Literature review

Mouldable technology in ostomy care: a scoping review of the literature using a novel, explainable artificial intelligence

ABSTRACT

Pouching systems play a key role in ostomy care. However, peristomal skin complications due to leaked effluent are a common problem. Mouldable skin barriers are an alternative to traditional cut-to-fit or precut barriers and may provide improved benefits for ostomates. We examined the best available evidence describing the use of mouldable stoma baseplate technologies in ostomy care. The objective was to determine the best evidence describing the differences between mouldable versus cut-to-fit products to inform healthcare providers, caregivers, and patients with ostomies about their recommended use. 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 artificial intelligence (XAI) system, the process and methods behind LRN's decision making processes were explained in human terms. Researchers programmed the AI search based on study inclusion and exclusion criteria with iteration reports presented by recall percentage, precision and F-score. LRN's outputs are explained for transparency in search iteration model accuracy, Cohen's kappa and average potential. The human researchers then read all abstracts and full texts for final inclusion and analysis. Seventeen studies evaluating mouldable technology were identified. Key findings emerged in favor of the use of mouldable technology compared to cut-to-fit appliances regarding the following themes: overall satisfaction, reduced stoma complications, decreased nurse time to teach patient self-care, benefits over cut-to-fit stoma skin barriers, and costs with consistent outcomes demonstrated globally with diverse populations.

Keywords ostomy, stoma, peristomal, leak, mouldable

For referencing Beitz J, et al. Mouldable technology in ostomy care: a scoping review of the literature using a novel, explainable artificial intelligence. WCET® Journal 2025;45(2):22-35.

DOI https://doi.org/10.33235/wcet.45.2.22-35

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INTRODUCTION AND BACKGROUND

The number of individuals living with an ostomy globally is unknown; however, estimates include: 1,000,000 ostomates in the United States, 1,000,000 ostomates in China and around 780,000 across Europe.[1–3] Pouching systems play an important role in ostomy care, enabling users to observe their stoma and collect stool while protecting the peristomal skin. However, peristomal skin complications due to leaked effluent (such as moisture-associated skin damage and irritant dermatitis) are common, with a systematic review of 23 studies reporting rates of 36.3–73.4% among ostomates.[4] An individual with compromised peristomal skin can enter a sequence of poor skin barrier adhesion, continued leakage, and further peristomal skin complications. Therefore, appropriate assessment of the patient and selecting a pouching system that will achieve an optimal fit and prevent leakage is crucial. Wear time, or the establishment of a routine schedule for pouch change, is dependent on multiple factors such as patient preference, regional reimbursement of medical devices, and

the unique clinical presentation of the ostomy in relation to the patient's anatomical shape, and ease of pouching. Whether the goal is for daily pouch changes or up to one pouch change per week, achieving an ideal fit to prevent effluent contact with the peristomal skin and reduce the likelihood of complications is paramount.

A range of solutions exist that can help improve fit and/or prevent leakage underneath the skin barrier, from pastes and separate sealing components to convex skin barriers. Mouldable technology entered the market 15 years ago, as an alternative to the traditional cut-to-fit or precut barriers. The center hole of mouldable skin barrier can be rolled back to securely fit the base of the stoma. The more 'personalised' fit with mouldable barriers addresses patient-to-patient variation (for example, irregularity, peristalsis, changes in stoma size and stoma protrusion), minimises the exposed area of peristomal skin that is vulnerable to breakdown, and reduces the risk of mechanical trauma associated with the rough edges of traditional barriers.[5]

Currently, there are over seven countries with existing best practice guidelines for the management of ostomies globally.[6–14] In addition, a recent guideline for the management of neonates, pediatrics and adolescents has been developed.[10] However, translation of these guidelines into consistent clinical practice is lacking, resulting in high variability in the delivery of care globally. Often, clinicians may be more likely to follow local praxis and experience over established guidelines.

Given the importance of selecting the appropriate pouching system to prevent postoperative leaking, we examined the best available evidence describing the use of mouldable stoma baseplate technologies in ostomy care. The aim was 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.

METHODS

Search strategy, data preparation, data extraction, and human researcher review procedures

This study was conducted for the evaluation of available evidence on mouldable stoma baseplate technologies. The objective was to determine the best evidence describing the use of these technologies to inform healthcare providers, caregivers, and patients with ostomies about their recommended use. 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.[15] 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.[16] During study identification, references were required to be indexed in PubMed to be considered for screening. Inclusion criteria encompassed adult and pediatric studies, various types of ostomies, original research and gray literature, and both quantitative and qualitative research. Exclusion criteria were clearly defined to maintain focus; inclusion and exclusion criteria were converted into two separate search strings covering different concepts, producing two separate versions at the fourth iteration of training of the same LRN model for this study (Table 1). The creation of two separate versions of a LRN model at Iteration Four ensured that the XAI was covering a broad enough scope with the inclusion criteria, while also limiting the influence of noise with the exclusion criteria. One LRN model had a larger set of inclusion and exclusion concepts, and therefore narrower scope, reducing the impact of biases in the language data when training during the fourth iteration, followed by model deployment[17]. Quality management involved manual risk of bias assessments using ROB2,[18] ROBIS 1.2,[19] and the Newcastle Ottawa scale,[20] alongside strength of evidence scoring with the Johns Hopkins Nursing Evidence-Based Practice Guide[21] by the authors.

