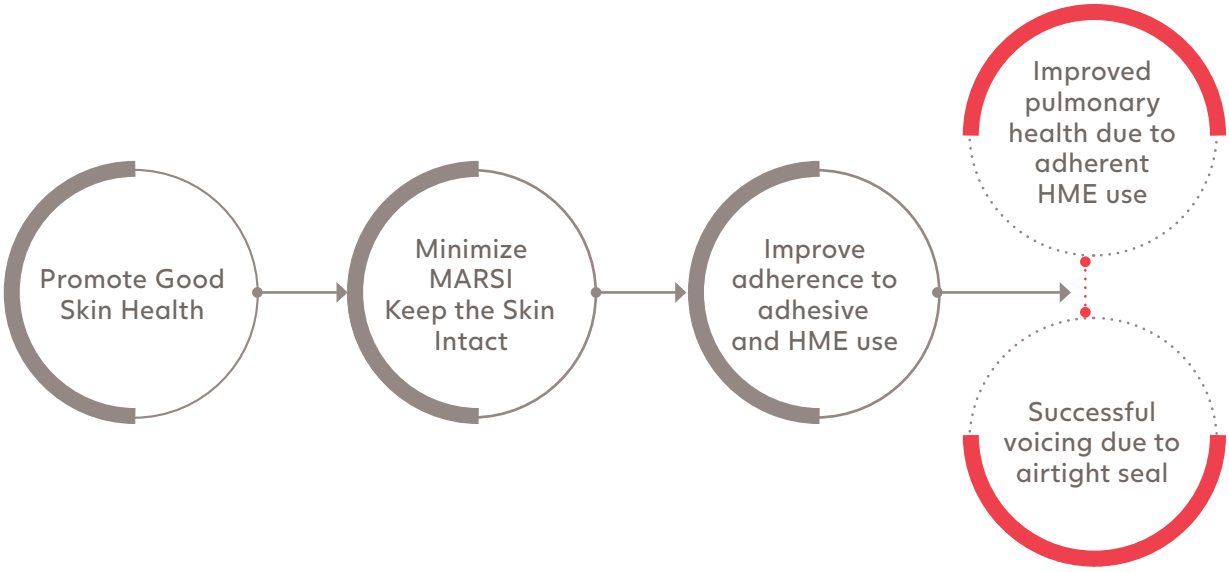
evidence & experience

WHITEPAPER

Healthy peristomal skin: a foundation for successful voice and pulmonary rehabilitation



Abstract

Heat and Moisture Exchangers (HMEs) and their attachment devices are important medical devices for pulmonary and voice rehabilitation after total laryngectomy. Their positive impact is evident, particularly when adhering to HME use. Adherence to HME use and efficiency of tracheoesophageal (TE) voice production can be challenged by Medical Adhesive-Related Skin Injuries (MARSI) and Peristomal Skin Complications (PSC). Understanding of the skin and the factors that influence laryngectomy peristomal skin and skin in general helps identify patients that may be at risk for development of MARSI. Careful adhesive selection and appropriate application and removal techniques can help prevent MARSI and maintain the integrity of the peristomal skin. Healthy peristomal skin forms the foundation for adherent HME use and an airtight seal for efficient TE speech.

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List of abbreviations

ASL	Airway Surface Liquid
HCP	Healthcare Professional
HME	Heat and Moisture Exchanger
MARSI	Medical Adhesive Related Skin Injuries
MVTR	Moisture Vapor Transport Rate
PSC	Peristomal Skin Complications
QoL	Quality of Life
SCM	Sternocleidomastoid muscle
TE	Tracheoesophageal
TL	Total Laryngectomy
VP	Voice Prosthesis

1. Background

1.1 Attachment of Heat and Moisture Exchangers

Heat and Moisture Exchangers (HMEs) are essential for optimal pulmonary rehabilitation after total laryngectomy (TL) and their benefits have been extensively documented [1-5]. They are usually attached in front of the tracheostoma with a peristomal adhesive, although some patients require a laryngectomy tube or stoma button to prevent narrowing of the tracheostoma. The use of these intratracheal devices can pose problems such as stoma irritation leading to further narrowing of the stoma, crust formation and more serious consequences such as mucosal infection, difficulty clearing secretions and obstruction [6, 7]. Furthermore, air escape around the tube complicates voice rehabilitation and the use of heat and moisture exchangers [7]. The COVID19 pandemic further emphasized the importance of a complete seal provided by peristomal adhesives; when properly applied they prevent airflow outside of the HME and reduce mucus contamination of clothes and other physical barriers [8]. Furthermore, it was demonstrated that TL patients using laryngectomy tubes pose a higher risk for spreading viral aerosols due to increased velocity of exhaled airflow caused by the presence of the tube as a narrowing factor; it is therefore recommended to use an HME with viral filter, or preferably to change laryngectomy tubes to peristomal adhesives when possible [9]. Using HMEs together with an adhesive provides an airtight seal which makes the conditioning of air more reliable and facilitates speech in patients utilizing voice prostheses [3].

