Original article

Use of mouldable ostomy technology in clinical practice: Delphi clinical consensus of ostomy experts

ABSTRACT

This paper reports the results of a global expert panel utilising a modified Delphi technique, to reach consensus on the use of mouldable ostomy technologies in ostomy practice. The aim of this document is to describe the current state-of-the science related to product selection in current ostomy practice. The objective of the project was to determine the best available evidence describing the use of mouldable stoma baseplate technologies in ostomy care compared to traditional cut-to-fit appliances. The rates of peristomal ostomy complications reported in the literature are unacceptable and reflect many factors such as lack of appropriate education, access to stoma care certified providers and the selection of appropriate ostomy products. The purpose of using the Delphi technique was to accomplish three specific objectives: 1) summarise the current state of mouldable ostomy technology knowledge, based on a scoping review of the literature; 2) formulate recommendations for clinical practice change in ostomy care; 3) consider expert experience to guide practice where published evidence could not be found. Six consensus statements with their aggregate level of evidence, risk of bias, and recommendations for clinical practice are presented herein.

Keywords ostomy, mouldable, stoma, leaking, Delphi consensus

For referencing Beitz J et al. Use of mouldable ostomy technology in clinical practice: Delphi clinical consensus of ostomy experts. WCET® Journal. 2025;45(1):13-19.

DOI https://doi.org/10.33235/wcet.45.1.13-19

Submitted 25 October 2024, Accepted 29 November 2024

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INTRODUCTION

The ability of an ostomate to establish a high level of independence following ostomy surgery is paramount to adaptation and quality of life. Complications associated with ostomy management and self-care add additional complexities to the lives of ostomates recovering from a significant underlying condition, such as cancer. In a large cross-sectional study of long-term rectal cancer survivors, quality of life was greatly influenced by self-care factors such as leakage, peristomal moisture associated skin damage, and difficulty managing care.[1] In fact, 14% of respondents indicated that they needed more than 30 minutes to care for their ostomy every day and 26% reported having to change their pouches frequently. Often, challenges with ostomy self-care begin immediately after surgery, especially in the absence of a certified wound, ostomy, continence nurse (WOCN) or enterostomal therapy nurse (ETN), working in partnership with the surgeon.

In a qualitative content analysis study of 17 nurses from surgical wards, the findings demonstrated that non-certified nurses often have insufficient knowledge and are unaware of up-to-date best practice recommendations, guidelines and guidance to provide the best care.[2] Themes emerging from these interviews identified inefficient educational systems for staff, lack of acquaintance with ostomy complications and proper planning of patient education as key issues.

The delivery of adequate stoma care may be most challenging in low-income countries. In a mixed methods study of six hospitals in the Philippines, Malawi, Nigeria and India, data from 446 patients was analysed in a six month retrospective review.[3] The study highlighted the lack of stoma care knowledge of nurses, ostomates and caregivers, and cited poor access to stoma care resources and appropriate products to provide care. Education and guidance for providers and ostomates to deliver an appropriate standard of care, requires an understanding of appropriate clinical assessment, skin and stoma care basics and identification of complications rapid triage to a WOCN/ETN for care. Recently, the first peristomal skin classification scale for ostomates was developed in order to help ostomates identify peristomal challenges and improve communication with their caregivers, while continuing to provide guidance to health care providers.[4] The SACS Evolution Tool is currently being validated in clinical care and will improve self-care through enhancing peristomal skin assessment and early identification.

Selection of the right product following clinical assessment is critical to prevent complications such as leaking and irritant contact dermatitis while ensuring confidence and quality of life through achieving a reliable seal. Often, ostomates are unaware of the variety of options available to them. Additionally, lack of access to stoma care certified providers often leads to selection of inappropriate products, leading to higher rates of leaking and complications. The ability of the ostomate to learn, prepare, and perform tasks associated with self-care, such as fine manual dexterity movements needed for cutting, marrying pouches and baseplates in two piece appliances, and the use of additional accessories needs to be considered.