All four subject matter experts collaboratively developed search strings based on inclusion and exclusion criteria using the LRN v2.0 platform, as detailed in Table 1. These queries were executed via LRN interfacing with the PubMed API for study retrieval. LRN was configured to automatically exclude articles lacking abstracts, duplicates, and those published in Russian or Chinese due to linguistic processing limitations with Cyrillic and Chinese texts.[22] Two separate negative datasets labeled 'EXCLUDE' were generated from records meeting the different exclusion criteria (Table 1) to train LRN's discriminative models, serving as pseudo-ground-truth for algorithm reinforcement.[23] Article deduplication was performed using a unique identifier generated by LRN. This study focused on the best evidence regarding the use of mouldable versus cut-to-fit technologies to inform healthcare providers, caregivers, and patients with ostomies. LRN v2.0 employed its proprietary word embedding model to map terms, phrases, and measurement units for text classification by the generative AI.[24,25]

For this study, LRN v2.0 was implemented within a reinforcement learning with human feedback (RLHF) framework and configured by TB, JB, CM, and LI. The model underwent four training iterations, incorporating different exclusion search strings before deployment. Criteria were translated into linguistic rules categorised as "INCLUDE" or "EXCLUDE," as detailed.

Explainable artificial intelligence framework for a scoping review of mouldable stoma baseplate technology

In this scoping review, LRN v2.0 explained its parameters as the derived correlations between linguistic rules and identified concepts to researchers TB, JB, CM, and LI. These correlations were quantified using Pearson's chi-squared test, adjusted with Cramer's V, and further corrected for significance with the Benjamini-Hochberg method.[26–28] LRN's transparency was maintained through word cloud visualisations and

correlation tables produced in each iteration, collated in the 'AI Package Insert' alongside an auto-generated PRISMA 2020 flow diagram, providing a detailed, audit-ready report of the decision-making process. LRN employed generative AI and discriminative machine learning models that screened, identified, and synthesised studies. This integration was facilitated by a metaheuristic wrapper that refined the natural language feature space to isolate the most pertinent features. Initially, LRN utilised a generative model under weak supervision to assign preliminary labels based on predefined rules and identified key concepts, evolving these through matrix completion. Subsequent phases leveraged discriminative algorithms to refine these outputs. This approach not only managed dependencies and correlations typical of unlabeled data but also improved robustness and reduced overfitting risks. Each iteration of LRN underwent hyperparameter optimisation and 10-fold cross-validation to ensure domain-specific adaptation. Performance metrics, including overall accuracy, Cohen's kappa, recall, precision, and F-score, were calculated, guiding the manual review of critical records by subject matter experts. Those concepts that were the most significant parameters (p-value<0.05), after FDR-adjustment, in guiding LRN's decision making processes were presented in Table 2. Upon the fourth and final iteration, the inclusion-exclusion strings combination yielding the highest Cohen's kappa and accuracy was selected as the optimal model for deploying across the entire literature corpus for summarisation. This optimal model was then finalised and deployed to screen and identify those final studies used in this scoping review. The final set of studies labeled to be included by the deployed LRN model were then subjected to LRN's average potential filter, which narrowed the studies down further.

Evaluation of XAI output in the recommended use of mouldable stoma baseplate technologies

In this prospective study, four investigators (TB, JB, CM and LI) identified, screened, and selected studies using the LRN platform to expedite these processes. The subject matter experts (JB, CM, LI) independently validated the accuracy of the LRN-assigned labels against their own identified records. Classification discrepancies resolved via consultation with a fourth investigator (TB). Ground truth was established for both datasets based on this combined review from the four subject matter experts. When working with AI, ground truth refers to the most accurate and reliable real world data for a defined problem to train an AI model. Additionally, as this was the first time the LRN model has been deployed in a scoping review in the ostomy literature, one of the experts (TB) was assigned to review the integrity of the entire corpus, the complete list of LRN included and excluded studies, to ensure the integrity of the LRN-assigned label; this was also to ensure that no studies were misidentified by the LRN model.

RESULTS

Performance metrics for XAI-led Scoping Review

In identifying mouldable stoma baseplate technologies, LRN model across three iterations of RLHF, Iteration 4b was determined to be the optimal model, achieving an overall accuracy of 71.72% and a Cohen's kappa of 0.4194 (Table 3). Interestingly, the Iteration 4a from the LRN model with the

Table 1. Search strategy configuration for XAI scoping review of mouldable technologies.