Using HMEs together with an adhesive provides an airtight seal which makes the conditioning of air more reliable and facilitates speech in patients utilizing voice prostheses

1.2 The challenge with peristomal medical adhesives

Patient adherence to HME use has been identified as an issue and a large variation (35%-73%) has been reported [10-13]. Intolerance to the breathing resistance is one reason for reduced adherence to HME use and this can to some extent be addressed with the use of HMEs with lower resistance levels, although these typically also provide lower levels of humidification [14]. Another common reason for reduced adherence to HME use is problems associated with peristomal adhesives and other attachments. These issues include skin irritation, poor attachment, as well as poor fit to stoma shape, particularly for deeper stomas [1, 13, 15]. Although deep stomas may be prevented to some extent by applying surgical techniques such as cutting of the heads of the Sternocleidomastoid (SCM) muscle, horizontal transection and suturing techniques preventing exposure of cartilage [16], prioritization of oncological outcomes and the need for flap reconstructions can lead to difficult stomas. Problems with peristomal adhesives are exacerbated in patients using automatic handsfree speaking valves; regular use is only achieved by about 20%-40% of patients, mainly due to problems achieving durable and airtight fixation with the adhesive due to the phonation pressures exerted onto the adhesive during handsfree speech [17-19]. Dermatological problems from adhesives have been reported for 20-60% of total laryngectomy patients [4, 13, 20] and lead to poor adherence to HME use, especially at night when they take 'skin rest' [21]. The development of more skin-friendly and better fitting peristomal adhesives and a portfolio of HMEs covering a wide range of breathability levels and offering optimal humidification has shown promising results in improving adherence to HME use [4, 5]. However, these new innovations may take time to become widely available due to local regulatory and reimbursement limitations.

A common reason for reduced adherence to HME use is problems associated with HME peristomal adhesive baseplates and other attachments

1.3 Medical Adhesive-Related Injuries

Laryngectomy patients are susceptible to Peristomal Skin Complications (PSC) and Medical Adhesive-Related Injuries (MARSI), just like patients with ostomies or urostomies. A consensus summit on MARSI held in December 2012 with a panel of 23 key opinion leaders concluded that skin care, including protection against MARSI, is a basic requirement for patient care [22]. Although tracheostomas are not mentioned specifically in that paper, the specialty practice areas represented by the members of the panel include closely related areas such as dermatology, oncology, perioperative, plastic surgery, wound, ostomy and continence. Therefore, this consensus work is to a large extent also applicable to the use of peristomal adhesives post-laryngectomy. The expert opinions presented in the paper suggest that appropriate selection of adhesive products and the use of proper application and removal techniques can help minimize MARSI.

This Whitepaper aims to raise awareness for PSC and MARSI in TL patients with healthcare professionals providing services to this patient population and to provide knowledge and tools necessary for preventing and managing MARSI and PSC in TL patients.

2. Research for a deeper insight

Published research indicates that issues related to HMEs and attachments limit the possibilities for adherence to HME use among TL patients, which could have a negative impact on their Quality of Life (QoL) [1-3, 15]. For a deeper insight into the lives and needs of TL patients in a contemporary context, and a better understanding of issues related to HME and attachment products, Atos Medical initiated an extensive collaborative research project in 2015, which was completed in 2019. Some of the results were published in Leemans et al. [23]. The research was complemented by a large market research project into HME attachments conducted by Atos Medical in 2022.

Research methods

Stage 1.

Anthropological studies in collaboration with ReD Associates (www.redassociates.com, Copenhagen, Denmark):

- Extensive first study of 26 total laryngectomy patients and >50 healthcare professionals (HCPs) in four countries (US, Spain, Germany, and Sweden) by way of interviews and observations. Data included 100+ hours of video recordings, 1000+ pages of notes and 1000+ photographs.
- In-depth second study focused on pulmonary health and HMEs including 18 patients and 18 HCPs by way of interviews and observations.

Stage 2.

Validation of stage 1 findings by a questionnaire-based quantitative survey in collaboration with ReD Associates and the Netherlands Cancer Institute (Amsterdam, the Netherlands):

- Survey questionnaire covered patient demographics, pulmonary health, impact of total laryngectomy on QoL and use of medical products related to total laryngectomy.
- 1734 total laryngectomy patients in 9 countries (UK, US, Germany, France, the Netherlands, Brazil, Italy and Spain) completed the questionnaire (participation rate 21%).
- The respondents' group was demographically representative of the total laryngectomy population and included patients at different postoperative stages using different medical products.

Stage 3.

Market research for better understanding of issues with HME attachments

- A web-based survey questionnaire was sent via e-mail to 16,514 TL patients who were customers of Atos Medical, had an email address on file, and who had consented to receive marketing communications from Atos Medical.
- 2852 TL patients in 12 countries (US, UK, Germany, Italy, France, Canada, the Netherlands, Australia, Portugal, Denmark, Switzerland, and New Zealand) completed the survey (participation rate 17%).
- The respondents' group was demographically representative of the total laryngectomy population and included patients of different ages and at different postoperative stages.
- 256 patients did not use any attachment (adhesive, tube, or button) at the time of the survey and were excluded from further analyses, leaving a total of 2596.
- The majority used an adhesive (n=1882, 72.5%) and 27.5% (n=714) used a tube or button. Thirty-eight percent (n=709) of the adhesive users sometimes used a laryngectomy tube or stoma button in addition to their adhesive.

2.1 A wide variety of stoma configurations

The ethnographic research completed during Stage 1 demonstrated that a TL rarely results in a 'perfect stoma' due to tissue scarring, reconstructive surgeries and the surgical priority of cancer removal. Thus, the TL patient population exhibits a wide variety of tracheostoma configurations (see Figure 1). Healthcare Professionals wanted their patients to wear HMEs but recognized there are barriers. Adhesive-related problems experienced were adhesives not sticking to the skin, not properly covering the stoma, not forming a seal, irritating the skin, being uncomfortable to wear for a long period of time, and not having the right shape for the stoma. Patients reported red, sore, and itchy skin from adhesive materials and pressure.

