen. At the 90% CI, UL had a statistically higher rate of firm abdomens (25%) compared to BWH (5%) and MGH (5%) respectively. Increased abdominal firmness may result due to third spacing from fluid resuscitation during surgery or from bowel edema especially in the presence of complications, such as peritonitis. This difference at UL may be related to the patient selection which consisted mainly of high-acuity trauma patients.

When considering peristomal plane shape, the facilities reported consistent findings with flat peristomal planes representing only 31% of patients. On average, 69% of all patients required management of shallow skin folds (28%), creases (26%), deep skin folds (9%) and incisions within the pouching area (7%) which may have compromised an effective seal. Stoma complications were reported in 26% of all patients across the study sites, with retraction (11%) and "other" (12%), which included comments including: edema, fistula, side effects of Avastin, hypergranulomas, skin ulceration and contact dermatitis at the time of Convatec EsteemBody™ application. In contrast, MSK reported no complications in 94% of their patients, while BWH and MSK had higher levels of "other" and retraction respectively. This may again be related to case mix, as the majority of MSK patients presented as elective surgeries for ostomy creation whereas other facilities may have had a higher incidence of emergency cases which are associated with greater complications. In addition, studies suggest that facilities with high surgical volumes will have lower complication rates, with MSK being one of the largest cancer referral facilities in the country.[18]

CONVATEC ESTEEMBODY™ PERFORMANCE

The first product performance indicator studied was wear time. In the US, typical wear time of an ostomy appliance is 3–5 days, whereas most individuals with an ostomy using drainable ostomy appliances for urostomy or ileostomy, will aim to change their pouches 1–3 times weekly. Given the high rate of Convatec EsteemBody™ application in this study during the immediate post-operative period, wear time was dependent also on the routine changes associated with ostomy education before discharge. Therefore, the ostomy nurses evaluated performance based on the individual and expectations based on provision of care. Convatec EsteemBody™ was reported to have wear time "longer than expected" or "as expected" at a mean of 96% across all institutions. Additionally, satisfaction that Convatec EsteemBody™ has the ability to create an intact seal around the stoma had a mean of 89% for "strongly agree," with one facility (UL), reporting their satisfaction at 100% "strongly agree" which was statistically significant compared to the other three facilities (MSK at 95%CI, and BWH/MGH at 90%CI). Nurses at this facility indicated that the reason for their satisfaction was that the patients they selected for evaluation were primarily intensive care unit patients who had challenging stomas, which resulted in inconsistent wear time or seal around the stoma when using other ostomy products on formulary. The use of Convatec EsteemBody™ led to increased wear time immediately after application in these challenging patients, leading to the perfect score from this team. One way to manage clinical variation between patients is having a wide range of products with different tension locations and depths available to respond to clinical need. With four tension locations and two depths, Convatec EsteemBody™ has eight variations to support clinician choice. During the evaluation, 91% of nurses from all facilities felt that the characteristics of the convexity met the clinical need of the patients evaluated. The UL reported 100% strongly agree to the statement which was statistically different than MGH (95% CI) and MSK (90% CI). Additionally strong agreement across facilities was found in accommodation of the patients' unique stoma and anatomical needs. Less respondents reported strong agreement with the product improving fit/decreasing leaks compared to their current formulary (72%), however, this may have been related to the large number of acute care new patient starts and the need for more frequent than normal changes associated with patient education, return demonstrations and stoma assessment in the immediate post-operative period. MGH has access to a much wider range of products with varying cutting surfaces, firmness and depths compared to other hospitals. This may explain why there was no strong agreement that the product improved fit or reduced leaks compared to the current formulary. Most patients at MGH were in the immediate post-operative group, requiring more frequent pouch changes for teaching purposes. At BWH, stoma assessment is conducted during the immediate post-operative period, and a pouch change is performed before discharge. More frequent pouch changes are not carried out for educational purposes.

Another performance feature, flexibility, was noted by a mean score of 92% to allow for natural movement of the patients in the evaluation. Of interest, at least two patients who had a stoma for greater than 6 months using a 2-piece appliance asked if they could evaluate the product based on its appearance. After application, the patients described that there was almost no perception of them having a pouch on their skin, compared to their previous 2-piece appliance. They indicated that flexibility led to increased comfort, which was not an original evaluation question for the study. Finally, 93% of nurses indicated that the pouch volume and capacity was appropriate.

Additional pouch features received high marks from all facilities. First, all facilities indicated the new, woven, water repellant flocking was comfortable on the skin (100%) and 99% mean score that the material was visually appealing and provided a premium feel. Ease of use had a mean score of 98%, as well as ease of application to the skin scoring 97% across all four facilities.

Finally, the overall experience with Convatec EsteemBody™ was rated as excellent or good by 100% of respondents. There were no poor ratings from any of the facilities. The mean score of "excellent" was 90% across the four facilities. Nurses reported that Convatec EsteemBody™ would improve wear time compared to other pouches they currently use with a mean score of 86% (range 74–100%). On a scale of 1–10 with one being (highly unlikely) to 10 (highly likely) to recommend Convatec EsteemBody™ to others the mean score was 8.8 out of 10, range 7.7–10. In summary, Convatec EsteemBody™ was rated very highly for, not only its performance but also, its new features for individuals with an ostomy across various patient types and geographic locations.

DISCUSSION

Having a product with reliable performance and the ability to achieve an intact seal leads to a reduction in leaking and, therefore, reduces the risk of skin breakdown and improves patient satisfaction. As the study was not designed to capture narrative comments or case examples, the authors were asked to report on any observations or specific cases that represented their experience with Convatec EsteemBody™ since using the product.