Criteria	Query	Record Count
Deployed Model Inclusion (Corpus)	(((adult) OR (pediatric))) AND (((ileostomy) OR (jejunostomy) OR (colostomy) OR (urostomy))) AND (2009/01/01:2023/12/31[dp])	6049
Inclusion A	(((adult) OR (pediatric))) AND (((ileostomy) OR (jejunostomy) OR (colostomy) OR (urostomy))) AND (2009/01/01:2023/12/31[dp]) AND ("pubmed pmc"[sb])	1549
Inclusion B	(((adult) OR (pediatric))) AND (((ileostomy) OR (jejunostomy) OR (colostomy) OR (urostomy))) AND ((("medical device") OR ("ostomy bag") OR ("ostomy wafer") OR ("cut-to-fit") OR ("mouldable") OR ("roll-to-fit") OR (skin care) OR (skin barrier) OR (appliance) OR ("product"))) AND (2009/01/01:2023/12/31[dp])	563
Exclusion A	(((adult) OR (pediatric))) AND (((ileostomy) OR (jejunostomy) OR (colostomy) OR (urostomy))) AND (2009/01/01:2023/12/31[dp]) AND ("pubmed pmc"[sb]) AND (((esophagostomy) OR (gastrostomy) OR (ureterostomy) OR (healthy volunteer studies) OR (in vitro performance testing) OR (in vitro) OR (healthy)))	111
Exclusion B	(((adult) OR (pediatric))) AND (((ileostomy) OR (jejunostomy) OR (colostomy) OR (urostomy))) AND ((("medical device") OR ("ostomy bag") OR ("ostomy wafer") OR ("cut-to-fit") OR ("mouldable") OR ("roll-to-fit") OR (skin care) OR (skin barrier) OR (appliance) OR ("product"))) AND (2009/01/01:2023/12/31[dp]) AND ("pubmed pmc"[sb]) AND (((esophagostomy) OR (gastrostomy) OR (ureterostomy) OR (healthy volunteer studies) OR (in vitro performance testing) OR (in vitro) OR (healthy)))	65

Inclusion and exclusion criteria used by LRN for identification, screening, and inclusion of studies. Different versions (A or B) explored in the 4th iteration of training. Studies that were indexed or cross-referenced in PubMed were retrieved. Record count refers to the total number of potential studies (records, not full-text reports) given that search string. Date of execution was December 13, 2023, and for the deployed model, 31 January, 2024.

broader exclusion criteria (Table 1) led to a model with lower accuracy and Cohen's kappa, demonstrating high noise with broad exclusion criteria; the narrower scope model at the same iteration excluded more irrelevant studies, as evidenced by its superior EXCLUDE class performance metrics (Tables 2–3). During model training and validation, the LRN model evaluated 492 full-text reports, of which LRN Iteration 4b (the narrower exclusion criteria) of the LRN model selected 224 reports for inclusion from this training and validation dataset. A total of 6092 studies were initially identified as candidates for inclusion at execution of the deployed LRN model (January 31, 2024). Coinciding with the superior EXCLUDE class performance metrics, and upon automatically applying the average potential filter of 86.03%, Iteration 4b of the optimal model classified 148 studies as INCLUDE while the remainder was assigned to the EXCLUDE class.

Table 2. Significant concept rules defined by subject matter experts used by XAI to guide decision-making processes.

Concept 1	Concept 2	Rule 1 Label	Rule 2 Label	Correlation value	P-value	FDR-adjusted P-value
jejunostomy	esophageal	Exclude	Exclude	0.4097	1.000E-16	7.678E-15
oesophageal	jejunostomy	Exclude	Exclude	0.4097	1.000E-16	7.678E-15
suture	suturing	Exclude	Exclude	0.3984	6.000E-16	4.518E-14
cholangitis	stricture	Exclude	Exclude	0.3834	7.600E-15	5.615E-13
cholecystectomy	cholangitis	Exclude	Exclude	0.3758	2.570E-14	1.830E-12
cholangitis	cholecystectomy	Exclude	Exclude	0.3758	2.570E-14	1.830E-12
stricture	bile	Exclude	Exclude	0.3725	4.290E-14	3.000E-12
duct	cholangitis	Exclude	Exclude	0.3652	1.324E-13	9.096E-12
infant	hirschsprung	Exclude	Exclude	0.3626	1.968E-13	1.329E-11
duct	cholecystectomy	Exclude	Exclude	0.3569	4.641E-13	2.931E-11
cholecystectomy	duct	Exclude	Exclude	0.3569	4.641E-13	2.931E-11
duct	hepatic	Exclude	Exclude	0.3569	4.641E-13	2.931E-11
duct	hepatico	Exclude	Exclude	0.3569	4.641E-13	2.931E-11
giant	aortic	Exclude	Exclude	0.3492	1.443E-12	8.972E-11
peritoneal	cerebral	Exclude	Exclude	0.3366	8.797E-12	5.383E-10
stricture	cholecystectomy	Exclude	Exclude	0.3316	1.795E-11	1.065E-09
cholecystectomy	stricture	Exclude	Exclude	0.3316	1.795E-11	1.065E-09
acute care	spontaneous	Include	Exclude	0.3284	2.769E-11	1.619E-09
flange	adhesion	Include	Include	0.3247	4.633E-11	2.668E-09
hepatic	cholecystectomy	Exclude	Exclude	0.3235	5.472E-11	2.976E-09
hepatico	cholecystectomy	Exclude	Exclude	0.3235	5.472E-11	2.976E-09
cholecystectomy	hepatic	Exclude	Exclude	0.3235	5.472E-11	2.976E-09
cholecystectomy	hepatico	Exclude	Exclude	0.3235	5.472E-11	2.976E-09
ostomy pouch	peristomal lesion	Include	Include	0.3221	6.552E-11	3.421E-09
ostomy pouch	peristomal skin complication	Include	Include	0.3221	6.552E-11	3.421E-09
ostomy pouch	peristomal skin health	Include	Include	0.3221	6.552E-11	3.421E-09
skin barrier	ostomy pouch	Include	Include	0.3207	7.979E-11	4.111E-09
barrier ring	peristomal lesion	Include	Include	0.3178	1.177E-10	5.423E-09
skin barrier	peristomal lesion	Include	Include	0.3180	1.136E-10	5.423E-09
stoma barrier	peristomal lesion	Include	Include	0.3178	1.177E-10	5.423E-09
barrier ring	peristomal skin complication	Include	Include	0.3178	1.177E-10	5.423E-09
skin barrier	peristomal skin complication	Include	Include	0.3180	1.136E-10	5.423E-09
stoma barrier	peristomal skin complication	Include	Include	0.3178	1.177E-10	5.423E-09
barrier ring	peristomal skin health	Include	Include	0.3178	1.177E-10	5.423E-09
skin barrier	peristomal skin health	Include	Include	0.3180	1.136E-10	5.423E-09
stoma barrier	peristomal skin health	Include	Include	0.3178	1.177E-10	5.423E-09