Mouldable ostomy technologies were introduced to the market in 2009 and offered alternatives to traditional cut-to-fit products, to directly address the challenges with preparation, achieving a consistent size/seal around the stoma and a decreased need for accessories. Given the potential benefit to ostomates provided by these technologies, a group of experts sought to determine the available evidence. A scoping review of the literature was performed to compare mouldable technology and cut-to-fit ostomy appliances, and identified 17 studies, using a novel explainable AI platform.[5] Several key themes were identified across the studies. Most studies reported high overall user satisfaction with mouldable skin barriers compared cut-to-fit products, including among individuals with visual or manual dexterity challenges, with high ratings observed for ease of preparation, application, and removal.[6–16] Mouldable skin barriers were associated with reduced peristomal skin complications compared to cut-to-fit products (e.g., peristomal irritant dermatitis, skin breakdown, contamination under the skin barrier), which might be attributed to a more secure fit with mouldable technology.[6,7,12,13,17,18] The improved sealing with mouldable skin barriers was supported by several case studies which reported "more predictable", "effective" or "increased" wear time.[12,14–16,19,20] WOCN/ETs also found that mouldable technology was easy to teach and learn across all ostomy types, including for elderly patients.[7,18,21,22] Lastly, a small number of studies found decreased costs with mouldable skin barriers compared to cut-to-fit products due to a reduction in accessary use.[6,11,15,16]

The results of this scoping review will form the foundation of a consensus meeting discussing mouldable technologies. While in some countries mouldable products have become standard practice, sales trends demonstrate these technologies may still be unknown by many clinicians. The purpose of this paper is to report the results of a Delphi consensus conference of ostomy experts on the use of mouldable ostomy technologies in global clinical practice.

SCOPE OF THE CONSENSUS DOCUMENT

The aim of this document is to describe the current state-of-the science related to product selection in current ostomy practice. The objective of the project was to determine the best available evidence describing the use of mouldable stoma baseplate technologies in ostomy care compared to traditional cut-to-fit appliances. The purpose of the project is to inform health care providers, caregivers and ostomates of the recommended use of mouldable ostomy products, including key considerations that differentiate mouldable products from other technologies. The research was inclusive of all ostomy manufacturers and sought to identify publications on any comparison of mouldable technologies available from multiple manufacturers.

The principle focus of the mouldable consensus project was to guide clinical recommendations for health care providers who care for ostomates through evidence-based recommendations and experiential considerations from expert providers. It is the position of this expert panel, that the *ostomate should be made aware of all options for their care and how product selection may impact their experience and quality of life.*

METHODS

State-of-the-science for this consensus was accomplished via the execution of a scoping review of the literature in accordance with preferred reporting items for systematic reviews and meta-analysis protocols (PRISMA) statement[23] and follows the published checklist for reporting. The scoping review was performed prior to the meeting of the advisory board, by four selected members. It was then presented to the advisory board for review and comment. The following research question guided the scoping review of the literature: for ostomates and their care providers, what are the differences between mouldable barrier products compared to cut-to-fit barrier products in outcomes associated with barrier fit and user experience?

The methods and results of each systematic review will be published.[5] In this study, four subject matter experts (TB, JB, CM, LI) employed a PRISMA-P methodology utilising the Literature Review Network version 2.0 (LRN v2.0) for literature searches across PubMed, Embase, CINAHL, and Google Scholar. As an explainable AI (XAI) system, the processes and methods behind LRN's decision making processes were explained in human terms.[24] A state-of-the-art XAI, the development and validation of LRN, as well as a comprehensive description of its architecture and application for literature reviews such as the protocol described herein, is reported by Morriss and Brindle et al (2024)[25] The research team trained the XAI system through four iterations to achieve the final corpus of articles. All abstracts and full text analyses were done by the researchers. No generative AI was used for analyses nor writing of the final manuscript. Critical appraisal was carried out by virtual meeting to verbally discuss inclusion versus exclusion designation. Following agreement of which abstracts to send for full review, the reviewers independently read all full-text manuscripts and subsequently met to determine final studies for analysis. Meta-synthesis of study outcomes was performed to identify themes across studies. Data collection process for extraction of each study was performed by the researchers in tandem over multiple virtual and in-person meetings where data reporting was categorised by outcome domains and transferred along with study demographics into evidence tables. Visual tables outlining final included studies with their level of evidence and risk of bias scores guided the identification of the highest level of evidence available by which to draft consensus statements.