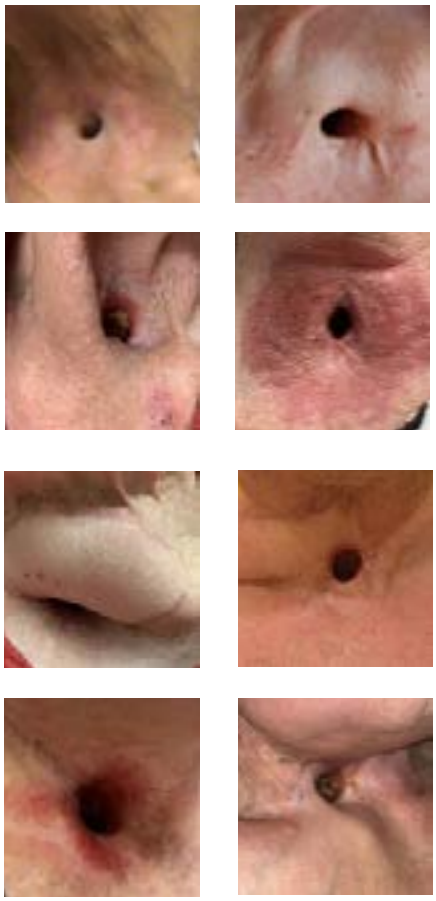

FIGURE 1. Collage of laryngectomy stomas, demonstrating the large variety in skin types and stoma configurations.

2.2 Importance of peristomal adhesives for adherence to HMEs

The quantitative survey conducted in Stage 2 provided in-depth insights into problems specifically reported for HME attachments. The results indicate that problems with adhesives play an important role in reduced adherence to HME use. Half of the patients reported that wearing adhesives caused their stomas to become red, raw, or irritated and 48% kept their stoma uncovered to allow the skin to heal or breathe (Table 1). Parts of this research have been published by Leemans et al. [23].

TABLE 1. Percentages of patients reporting problems with HME attachments

HME attachment	Problem with attachment	% of patients
Adhesives	The skin around my stoma has become red, raw or irritated after wearing adhesives	50%
	I have left my stoma uncovered without an adhesive to let my skin heal or breathe	48%
	I have had difficulties getting adhesives to stay on because of my stoma or neck shape	38%
	I have had difficulties getting adhesives to stay on because of sensitive, irritated or wet skin	33%
	My adhesive has come loose or has leaked air earlier than expected	53%
Buttons, tubes	My adhesive, tube or button has come loose because of coughing	51%
Interface	My HME has popped out because of coughing	45%

2.3 Relationship between adhesive problems and skin irritation

The HME attachments market research conducted in Stage 3 indicated that the majority of the 1882 adhesive users used adhesives without any problems (n=1182, 63%), 36% (n=677) experienced problems (with 64 of them experiencing 'a lot of problems') and 1% (n=23) responded 'I don't know'. Table 2 outlines the specific problems patients most reported.

TABLE 2. Frequency of patient-reported adhesive problems.

Problem with adhesive*	Number (%) of respondents
It did not stick to my skin for as long as I needed it to	275 (41%)
It didn't provide an airtight seal when speaking	244 (36%)
My skin could not tolerate it (irritation or reaction)	94 (14%)
It did not provide a comfortable fit to my stoma	63 (9%)

* Question (to patients experiencing adhesive problems): Can you please clarify the problems you experience wearing an adhesive? N = 677 patients. Multiple answers possible. Answer options also included a few other options that are not shown here due to low response rates and/or not medical in nature such as reimbursement restrictions, stoma stenosis and not using an HME at the moment.

A total of 1423 patients used tubes and/or buttons of which 714 used them exclusively and 709 used them in combination with an adhesive. Tubes and buttons were mainly used to keep the stoma stable or open (N= 871, 61%) and for 'skin rest' (N=237, 17%) and for problems with adhesives (N= 175, 12%). Other reasons were 'preference', 'need to use for other reason', and 'don't know'. Tube/button use was more common in patients shorter than 2 years post-surgery with 24% (n=64) of patients < 2yrs post-surgery using a tube or button, versus 16% (n=422) of those 2-6 years post-surgery and 14% (n=352) of those 6 years or longer.

When specifically asked about the frequency and severity of skin irritation, 66% (N=1884) reported this to be 'never' or 'rarely the case, whilst 18% experienced skin irritation 'sometimes', 9% 'often', 5% 'always' and 3% answered 'don't know'. Of the patients with skin irritation, eighty-seven percent described the irritation

as mild or somewhat irritated, 7% as very irritated (red, hot, itchy) and 3% as very irritated (breaks down, oozes fluids).

A significant relationship was found between the frequency of peristomal skin irritation and problems with the adhesive (chi-square test, P< .00001, see Table 3).

Frequency of peristomal skin irritation and problems with the adhesive are significantly related

TABLE 3. Cross tabulation of relationship between peristomal skin irritation and adhesive problems (chi-square 126.99, p< .00001).