Significantly correlated concepts were those with strong evidence, false discover rate (FDR)-adjusted P-value < 0.001, (Benjamini-Hochberg method). The training and validation set consisted of 492 studies screened by LRN, the deployed model was subjected to identifying and screening 6092 studies. Normalised chi-square values with Cramer's V constrained values into a range of [0,1].

LRN demonstrated its decision-making process for including or excluding studies in this SLR via word clouds (Figure 2) and correlation tabularisations (Table 2). The LRN model's performance was demonstrated by its ability to identify and prioritise novel concepts relevant to stoma baseplate technologies from the studies reviewed, such as "urostomy," "ileoanal," "drain(age)," "abdomen," "pouch," "complex," (referring to the interaction of the baseplate and abdomen), and "base" (Figure 1). Moreover, concepts that belonged to "pancreatic," "esophagectomy," "ingestion," "suturing," as well as "cholecystectomy" were parameters utilised by LRN to exclude articles. LRN therefore identified concepts that were not originally provided within its natural language rule list by TB, JB, CM, and LI. By RLHF, the LRN model processed human feedback and incorporated this into its learning algorithm by establishing semantic connections between distinct concepts. This approach allowed the model to identify and quantify significant correlations between its parameters, such as between the concepts "ostomy pouch" and equally between "peristomal skin complication," "peristomal skin health", and "peristomal skin lesion" (*r*=0.3221, p-value=6.552E-11, FDR-adjusted p-value=3.421E-09), as well as "flange" and "adhesion" *(r*=0.3247, p-value=4.633E-11, FDR-adjusted p-value=2.668E-09), both concepts sets of which were associated with the INCLUDE class label. Other notable correlations were "(o)esophageal" and "jejunostomy" *(r*=0.4097, p-value=1.000E-16, FDR-adjusted p-value=7.678E-15), and "barrier ring" and equally "peristomal skin complication," "peristomal skin health", and "peristomal skin lesion" *(r*=0.3178, p-value=1.177E-10, FDR-adjusted p-value=5.423E-09), which was indicative of interaction effects between the different rules (Table 2).

Table 3. Overall performance metrics for training XAI model to review mouldable technologies.

Iteration	Model Accuracy	Cohen's Kappa	Average Potential
1	79.67%	0.1242	40.31%
2	75.33%	0.1222	59.84%
3	76.53%	0.4182	67.71%
4a	62.24%	0.0679	64.77%
4b	71.72%	0.4194	86.03%

The final iteration for LRN model was Iteration 4, two versions of final iteration were run. Iteration 4a = LRN model version with broad exclusion criteria; Iteration 4b = LRN model version with broad exclusion criteria.

Figure 1: Word Cloud from optimal XAI model visualising significant data-driven parameters and novel insights into clinician use of stoma baseplate technologies.
This word cloud visualisation showcases associations identified by the LRN model within the literature on mouldable technologies. It captures both expected concepts and novel insights, including numerical values, measures, phrases, and acronyms. The size of each term correlates with its frequency, while color indicates relevance to classification: green for INCLUDE and red for EXCLUDE. Derived from the 4th iteration, significant parameters used by XAI.