Delphi technique: process and variants

The Delphi Technique for health sciences was used to develop consensus statements based on the scoping review. A modified, group technique was used, defined as, anonymous voting of an expert panel on a list of statements during a live, in-person meeting allowing for justification of deviating responses through group discussion.[26] The meeting occurred on 21 June 2024 in Lexington, Massachusetts, USA. The purpose of using the Delphi technique was to accomplish three specific objectives:

1. Summarise the current state of mouldable ostomy technology knowledge, based on scoping review of the literature
2. Formulate recommendations for clinical practice change in ostomy care
3. Consider expert experience to guide practice where published evidence could not be found.

DELPHI VARIANTS

Expert selection

Member selection was determined based on the respective research questions and specific to the clinical practice setting of the operating room. Expert identification was focused on representation from a global community of diverse clinical backgrounds, diverse patient populations, licensed professions, years of expertise, geographic representation, gender diversity and specialty. In total, 14 experts were invited to participate, with 10 acceptances. An expert was invited from the Asia-Pacific region but had to decline last minute due to a conflict. However, given the importance of feedback from clinicians in this region of the world, a separate meeting is planned to review these results with clinicians in China, based on the high rate of utilisation of mouldable technologies in this region.

Statement development

The method to develop statements was analysis and interpretation of scoping review of the literature using PRISMA methodology. Draft consensus statements were created by the original scoping review researchers (JB, LI, CM, JM, TB) and were provided to the entire expert team for consideration three weeks prior to the Delphi consensus meeting for review.

Definition and measurement of consensus

Consensus voting was moderated by Dr Chris Blagden, PhD, of Educational Resource Systems, via an in-person meeting using an encrypted and blinded polling app which allows for anonymous voting and blinded presentation of polling results. A quorum for this group defined as (N/2)+ 1 members, was established for this study where N=10, and the quorum was 6. Ultimately, 9 of 10 members were able to attend live voting. Group discussions were moderated by Dr Blagden after each voting session. A Group Delphi Technique was used, whereby the reviewers for the scoping review represented the contextual justification and evidence-based rationale for formulating each consensus statement and reviewed the strength of evidence, quality and risk of bias for each supporting study. Modifications were made in real-time based on group feedback and statements were amended for the

next round of voting. Three rounds of voting with a threshold for consensus of 75% was established apriori. Following three rounds of voting, the results were handled as follows:

1. Consensus of ≥75%: accept the statement and include in published recommendations
2. Near consensus: 50–75%: do not include in recommendations but consider obstacles to consensus as topics for future research recommendations
3. No consensus <50%: do not include in recommendations.

Clinical practice change and evidence base

The final clinical recommendations that reached consensus are reported in the following format:

Consensus statement

- Level of evidence and quality using the Johns Hopkins Nursing Evidence-Based Practice Model[27]
- Risk of bias scoring (ROB-2; Robis 1.2; Ottawa-Newcastle Scoring Tool)[27–30]
- Rationale and references from respective scoping review
- Clinical practice recommendations accompany each statement for potential adoption based on aggregate strength of evidence:
    - **Change practice**—practice change is supported by high level research of good quality and low bias
    - **Consider this**—practice change should be considered based on moderate to high level research and low to moderate bias
    - **Expert opinion**—the recommendation is made by the expert panel for consideration based on clinical experience, general common sense and may be supported by *in vitro, qualitative* or similar studies of low to moderate quality and moderate to high levels of bias.