		Skin irritation			
		Frequent (always/ often)	Infrequent (sometimes)	No skin irritation (rarely/ never)	Total
Adhesive problems	No problems (without any problems)	102 (38.8 %)	182 (52.1 %)	874 (72.1 %)	**1158**
	Problems (some/a lot of problems)	161 (61.2 %)	167 (47.9 %)	339 (27.9 %)	**667**
	Total	**263 (100 %)**	**349 (100 %)**	**1213 (100%)**	**1825**

While the adhesive may be the initial cause of the skin irritation, the irritated skin causes problems with the adherence of the adhesive, causing the adhesive to detach, increasing the frequency of replacement, and further exacerbating the problem (see Figure 2). This strong relationship highlights the importance of preventing and managing skin irritation and has been acknowledged in related clinical fields [24-26].

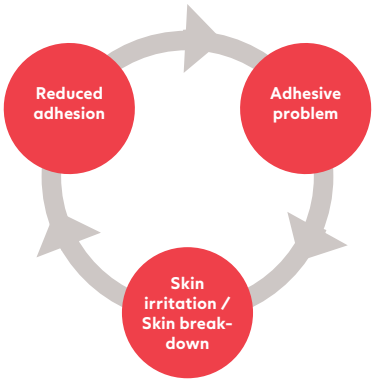

FIGURE 2. Vicious circle of adhesive problems leading to skin irritation and irritated skin causing further problems with the adhesive sticking to the skin.

2.4 Factors influencing adhesive problems

As a next step, relationships were explored to further our learnings about adhesive problems, skin irritation and factors of potential influence such as age, postoperative stage, prior radio and/or chemotherapy, stoma depth, neck distension during TE speech, perspiration levels and communication method. These relationships are shown in Table 4.

TABLE 4. Exploration of relationships (chi-squared tests, p-values are shown in the cells, n.s.: not significant) between adhesive problems and age, postoperative stage, (chemo)radiotherapy, stoma depth, speaking method, neck distension and perspiration represented in the columns.

Potentially influencing factor	Level of significance (p)
Age	p = .478 (n.s.)
Postoperative stage	p = .005
CRT	p = .331 (n.s.)
Stoma depth	p < .00001
Speaking method	p = .003
Neck distension during TE speech	p < .00001
Perspiration	p = .056 (n.s.)

As can be seen from Table 4, adhesive problems demonstrated a significant relationship with postoperative stage, stoma depth, speaking method, and neck distension during TE speech. Further details on the significant relationships are provided in Table 5.

TABLE 5. Overview of factors significantly related to problems with the adhesive.

		Problems with Adhesive		Level of significance (p)
		No (%)	Yes (%)	
Time since TL surgery (yrs)	<2	59.7	40.3	p = .005
	2 – 6	63.4	36.6	
	>6	68.7	31.3	
Stoma depth	Flat	72.3	27.7	p < .00001
	Deep	58.2	41.8	
	Very Deep	47.7	52.3	
Speaking method	Voice prosthesis	61.5	38.5	p = .003
	No voice prosthesis	68.8	31.2	
Neck distension	No/minor	69.5	30.5	p < 0.00001
	Moderate/Much	53.3	46.5	

The details provided in Table 5 indicate that problems with the adhesive are more frequent in the earlier postoperative stages, in patients with deeper set stomas, in patients speaking with a voice prosthesis, and in patients with neck distension during TE speech. Understanding these factors can help predict which patients are more likely to experience adhesive problems and identify those that may need extra support. Furthermore, surgical techniques aimed at creating flatter stomas should be considered.

2.5 Factors influencing peristomal skin irritation.

The same factors were explored to expand our understanding of peristomal skin irritation and potential influencing factors such as age, postoperative stage, prior radio and/or chemotherapy, stoma depth, speaking method, neck distension during TE speech and perspiration levels. These relationships are shown in Table 6.

TABLE 6. Exploration of relationships (chi-squared tests, p-values are shown in the cells, n.s.: not significant) between peristomal skin irritation and age, postoperative stage, (chemo)radiotherapy, stoma depth, speaking method, neck distension and perspiration represented in the columns.

Potentially influencing factor	Level of significance (p)
Age	p = .001
Postoperative stage	p = .0001
CRT	p = .960 (n.s.)
Stoma depth	p = .001
Speaking method	p = .248 (n.s.)
Neck distension during TE speech	p = .00003
Perspiration	p = 0.056 (n.s.)

The frequency of skin irritation showed a significant relationship with age, postoperative stage, stoma depth, neck distension during TE speech and perspiration. Details on the significant relationships are provided in Table 7.

TABLE 7. Overview of factors significantly related to skin irritation.

		Frequency of skin irritation			Level of significance (p)
		Never/ Rarely (%)	Sometimes (%)	Often/ Always (%)	
Age (yrs)	<39	44.8	22.2	33.3	p = .001
	40-49	51.9	24.1	24.1	
	50-59	60.0	20.7	19.3	
	60+	68.5	18.6	12.9	
Time since TI surgery (yrs)	<2	62.5	19.4	18.2	p = .0001
	2 – 6	64.8	20.2	15.0	
	>6	73.2	17.6	9.2	
Stoma depth	Flat	70.0	17.6	12.4	p = .001
	Deep	66.2	18.6	15.2	
	Very Deep	55.7	27.1	17.2	
Neck distension	No/minor	45.5	47.6	6.9	p = .00003
	Moderate/ much	60.3	22.0	17.3	
Perspiration	Never/ rarely	67.0	18.8	14.2	p = .0007
	Sometimes	66.5	21.1	12.5	
	Often/ always	62.3	13.0	24.7	

The details provided in Table 7 indicate that peristomal skin irritation is more frequent in younger patients, in earlier postoperative stages, in patients with deeper set stomas, in patients with neck distension during TE speech and in patients who experience perspiration more often. Whilst adhesive problems and skin irritation are strongly related (see Table 3 and Figure 2), the insights presented in Table 7 can help identify patients that may be more likely to develop skin irritation and provide them with support. Surgical techniques aimed at preventing deeper set stomas should be considered.