Levels of Evidence

The Johns Hopkins Nursing Evidence-Based Practice, Evidence Level and Quality Guide, Appendix D, was used for review of all identified articles.[21] Quantitative and qualitative studies can be reviewed using the tool. Evidence levels are divided into five levels:

- Level I: experimental studies, randomised controlled trials; explanatory mixed method designs that include only a level I quantitative study; systematic reviews of RCTs with or without meta-analysis.
- Level II: Quasi-experimental studies; explanatory mixed method designs that include only a level II quantitative study; Systematic review of a combination of RCTs and quasi-eperimental studies, or quasi-experimental studies only, without or without meta-analysis.
- Level III: nonexperimental studies; systematic review of mixed RCT, quasi-experiemental and nonexperimental studies with or without meta analysis; exploratory, convergent or multiphasic mixed methods; explanatory mixed method designs that include only a level III quantitative study; qualitative study meta-synthesis.
- Level IV: Opinion of respected authorities and/or nationally recognised expert committees or concensus panels based on scientific evidence; includes clinical practice guidelines and position statements.
- Level V: based on experiential and non-research evidence such as integrative reviews, literature reviews, quality improvement projects, case reports and opinions of recognised national experts.

Quality of evidence scoring is rated A (highest) through C (lowest). Studies with consistent and generalisable results with sufficient sample sizes, controls and recommendations based on comprehensive literature reviews are ranked as Quality A, while those with little evidence, inconsistent results, insufficient sample sizes for the design and inconclusive results are categorised as Quality C. Risk of bias using the aforementioned tools is considered as low risk, some risk, or high risk of bias. A total 17 studies were included in final review and the respective level of evidence, quality and risk of bias scoring is found in Table 5.

User Satisfaction

Thirteen studies evaluated user satisfaction with mouldable technology.

A 2017 randomised controlled trial Liu et al[29] found (with Level I evidence) that 104 elderly stoma patients with colostomies after colorectal cancer reported higher self-satisfaction scores in the mouldable skin barrier group compared to the cut-to-fit group (p=0.02).[29]

A 2009 prospective, multicenter survey by Hoeflok et al [30] (with Level II evidence) involved172 ostomy patients and 49 enterostomal therapy nurses (ETs). The mean percentage of "excellent" or "very good" ratings across 10 criteria given by patients who received mouldable products was 84.2% for colostomies, 85.4% for ileostomies and 92.5% for urostomies.[30] Specifically, the majority of patients rated mouldable skin barriers as "excellent" or "very good" for ease of creating customised fit (37.5–62.5%), ease of molding (37.5–62.5%), and ease of application (35.5–54.8%) across all ostomy types. Similar proportions of "excellent" or "very good" ratings were observed for other evaluation criteria such as effective skin protection, painless to apply/remove, ability to shape and reshape, adherence and overall comfort, convenience, and satisfaction.[30] ETs rated mouldable products "excellent" or "very good" in 89% of cases for colostomies, 92.7% for ileostomies, and 92.7% for urostomies. Across all ostomy types, ETs ratings were higher than patient ratings across all the evaluation criteria.

A French observational, prospective, multicenter study by Chaumier[31] in 2012 (with Level III evidence) evaluated ostomy patients who either used a mouldable skin barrier as their first ostomy system (n=481) or who switched over from another product (n=195). For both groups, at least 80% of participants rated the mouldable skin barrier as "excellent or good" throughout the 60-day study period. The authors noted that the highest ratings were associated with comfort, ease of use, preparation, application, and removal.[31]

A 2003 multicenter study by Durnal[32] (with Level III evidence) compared mouldable technologies between two manufacturers. Convatec Mouldable Technology and Hollister Forma Flex were compared in 60 patients, who were instructed not to use additional ostomy accessories. The Convatec product was rated as superior in performance especially in ease of removal, security from leaks, peristomal skin health and overall protection.[32]

A 2020 study by Huang et al[33] (with Level III evidence) in Taiwan assessed patient satisfaction between mouldable technology (n=41) and cut-to-fit (n=19) ostomy barriers in ileostomates. The authors reported significantly 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).[33]

A large prospective, observational, multinational across Germany, the United States and Poland by Szewcyk et al[34] in 2014 (Level III evidence) evaluated 551 ostomates who started mouldable technology immediately after surgery (Group A) or had documented peristomal skin breakdown with a cut-to-fit barrier and was switched to mouldable (Group B). At a two month follow-up, 98% (Group A) and 96.5% (Group B) rated overall satisfaction with the mouldable barrier as "excellent or good." In both groups, at least 95% of patients rated the mouldable barrier as "excellent or good" in comfort,

Table 4. Class-specific performance metrics for training XAI model to review mouldable technologies.

	Class	Recall	Precision	F-score
Iteration 1				
	INCLUDE	95.45%	82.21%	88.34%
	EXCLUDE	13.79%	42.11%	20.78%
Iteration 2				
	INCLUDE	97.31%	76.14%	85.43%
	EXCLUDE	11.69%	60.00%	19.57%
Iteration 3				
	INCLUDE	92.31%	76.92%	83.92%
	EXCLUDE	45.45%	75.00%	56.60%
Iteration 4a				
	INCLUDE	76.47%	71.23%	73.76%
	EXCLUDE	30.00%	36.00%	37.73%
Iteration 4b				
	INCLUDE	80.00%	72.13%	75.86%
	EXCLUDE	61.36%	71.05%	65.85%

Class labels were either INCLUDE or EXCLUDE, and all studies were assigned a label by LRN upon each iteration. Final iteration for LRN model was Iteration 4, two versions of final iteration were run. Iteration 4a=LRN model version with broad exclusion criteria; Iteration 4b=LRN model version with broad exclusion criteria.