RESULTS

Consensus statement

1. **Consider the use of mouldable ostomy technology in patients with disabilities such as poor manual dexterity, altered sensation or impaired visual capability [aggregate Level of Evidence III; Fair quality; Some risk of bias]. Recommendation: Consider in your practice setting.**

Members of the panel discussed how the use of mouldable technology can benefit individuals with disabilities and that ostomates should be educated on the availability of mouldable options and how they may improve ease of use and independence. One Level II[7], two Level III,[10,11] and seven Level V studies[12–16,21,22] support this recommendation.

Hoeflok and colleagues in a Canadian survey of 172 ostomates and 49 enterostomal (ET) nurses reported that 90.3% of ostomates found ease of molding "excellent" or "very good", while 100% of ET nurses indicated the same with urostomies.[7] Additionally, ease of use and ease of teaching was reported as "excellent" or "very good" by 95.9% of ET nurses. The ease of use of mouldable skin barriers was linked to irregularly shaped stomas, poorly visible stomas and persons with limited hand strength or dexterity. Two Level III prospective cohort studies with high quality and low risk of bias[10,11] reported ease of preparation, application and overall ease of use was superior to cut-to-fit appliances.[10,11]

Level V studies showed similar observations: Erbe (2011) indicated the lack of need for scissors was of benefit[12]; Haas and Reider (2011) identified ease of molding as preferred for manual dexterity and mental health challenges[13]; and Philbin et al indicated the ease of use of mouldable products led to higher independence and ostomate satisfaction.[14] A further four additional reports generally supported improved ease of use with mouldable barriers compared to cut-to-fit,[15,16,22] with Tomlinson (2009) reporting reduced patient anxiety with mouldable products from an ease of use perspective.[21] Moreover, the panel highlighted that ostomates who are incarcerated with limited access to sharp objects, such as scissors, may be better suited to mouldable technology.

2. **Consider the use of mouldable technology for ostomates with budded stomas who experience leaking with cut-to-fit appliances. [Aggregate Level of Evidence III; Fair quality; Some risk of bias] Recommendation: Consider in your practice setting.**

The panel further discussed how ostomates with a budded stoma—one that is not flush or retracted and protrudes into the pouching system—who experience leaking with traditional cut-to-fit barriers may benefit from mouldable technology. One level I,[6] four level III,[8,10,11,17] and two level V studies[12,13] compared the use of mouldable technology with standard cut-to-fit flat one-piece and two-piece products.

A randomised clinical trial of 104 patients with a primary endpoint of irritant contact dermatitis demonstrated that the incidence in irritant dermatitis was significantly lower in the mouldable group compared to the cut-to-fit group (χ 2 = 6.50, p=0.01).[6]

A cohort study by Szewcyk et al (2014) at 67 centers across three countries involved 551 ostomates who either started mouldable technology immediately after surgery (Group A) or were converted from cut-to-fit due to skin breakdown (Group B). The proportion of patients with intact skin in group A was consistently high over time, while the proportion in group B increased by two months after switching to mouldable: 90.4% vs 39.5% (day 8–15); 95.6% vs 77.4% (1 month); and 95.6% vs 86.2% (2 months).[11]

Huang et al assessed patient satisfaction between mouldable technology (n=41) and cut-to-fit (n=19) ostomy barriers in ileostomates. There was higher satisfaction among patients in the mouldable group compared to the cut-to-fit group in effective skin protection (p=0.0031), sealing effect (p=0.0049),

and ease application (p=0.0006).[3] No difference in skin breakdown was identified, however, this may have been related to low sample size overall and between cohorts.[10]