Interestingly, previous radiotherapy or chemoradiotherapy did not have an influence on reported skin irritation; in all subgroups, around two-thirds reported to never/rarely have skin irritation, 19% sometimes and 14% often/always.

2.6 Peristomal adhesives and voice rehabilitation

Sixty-five percent of the respondents (n=1844) used a voice prosthesis and nearly half of them (48%) reported that the adhesive influenced their speaking, highlighting the importance of the adhesive for voice rehabilitation. TE speakers put higher demands on their adhesive due to the requirement of an airtight seal for efficient TE speech, which is reflected in the proportion that experiences problems with their adhesive: 38.5% of the VP users reported problems with the adhesives, compared to 31.2% of the non-VP users. About two-thirds of the VP users (n=1262, 68%) had tried a handsfree speaking valve, but 65% of them (n=822) had not been successful for various reasons. Problems with the adhesive accounted for nearly half (n=405, 49%) of the handsfree speaking failures. Another problem seen in patients using TE speech is neck-distension during speech. Results of this research showed that 46.5% of patients with neck distension during TE speech experienced problems with their adhesive versus 30.5% of those without, indicating that neck distension negatively impacts success with peristomal adhesives.

TE speakers put higher demands on their adhesive due to the requirement of an airtight seal for efficient TE speech

3. Medical adhesives technology for TL patients

3.1 General composition of medical adhesives

Medical adhesives are generally composed of 3 layers: A carrier, also called backing, to which the adhesive ('glue') is applied, and a liner which is removed prior to application (see Figure 3). The carrier can consist of a variety of materials such as cloth, paper, or plastic. The adhesive can consist of a variety of materials such as acrylates, hydrocolloids, hydrogels, silicones, and polyurethanes. The liner is typically paper or plastic.

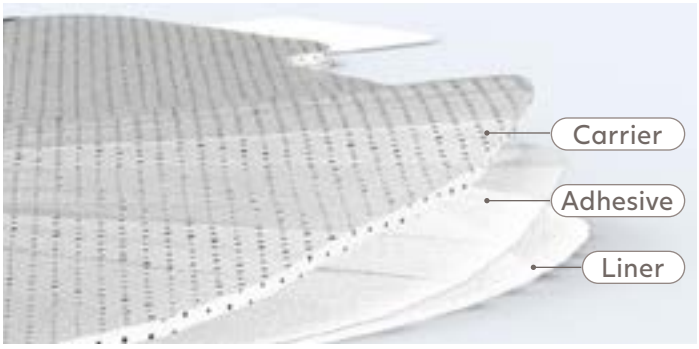

FIGURE 3. Layered composition of medical adhesives

The primary purpose for medical adhesives for TL patients is to place a Heat and Moisture Exchanger in front of the tracheostoma. Secondary purposes are for example placement of a showering device or laryngectomy tube. Therefore, a fourth component is added to peristomal adhesives for TL patients: a connector for these devices, also referred to as an adaptor. The characteristics of this connector play a role in comfort and fit, as well as security of the connection with the devices it holds. Figure 4 shows the layered composition of a Provox Adhesive including the connector.

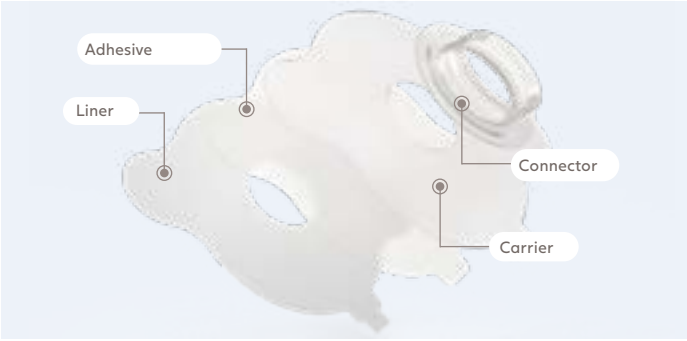

Figure 4. Layered composition of Provox adhesive.

Medical adhesives are pressure sensitive, meaning that pressure applied to the surface of the adhesive will activate the adhesive by increasing the surface area contact with the skin. Over time, as the adhesive (i.e. glue) warms up, it thins and flows to fill in the gaps between the adhesive and the irregularities in the skin surface, and this increases the bond between the adhesive and skin. The speed at which this process occurs is different for different adhesive materials. Adhesive materials such as hydrocolloids benefit from being pre-warmed, for example by rubbing them between the hands, prior to application [27].

Medical adhesives are pressure sensitive - pressure applied to the surface of the adhesive will activate the adhesive

3.2 Material characteristics

Key factors to consider for medical adhesive materials in TL patients are:

Flexibility - more flexible and thinner materials of the adhesive tape and the adaptor can be fitted closer to the stoma and feel more comfortable in the neck. However, more rigid and thicker materials may be required to counteract neck-distension during (handsfree) TE speech.