Table 5. Evidence table

Year	Author/s	Article title	Study type	Study aim	Primary outcomes	JHEBP Level Quality	ROBIS 1.2	ROB2	Newcastle Ottawa Star Score/ AHRQ Quality
2012	Chaumier D	An evaluation of the peristomal skin condition in ostomates using mouldable skin barriers	Prospective observational	To evaluate patient satisfaction with mouldable products	For both primary patients (n=481) and switching patients (n= 195) mouldable performance was rated highly for ease of use, comfort, and application	III-B	NA	NA	Fair quality (5*)
2013	Durnal A	Clinical comparison of two different mouldable technologies	Multicenter, prospective, observational study comparing two manufacturers	To compare the performance of two kinds of mouldable technology in 60 patients	ConvaTec rated higher in ease of removal, security from leaks; overall skin protection; had better fit	III-C	NA	NA	Not cohort
2011	Erbe JM	Skin barrier selection in an outpatient ostomy clinic	Case series	Evaluation of use of mouldable outcomes	Over six months, 70 patients were followed; one out of every four was placed in mouldable with good outcomes	V-B	NA	NA	Fair quality (5*)
2011	Haas S, Reider K	The road to independence: successful use of mouldable ostomy skin barriers to improve patient outcomes	Case series	To evaluate the use of mouldable technology in improving skin challenges	Patients reported easy to use, to create a good seal and prevent peristomal skin issues	V-C	NA	NA	Not cohort
2009	Hoeflok J, et al	Prospective multicenter, observational study	Prospective user evaluation	To assess satisfaction of patients (n=172) and ET nurses (n=49) with new mouldable technology	Regardless of ostomy type; very good or excellent ratings given by patients; ratings also high from ET nurses; ratings of skin barrier effectiveness also rated highly	II-C	NA	NA	Not cohort; Fair quality (5*)
2020	Huang H, et al	Mouldable skin barriers as a clinical option for patients following ileostomy	Prospective, observational	To assess the incidence of peristomal skin lesions and patient satisfaction	Mouldable achieved significant satisfaction among patients as well as in effectiveness of skin protection, sealing effect and ease of application	III-A	NA	NA	Good quality (7*)
2010	Ison R, Hadley G	Mouldable technology simplifies pouching over rods	Case study	To improve patient outcomes by implementing mouldable skin barrier to provide consistency in care	Improved patient outcomes, improve efficiency, knowledge in ostomy care, reduce peristomal skin damage	IV-C	NA	NA	NA, case study

Year	Author/s	Article title	Study type	Study aim	Primary outcomes	JHEBP Level Quality	ROBIS 1.2	ROB2	Newcastle Ottawa Star Score/ AHRQ Quality
2017	Liu G, et al	The application of a mouldable skin barrier in the self-care of elderly ostomy patients	RCT	To investigate the application of a mouldable skin barrier in the self-care elderly after CR	Reduce irritant dermatitis, improve self-care, reduce cost of leakage compared with conventional cut to fit barrier	I-C	Some concerns	NA	NA
2010	Marescalco K	Improving patient outcomes by increasing consistency of ostomy care	Case study	To use Mouldable Technology pouching system over stoma rods	Helps keep rods flat, wear time is 3–4 days; to increase patient comfort by eliminating frequent pouch changes, increase wear time, decrease nursing time	V	NA	NA	NA, case study
2008	Philbin S, Rochette J	A new mouldable barrier provides solutions for people with ostomies and dexterity challenges	Case Series Poster n=5	To assess mouldable technology compared to cut-to-fit	5 patients improved ability to self-manage ostomy with mouldable when moved from cut-to-fit barrier. All had reduced outpatient clinic visits after switch, improved comfort. Improved peristomal skin also reported (no N reported for this)	V-C	NA	NA	NA, case study
2008	Sellers D, Matson S	Clinical experiences with a new flat mouldable skin barrier	Case series poster n=3	To evaluate a new flat, standard and extended wear mouldable barrier system	Wear time: achieved effective seal without accessories; no scissors or template used; no mucosal injury from snug barrier, ease of application; simplified education, skin protection	V-C	NA	NA	NA
2011	Stallings B	The perfect fit: the use of flat mouldable skin barriers in home care	Prospective user survey	To evaluate the results of implementing mouldable tech at a large home health service (200 sites)	RN & Pt feedback: high reporting of ease of use; improved wear time; effective for irregular stomas; "no cutting required", fewer accessory products used	V-C	NA	NA	NA