A French observational, prospective, multicenter study by Chaumier evaluated ostomy patients using mouldable technology as their first ostomy system (n=481) or who switched over to mouldable from another product (n=195). Throughout the 60-day study period, at least 80% of participants in both cohorts rated the mouldable skin barrier as "Excellent or Good". The authors noted that the highest ratings were associated with comfort, and ease of use, preparation, application, and removal.[8]

A study by Watanabe et al of 64 ostomy patients found that 25% of patients using mouldable technology had contamination under the skin barrier at the time of initial replacement compared to 50% in the cut-to-fit cohort (p=0.0375). The authors also reported significantly fewer incidents of skin problems during hospital stay in mouldable group compared to the cut-to-fit group, as well as a significantly lower skin complication score at the time of discharge (43.7% vs 68.7%, p=0.019; 0 vs 2, p=0.033).[17]

Two Level V studies generally reported resolution of peristomal skin complications after switching from a cut-to-fit to a mouldable skin barrier.[12,13]

3. **Consider the use of mouldable technology for ostomates with budded stomas with existing peristomal skin breakdown with cut-to-fit appliances. [Aggregate Level of Evidence III; Fair quality; Some risk of bias] Recommendation: Consider in your practice setting**

Evidence supporting the use of mouldable technology for budded stomas with preexisting peristomal skin breakdown with cut-to-fit skin barriers is demonstrated by Szewcyk and colleagues who evaluated patients switching to mouldable technology from cut-to-fit due to skin breakdown.[11] At the two month follow-up visit, the proportion of patients in this cohort with peristomal lesions in all four quadrants decreased from 40.6% at baseline to 5.4%. Moreover, the study by Watanabe et al demonstrated reduced skin contamination under the skin barrier with mouldable technology compared to cut-to-fit (25% vs 50%).[17] An additional three Level V sources demonstrated reduction in peristomal skin complications, after switching practice from the use of cut to fit and introducing mouldable technology products.[12,18,19]

4. **Ostomates with flush or retracted stomas and/or peristomal skin folds may need to be assessed for an appropriate convex baseplate or accessory. [Aggregate Level of Evidence V; Expert opinion]. Recommendation: Consider in your practice setting.**

The panel discussed how some stomas are not appropriate for flat pouching systems. Namely, convexity should be considered in the presence of creases, folds, flaccid peristomal skin, repetitive leaking with flat pouching systems, liquid output, loop stomas and telescoping stomas. In a one year follow up of all ostomy patients in a University Medical Center in Sweden, almost all patients with loop or end ileostomies with a stoma height under 20mm had leakage problems.[31] The curvature of a convex baseplate can better suit flush and retracted stomas that do not protrude, or peristomal skin with creases or folds, compared to a flat baseplate design which is typically suitable for patients with a budded stoma and flat peristomal skin.[32,33] Of note, the strength of evidence for this recommendation was listed as expert opinion. The reason for this was that the consensus statements were made based on the results of the systematic review of the literature on mouldable technology, where convex products and their respective studies were not evaluated. However, the expert panel discussed that the use of convexity has been well described in the literature, with recent consensus statements on appropriate clinical use[32,33] and, therefore, the experts felt comfortable recommending that clinicians consider this in their practice.

5. **Consider the use of mouldable ostomy technology to reduce the time to teach patients ostomy care and promote independence. [Aggregate Level of Evidence V; Poor quality; High risk of bias] Recommendation: Consider in your practice setting.**

Four studies directly commented that mouldable technologies improved ease of education by stoma therapy nurses to patients, especially in the immediate post operative period.[15,19,21,22] Eliminating the need of scissors, including the time to measure, trace and cut the wafer, was replaced with a more simplified and straightforward mouldable approach. A principal component of time for teaching was the ease with which the ostomate could learn the technique, and "ease of use" was specifically reported in 70% of the studies identified in the scoping review (12/17). Specifically, authors reported ease of removal,[9] ease of application[9–11] and ease of preparing supplies for change.[11]