Permeability – materials with higher permeability allow the skin to breathe and allow moisture vapor to evaporate. Conversely, materials with lower or no permeability (occlusive tapes) do not allow the skin to breathe, and moisture vapor remains trapped underneath the adhesive. In TE speakers, high permeability materials can cause undesirable air leakage through the material during speech and may therefore be less suitable. This is especially the case in hands-free speech where there is no manual counterpressure keeping the adhesive materials pressed against the surface of the skin. A measure for permeability of vapor barriers and breathability of clothing is Moisture Vapor Transmission Rate (MVTR). MVTR is a measure of passage of water vapor through a substance or material over a specific period of time. An internationally accepted means of expressing MVTR is g/m2/24 hr and a higher MVTR reflects higher permeability.

Absorption – hydrocolloids and hydrogels are absorbent wound dressing materials. They adhere initially to dried surfaces and as they absorb moisture adhesion weakens according to water content. These materials are considered more skin-friendly than, for example, acrylics.

Adhesion – Adhesives with lower tackiness have lower peel-strength and are therefore easier to remove from the skin. However, TL patients using TE speech often require higher tackiness for the adhesive to withstand speaking pressure.

HYDROGEL SHEET DRESSINGS

Hydrogel sheet dressings are water- or glycerin-based products, best suited for dry wounds or those with minimal to moderate exudates [28, 29].They enable monitoring skin and/or wound without removing the dressing, as they usually are clear and translucent [27, 29, 30]. Furthermore, hydrogels maintain an adequate moisture balance by absorbing exudates and bacteria, and by rehydrating dry/irradiated skin [31]. These dressings are found to enhance epithelialization [32-34], and might decrease wound infections [35, 36]. Sheet hydrogels are effective, comfortable, and soothing and create a moist wound healing environment [27-29, 33, 37-39]. The development of a hydrogel adhesive for TL patients (Provox Luna) has demonstrated benefits for overnight peristomal skin recovery and adherence to HME use [20]. Patients using a hydrogel adhesive overnight (Provox Luna) were found to have less dermatological problems (14.3% versus 46.4% in the control group) and lower HME abandonment rates (10.7% versus 46.4% in the control group) [40].

HYDROCOLLOID SHEET DRESSINGS

Hydrocolloid wound dressings are occlusive or semi-occlusive dressings made of gelatin, pectin, polysaccharides, or sodium carboxymethylcellulose. The outside of the dressing is covered with a polyurethane foam or film which enables the exchange of water vapor and protects the wound against contamination from the outside [27, 33, 41]. The hydrocolloid dressing absorbs the wound fluid and as a result changes into a jelly-like mass, providing a moist wound healing environment and promoting autolytic debridement. Hydrocolloids are impermeable dressings with multiple benefits, including absorption of excess fluids, providing a barrier to infection, and facilitating debridement [27, 33, 42].

MEDICAL GRADE ACRYLIC ADHESIVES

Pressure-sensitive acrylic adhesives for application to skin are made from 2-ethylhexyl acrylate, isooctyl acrylate or n-butyl acrylate copolymerized with polar functional monomers such as acrylic acid, methacrylic acid, vinyl acetate, methyl acrylate, N-vinylcaprolactam, or hydroxyethyl methacrylate. Functional comonomers increase cohesive strength, provide surface polarity, and enhance wear performance. Tack, adhesion to skin, adhesive transfer to skin, and wear performance of the adhesive are governed by the molecular weight, glass transition temperature, and the viscoelastic behavior of the adhesive. Sweating skin, a moist environment, and physical activity are the most important factors influencing the failure of an adhesive tape during wear [27, 43].

Flexibility, permeability, absorption and adhesion are important adhesive material characteristics

4. The normal skin

The skin is the largest organ in the body [44] and it renews itself every 28 days [45]. The thickest skin is found on the soles of the feet, measuring 1.5 mm thick [46].

The functions of the skin are protection (trauma, UV light, temperature, dehydration, toxins, microorganisms), maintenance of body temperature (circulatory mechanisms, sweating, insulation), sensation (pain, pressure, vibration, temperature), metabolism (produces melanin, vitamin D, excretes waste e.g. sweat) and communication (facial expression, emotions, touch) [46, 47].

The skin provides a semi-permeable barrier that protects the body from the external environment and maintains homeostasis in the body [44, 47].

The skin is the largest organ in the body

4.1 The structure of the skin

The skin consists of 3 layers (Figure 5):

- The epidermis – traps moisture [47]
- The dermis – provides functionality due to variety of structures in this layer [46]
- The subcutaneous tissue provides insulation and cushion [44]

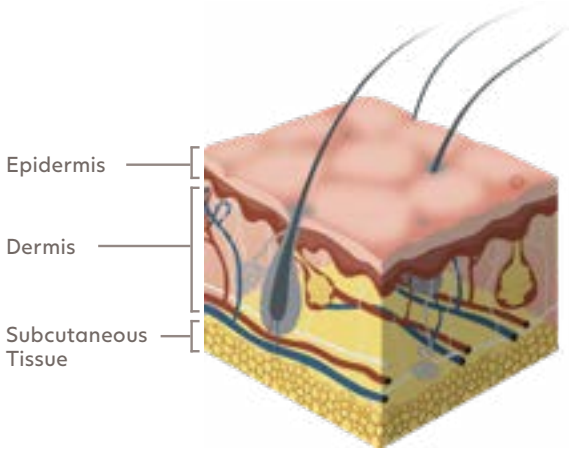

FIGURE 5. The three layers of the skin: Epidermis, dermis and subcutaneous tissue.