Year	Author/s	Article title	Study type	Study aim	Primary outcomes	JHEBP Level Quality	ROBIS 1.2	ROB2	Newcastle Ottawa Star Score/ AHRQ Quality
2003	Stallo, Kimberly	Ostomates response to the use of a new mouldable convexity wafer	Prospective user survey	Evaluate product performance and user feedback of "difficult to pouch stomas"	Increased wear time; ease of use, increased flexibility; teaching time reduced; continued use of same product despite stoma size reduction; no need to carry scissors on airplanes	V-c	NA	NA	NA
2014	Szewczyk, M, et al	The effects of using a mouldable skin barrier on peristomal skin condition in persons with an ostomy: results of a prospective, observational, multinational study	International, multicenter, prospective cohort study. 90 centers (48 Poland, 28 Germany, 14 US)	To determine the incidence of peristomal lesions, evaluate progression of peristomal skin condition at 8 &15 days post application and level of satisfaction in patients with new and existing ostomies	N-511 (250 NPS, 261 PSC) from 67 centers. Primary: 3.6% and 2.7% new lesions respectively at 2months; 90.4%, 95.6% and 89.2% intact skin NPS at days 8,15,60 respectively; PSC convert 39.5%, 77.4%, 86.2% at 8,15,60. User scores 95% of all consider ease of use, removal reliability and overall; with group NPS 96.9%, 95.8% and 96.5% at 8,15,60. Decreased leaks and improved wear time in PSC; less accessory use 73.7%, 64.2% at 2months	III-A	NA	NA	Good quality (8*)
2009	Tomlinson, Lynne	Ostomy-product selection and innovations: teaching older ostomy patients—mouldable technology eases the fear factor	Case series	Introduction of mouldable technology to elderly patients as an easier self-care option	Method and outcomes not determined *apriori*. One patient described increased ease of use in low dexterity caregiver; easier to learn and barrier had better fit than cut-to-fit	V-C	NA	NA	NA

Year	Author/s	Article title	Study type	Study aim	Primary outcomes	JHEBP Level Quality	ROBIS 1.2	ROB2	Newcastle Ottawa Star Score/ AHRQ Quality
2013	Watanabe, M, et al	Evaluation of stoma pouch with mouldable skin barrier for early postoperative outcomes after stoma construction	Prospective, observational cohort study	To determine if a stoma appliance with a mouldable skin barrier (Varicare Natura M Flange) is useful for early complications after stoma construction	Pts not randomised. Different application day. RN may change pouch based on their discretion. Protocol not described. –Stat sig Leak at time of first pouch change after surgery m-25% vs. C2F-50% p-0.0375). –Stat sig difference in % skin problems during hospital stay for mouldable (43.7% vs 68.7%, p-0.019) –Stat sig difference % skin complication at discharge for mouldable (0 vs. 6%, p-0.033)	III-B	NA	NA	Fair quality (5*)
2010	Wolfe L	A new tool in the Canadian ET toolbox	Case series (3)	Use of ostomy in challenging patient types compared to cut to fit	Pt 1– switched to mouldable after 4 weeks in C2F=ease of use improved seal; Pt2 – longer wear time, reduce skin complications Pt3 – easier to use, longer wear time. Mouldable hugged irregular shaped stomas, improve wear time, ease of use, less accessories, comfort	V-C	NA	NA	NA

Details on quality scoring. Robis 1.2 is used to assess systematic reviews only. ROB2 is used to review randomised clinical trials only. Newcastle-Ottawa Scale is used to assess quality in cohort studies and is reported with a total star score (range 0-9 with higher numbers representing higher quality. Low 0-2; Fair 5-7; Good 6-9). Level 5 studies are automatically considered to have low quality and high bias. NA represents when a study type did not meet design requirements to be scored by the tool listed.

ease of preparation, ease of attaching, ease of removing, and reliability.[34]

An additional seven case series/reports (with Level V evidence) reported that mouldable skin barriers were associated a more secure fit, improved comfort, simplicity, and overall satisfaction with application, as well as decreasing anxiety.[35–41]

Stoma complications

One Level I and one Level II study evaluated stoma complications with mouldable technology. The randomised controlled trial by Liu et al[29] found that the incidence of peristomal irritant dermatitis in patients with colostomies was significantly lower in the mouldable skin barrier group compared to the cut-to-fit group (P<0.05) (Level I evidence).[29] However, the authors noted that dermatitis in the study was self-reported which could be a source of bias.[29] The prospective, multicenter survey by Hoeflok et al[30] (with Level II evidence) found a low proportion of ETs (4%) and ostomy patients (6%) reported discontinuations or problems due to skin irritation.[30]

An additional three Level III studies and three Level V studies describing stoma complications were identified. The 2014 study by Szewcyk et al[34] observed that the rate of new lesions or worsening preexisting lesions was 3.6% for patients who started mouldable technology immediately after surgery (Group A) and 2.7% for patients with documented peristomal skin breakdown with a cut-to-fit barrier and then switched to mouldable (Group B). The incidence of patients with intact skin in Group A vs Group B were as follows: 8–15 days post baseline (90.4% vs 39.5%), one month post baseline (95.6%% vs 77.4%), and two months post baseline (95.6% vs 86.2%). In Group B, the number of patients with lesions decreased from 40.6% to 5.4% from baseline to two months post-baseline (Level III evidence).[34]

A 2013 study by Watanabe et al[42] of 64 ostomy patients found that the mouldable group was associated with a significantly lower incident rate of stoma edema compared to the cut-to-fit group (p= 0.020). Furthermore, 25% of patients in the mouldable group had contamination under the skin barrier compared to 50% in the cut-to-fit group (p=0.0375). The authors also reported significantly fewer incidents of skin problems during hospital stays in the mouldable group compared to the cut-to-fit group, as well as a significantly lower skin complication scores at the time of discharge (43.7% vs 68.7%, p=0.019; 0 vs. 2, p=0.033) (Level III evidence).[42]

Only one study by Huang et al[33] found no significant difference in overall peristomal skin lesion rates between the mouldable and cut-to-fit barrier groups two months post-ostomy (19.5% vs 26.3%, respectively) (Level III evidence).[33] However, the authors reported statistically significant differences in patient satisfaction for mouldable compared to cut to fit, especially regarding effective skin protection (p-0.0031), sealing effect (p-0.0049) and ease of application (p-0.006). While clinically no differences were noted by the investigators, the patients perceived improved protection.