6. **Clinicians using mouldable products should demonstrate competency on appropriate patient assessment and proper application of mouldable technology. [Aggregate Level of Evidence V; Expert opinion] Recommendation: Expert opinion.**

The expert panel described their relative experience and observation with the use of mouldable technologies in ostomy practice across the globe. Specifically, they reflected on countries where the use of mouldable technologies had become the standard of care, whereas other countries did not use mouldable technologies as often. Several members of the panel commented that mouldable products require specific inservicing that is unique to these technologies compared to the standard cut-to-fit device. Frequent and current users of these technologies on the panel indicated there were several practical considerations for appropriate application that needed to be understood and specifically return-demonstrated. The authors suggested that organisations should work with the respective mouldable technology

manufacturers to develop a staff competency specific to the products' indications for use and nuances with product specific specifications. Such competency not only ensures proper performance of the technology, but also ensures that the HCP is capable of appropriately teaching the ostomate appropriate practice to ensure the best outcomes.

DISCUSSION

This is the first expert consensus comparing the use of mouldable ostomy technologies to cut-to-fit appliances with clinical recommendations for use. The recommendations were based on the results of a scoping review of the literature using a novel combination of explainable artificial intelligence (LRN-XAI) and content experts in the field. In all, 17 articles were identified which ranged from a Level 1, randomised clinical trial to Level 5 clinical reports on mouldable technology performance. Despite an overall low quality of evidence and high risk of bias in aggregate, themes and user experience were found to be similar across these studies. Mouldable technology was reported to be superior to cut-to-fit appliances in terms of peristomal skin health and ease of use, especially in those with challenges to manual dexterity. Therefore, clinicians should consider prioritising the use of these technologies when possible. Cut-to-fit appliances continue to be appropriate, especially when irregular stomas exist, or secondary to size variations of stomas relative to available mouldable options. Given that the challenges of providing sufficient teaching to the ostomate limits the complexity of processes, mouldable technologies were found to improve user satisfaction, and at least in one report, decrease anxiety and teaching time.

LIMITATIONS

The limitations of this consensus document are related to the relative lack of high-quality evidence and risk of bias that prohibits stronger clinical recommendations or additional guidance at this time. Recommendations for future research were identified by the expert panel. Specifically, studies are needed that identify the optimal patient conditions in which mouldable technologies (or flat ostomy appliances in general) will provide sufficient patient outcomes compared the use of convex appliances. One particular consideration is at what point does stoma height limit the effectiveness of mouldable or flat technologies compared to convex counterparts? Product selection, especially for providers who are not stoma certified is confusing and difficult. The development and validation of a tool that allows appropriate product selection to the non-stoma trained provider is desperately needed. In addition, future studies on mouldable versus cut-to-fit technology should clearly follow a competency on the use of such technology. While the outcomes in the identified studies indicated preference toward mouldable devices, studies were not always clear on whether the nurses were competent in the unique application and handling of the product given its stark contrasts in preparation and application. Thus, a competency assuring the use of appropriate techniques may be valuable.

CONCLUSION

In 17 studies, mouldable technology was found to outperform cut-to-fit technologies in trends toward improved wear time, reduced complications, decreased time for teaching and reduced costs. An expert panel of ostomy providers developed six consensus statements for the use of mouldable technology in clinical practice, based on the results of a scoping review of the literature. Following a full clinical assessment, mouldable technologies should be prioritised over the use of flat, cut-to-fit barriers when appropriate.

ACKNOWLEDGEMENTS

The authors would like to thank the team at Educational Resource Systems including Rob Amorese, Helena Kravitz and Candice Logan for their support in the logistical planning of the consensus meeting with moderation by Dr Chris Blagden and oversight by Dr Michelle Daoud.

CONFLICT OF INTEREST

Janice Beitz, Dona Isaac and Cathy Milne are members of Convatec's International Advisory Board. Tod Brindle is the Medical Director-Ostomy for Convatec.

FUNDING

The article was funded by Convatec Ltd.

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