OBSERVATIONS AT UNIVERSITY OF LOUISVILLE

The cutting process was significantly easier with Convatec EsteemBody™ compared to the traditionally used system. Additionally, the closure, with its contrasting color and improved grip, facilitated easier handling, making both opening and separating the closure more efficient than the conventional system. UL found that the stool distribution in the pouch was less noticeable for the patients.

OBSERVATIONS AT MASSACHUSETTS GENERAL HOSPITAL

At MGH clinicians found that Convatec EsteemBody™ was much easier to cut than the products they traditionally used. It's wide variety of tension locations and two different distinct convexity depths in the skin barrier offer a comprehensive toolkit suitable for any stoma size, shape or protrusion level. The system also proved to be effective and safe to use in the immediate post-operative period.

A long-term ileostomy patient, who had undergone multiple takedowns and stoma re-siting procedures, had struggled for years to maintain a seal for more than 24 hours. The patient had been using a Coloplast 1-piece system with deep convexity and barrier rings, to address the unevenness in her stomal plane. Additionally, her os was positioned at the corner of the stoma, causing the stool to undermine the wafer despite various interventions, including belts, convex barrier rings, stoma paste, and protective sheets. As a result, the peristomal skin in that area was severely denuded. To manage this, she frequently used Domeboro® Rash Relief (Emerson Healthcare, Bridgewater, NJ) soaks to dry the skin and employed crusting with stoma powder and Cavilon™ Advanced Skin Protection Wand (Solventum Corporation, Eagan, MN). During her 30-day hospital stay, the Convatec EsteemBody™ #423666 system was trialed with a piece of barrier ring to even out the stomal plane near the os, along with an ostomy belt. This combination improved wear time to 2–3 days, providing valuable feedback on both durability and comfort.

OBSERVATIONS AT BRIGHAM & WOMEN'S HOSPITAL

At BWH, nurses introduced the Convatec EsteemBody™ product to patients either during their hospitalisation or at their first post-operative visit to the outpatient stoma clinic, which is typically scheduled 4 to 6 weeks after surgery. Patients with protruding stomas who achieve a three-day wear time during their hospital stay are generally not placed in a convexity system. In contrast, patients with flat or retracted stomas are fitted with skin barriers that offer a level of convexity. The first outpatient post-operative visit is often when changes in peristomal skin topography and stoma shape become apparent, potentially indicating the need for convexity. During this visit, patients frequently report episodes of leakage and may present with sore or irritated skin, prompting a reassessment of their pouching system.

A patient had surgery in April, for the creation of a urostomy. The patient is wheelchair-bound but remains independent with transfers and is highly motivated to manage her own stoma care. During hospitalisation, her stoma was assessed as moist, red and protruding, with two stents exiting from the stoma. The stoma was initially fitted with a flat skin barrier combined with a barrier ring. At her first post-operative outpatient visit in May, she reported episodes of leakage. Upon removal of her existing pouching system, the stoma was reassessed and found to be red, moist, slightly protruding and without stents. Additionally, the os of the stoma was directed towards the right (Figure 2).

After evaluating the patient in both lying and sitting positions, it was determined that she would benefit from the Convatec EsteemBody™ Cut-to-Fit 3.5mm one-piece convexity urostomy pouch, along with the addition of an Eakin Seal. The unique features of Convatec EsteemBody™ compared to her current pouching system were explained in detail. The patient expressed a preference for the "feel" of the pouch, particularly appreciating the absence of tape. She was provided with two product samples and enrolled in the Convatec Me+ Program. A follow-up telephone call conducted two weeks after her visit revealed that she achieved a four-day wear time with no episodes of leakage. Although she is scheduled for routine follow-ups at the outpatient stoma clinic, attending appointments remains challenging due to transportation

Figure 2. Clinical image demonstrating rightward orientation of the stoma Os in a patient at Brigham and Women's Hospital

difficulties and the distance from the hospital. This case study, along with similar experiences at BWH, demonstrates that Convatec EsteemBody™ provides convexity with flexibility, making it a valuable option for early post-operative recovery.

LIMITATIONS

This prospective, multicenter, product evaluation studied the use of Convatec EsteemBody™ in an observational and noncomparative evaluation. Questions associated with the performance of the product in comparison to existing products being used in the facility formularies were based on perception of difference based on experience and not a direct comparison trial.

CONCLUSION

In this observational study, Convatec EsteemBody™ performed favorably across a diverse range of acute care and outpatient ostomy populations in four major US institutions. Despite significant variation in patient acuity, surgical indication, stoma characteristics and institutional practices, healthcare professionals consistently reported high levels of satisfaction with product performance, including the ability to achieve and maintain an intact seal, flexibility, comfort, ease of application and accommodation of complex abdominal and peristomal contours. The findings reinforce the importance of individualised ostomy assessment and support the evolving consensus that convexity, including soft convexity, can be used safely and effectively throughout all stages of the ostomy journey, including the immediate post-operative period. In this evaluation, the majority of patients presented with non-flat peristomal planes, abdominal irregularities, or stoma-related challenges that could compromise seal integrity, highlighting the need for adaptable convex solutions tailored to patient anatomy and clinical presentation.

Clinician observations and case experiences further illustrated the potential of Convatec EsteemBody™ to improve wear time, reduce leakage, and enhance patient comfort, even among individuals with historically difficult-to-manage stomas. The flexibility and range of convexity options available within the system were viewed as important advantages in managing clinical variability and supporting individualised care.

Although this evaluation was observational and non-comparative, the consistently positive feedback across geographically and clinically distinct institutions suggests that Convatec EsteemBody™ represents a valuable addition to contemporary ostomy management. Future comparative and longitudinal studies are warranted to further evaluate its impact on leakage prevention, peristomal skin health, patient quality of life, and long-term clinical outcomes.

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CONFLICT OF INTEREST

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