4.1.1 The epidermis

The epidermis is the outermost visible part of the skin (Figure 6). It has a barrier function, controls water loss, and protects against UV light, bacteria and allergens [47]. It has a thin layer of cells varying in thickness from 0.05 mm on the eyelids to 1.5 mm on the palms and soles [46].

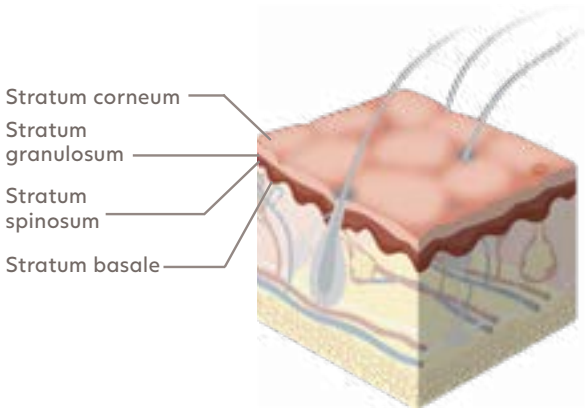

FIGURE 6. The epidermis and its four layers.

The epidermis is the skin layer that interacts directly with peristomal adhesives and therefore it is important to understand its composition and function. It is composed of 3 types of multi-layered epithelial cells: keratinocytes, melanocytes and Langerhans cells (Figure 7). The keratinocytes account for 95% of the cells and retain moisture to maintain the skin's barrier function [44], the melanocytes are responsible for skin pigmentation and protection against UV damage [44], and the Langerhans cells are part of the skin's immune system [44, 48].

The epidermis is the skin layer that interacts directly with peristomal adhesives

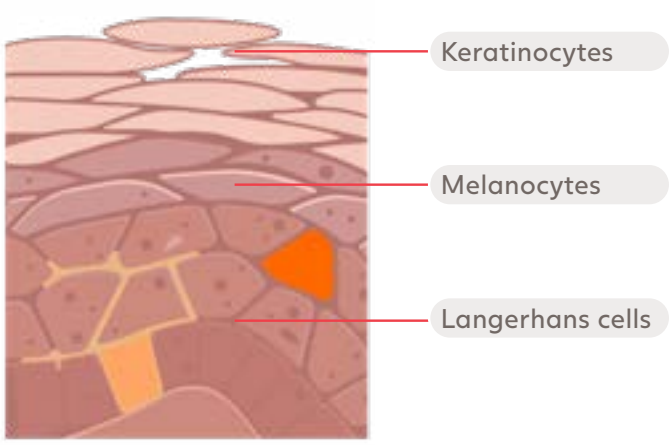

FIGURE 7. The epidermis and its multi-layered epithelial cells: keratinocytes, melanocytes and Langerhans cells.

The keratinocytes layer consists of 4 types of differentiated cells (Figure 8). The innermost layer is the stratum basale (also called germinative layer) and this is where the epithelial cells (keratinocytes)

originate [47]. From there, the keratinocytes divide and migrate upwards through the stratum spinosum and stratum granulosum, which are living cells. As the keratinocytes migrate towards the surface they degenerate and die (and are now called corneocytes) [44]. The outermost layer is composed of these dead keratinocytes (corneocytes) and is called stratum corneum or sometimes the horny layer [48, 49]. The stratum corneum is densely packed with 25 to 30 rows of flat corneocytes that give the skin structure and resilience towards bacteria and allergens [47, 48]. The corneocytes are connected by desmosomes and they are surrounded by an extra-cellular matrix that is hydrophobic and thereby waterproofs the epidermis and prevents dehydration [47]. The extracellular matrix and the desmosomes allow the skin to be flexible and less susceptible to sheering forces [47, 50].

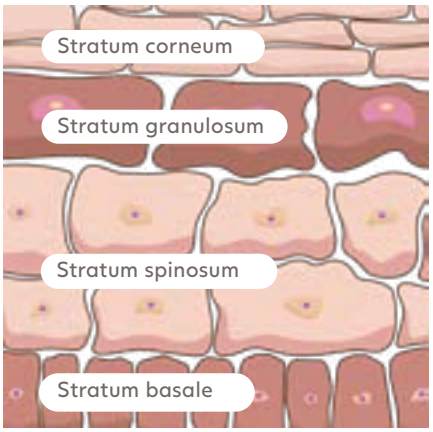

FIGURE 8. The four layers of differentiated keratinocytes in the outermost keratinocyte layer of the epidermis.

The outermost layer, the stratum corneum, has a 'bricks-and-mortar' like structure which helps to protect us from environmental hazards (Figure 9). The 'bricks' represent flattened, dead, keratinocytes that have matured into corneocytes and the 'mortar' represents the surrounding intercellular lipid membranes [47]. The bricks are tightly connected by desmosomes in overlapping layers to retain moisture while keeping allergens, pathogens and environmental toxins (e.g. UV radiation) out [47]. The stratum corneum is renewed about every 15 days, as dead epidermal cells are continuously shed (desquamation) [47].