Two Level V studies reported resolution of peristomal skin complications after switching from a cut-to-fit to a mouldable skin barrier.[35,36] Another Level V study reported a "decreasing number of hospital-acquired peristomal skin complications" with mouldable skin barriers from a training and implementation program at a US hospital.[43]

Wear time

Six Level V studies described wear time with mouldable technology. Four case series/reports found that mouldable skin barriers provided a "more predictable", "effective" or "increased" wear time[35,37–39] compared to cut-to-fit, while two studies showed that patients were able to achieve a wear time of 3–5 days.[41,44]

Teaching and learning

One Level II study and three Level V studies that described teaching and learning with mouldable technology were identified. The prospective, multicenter survey by Hoeflok et al. found 86.7% of ET nurses felt that mouldable skin barriers were easy to teach across all stoma types (Level II evidence).[30] Stallo et al[45] reported that teaching time was reduced for patients with ileostomies and Marescalco et al[43] found that 100% of nurses learned to effectively apply mouldable skin barriers in a training and implementation program at a US hospital (Level V evidence). Moreover, Tomlinson et al[40] reported that mouldable skin barrier products were easier to learn for elderly patients or their caregivers than cut-to-fit products (Level V evidence).

Cost

One Level I study evaluated the cost associated with mouldable technology. The randomised controlled trial by Liu et al[29] reported a significant reduction in the cost of leak-prevention cream use in the mouldable skin barrier group (16.93±2.56 CNY) compared to the cut-to-fit group (131.67±4.02 CNY; P<0.01). No significant differences in replacement cost or replacement time were observed between the two cohorts in the same study.[29] While an additional three studies did not directly evaluate cost of mouldable technology compared to standard skin barriers, the authors noted that the observed reductions in accessory use with mouldable skin barriers may provide cost savings (Level III and V evidence).[34,38,39]

LIMITATIONS

The limitations of this study are primarily related to the low number of total studies identified and their respective strength of evidence and risk of bias. In addition, while multiple mouldable technologies are available on the market, the studies represented a mouldable technology from one manufacturer, with exception of a singular comparative paper by Durnal et al.[32] Therefore, it is difficult to understand or compare performance of various products on the market.

These limitations lead to several gaps in the evidence and opportunities for future research. While there were several studies that identified themes of longer wear time and peristomal skin health, the overall differences in leak rates and

cost of care require more robust comparative studies. Further, studies to determine the clinical assessment characteristics which determine when mouldable technologies should be used and when convexity should be selected would ensure clear guidance for providers. Finally, given the decreasing length of stay for ostomates in the immediate post-operative period, the ability for mouldable technologies to reduce teaching time and enhance discharge satisfaction is warranted.

CONCLUSIONS

This scoping review identified 17 studies on mouldable technology, including a randomised controlled trial, observational studies, and case series/reports.

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.[29–39] Mouldable skin barriers were associated with reduced peristomal skin complications compared to cut-to-fit products (such as peristomal irritant dermatitis, skin breakdown, contamination under the skin barrier), which might be attributed to a more secure fit with mouldable technology.[29,30,35,36,42,43] The improved sealing with mouldable skin barriers is supported by several case studies which reported "more predictable", "effective" or "increased" wear time.[35,37–39,41,44] ETs also found that mouldable technology was easy to teach and learn across all ostomy types, including for elderly patients.[30,40,43,45] Lastly, a small number of studies found a decrease costs with mouldable skin barriers compared to cut-to-fit products due to a reduction in accessary use.[29,34,38,39]

Only one study compared mouldable technologies between manufacturers.[32] Convatec mouldable was rated as superior in performance compared to Hollister Forma Flex in ease of removal, security from leaks, peristomal skin health and overall protection. All remaining studies reflect the evaluation of mouldable technology by itself or compared to standard cut-to-fit barriers. No other mouldable technologies could be identified as having peer-reviewed and published manuscripts in the literature.

In conclusion, outcomes were similar for both historical studies published after the initial launch of the first mouldable technology to the market, and present-day studies, demonstrating consistency of results compared to cut-to-fit over time. Results for the benefits of mouldable technology compared to cut-to-fit appliances were demonstrated in a large variety of countries and facilities globally, demonstrating mouldable technology's consistency in outcomes across diverse populations and standards of care.

ACKNOWLEDGEMENTS

Medical writing support was provided by Kenny Tran (Convatec Ltd).

CONFLICTS OF INTEREST

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FUNDING

The scoping review was funded by Convatec Ltd.

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