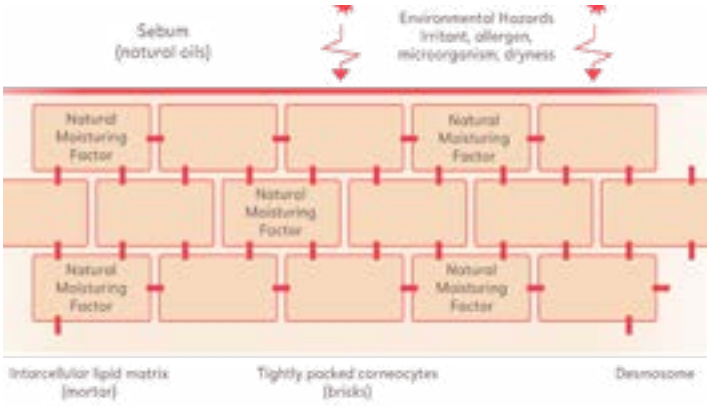

FIGURE 9. Graphic representation of the 'Bricks-and-Mortar' structure of the healthy epidermis

KEY TAKEAWAYS [44]

Epidermis must be kept intact.

Broken epidermis can allow interstitial liquid in the underling dermis to weep to the surface. Weeping compromises application and adherence of peristomal adhesives.

If the epidermis is broken, nerve endings are exposed and will trigger pain sensation.

Pain, itching and burning sensations are signals of erosion of the epidermis and the need for prompt action.

4.1.2 The dermis

The dermis is the middle layer of skin and is about 15 to 40 times thicker than the epidermis. It consists of connective tissue, a semi-fluid substance mainly consisting of collagen and elastin fibers, and it contains nerve endings, blood vessels and skin appendages such as hair follicles, sebaceous glands and sweat glands [44, 51]. See Figure 10.

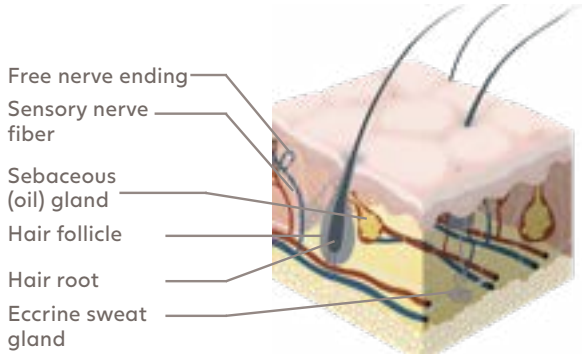

FIGURE 10. The dermis with blood vessels, nerve endings, hair follicles, sebaceous glands and sweat glands.

The skin is a sensory organ that collects information via the nerve endings in the dermis that provide vital information about touch, pressure, pain, vibration and temperature [44]. The location of the sensory nerve endings in the dermis explains why superficial wounds are often more painful than wounds with more tissue loss [52]. See Figure 11.



FIGURE 11. Superficial location of sensory nerve endings in the dermis.

The sebaceous glands are found around the hair follicles (Figure 12) and secrete sebum, a lipid rich, oily substance which is important to maintain the moisture of the epidermis and the pH of the skin [44]. The secretion of sebum is controlled predominantly by sex hormones and changes with age. It is acidic and when combined with lipids it forms a hydrophobic layer that prevents skin dehydration. This helps to prevent invasion and infection by microorganisms [44].



Figure 12. Sebaceous gland at hair follicle.

The sebum and sweat create an acidic environment on the skin surface in the pH range of 4 to 6 (acid), which is referred to as the acid mantle [44, 53] and therefore skin heals more rapidly in an acidic environment [35].

KEY PERSPECTIVES ON SKIN AND MEDICAL ADHESIVES

Weeping and/or bleeding from the dermis (broken epidermis) will compromise adhesion to skin surface [44].

If blood vessels are ruptured bleeding may be visible on the surface and impact adhesion [44].

The dermis and epidermis are normally firmly bonded by strong collagen anchoring structures. These structures may be weakened by immune suppressive therapy. The results can be a separation of the layers when removing an adhesive, also called 'tearing'. Choice of adhesive type and use of adhesive removers are extremely important for these user groups [53].

Heavy/sudden perspiration can challenge application, adhesion, and wear time. Patients with high perspiration levels must use an adhesive with sufficient absorption capacity (i.e. hydrocolloid). When absorption capacity is reached, the adhesive will start to disintegrate and loosen. Furthermore, a more frequent changing routine may be required, e.g. after sports [44].

Sebum production is important to keep the acid mantle intact and reduces with age. Choose and handle adhesive carefully and consider the age of the patient [44].

Pulling hairs when removing the adhesive can cause folliculitis. Therefore, it is recommended to shave or cut hairs prior to adhesive application [54].

If proper adhesive removal technique is not used, superficial layers of the skin are removed along with the adhesive product, which not only affects skin integrity but can cause pain and the risk of infection, increase wound size, and delay healing, all of which reduce patients' quality of life [55].

4.1.3 Subcutaneous tissue

The subcutaneous tissue is the lower layer of the skin between the dermis and fascia and is composed of connective tissue, fatty tissue and contains major blood vessels and nerves (see Figure 13) [44]. Subcutaneous fatty tissue can often be visible in deep wounds such as pressure ulcers or traumatic wounds [56]. Its functions include insulation, cushion and moisture retention and its thickness depends on several factors, including the body site and age [44].

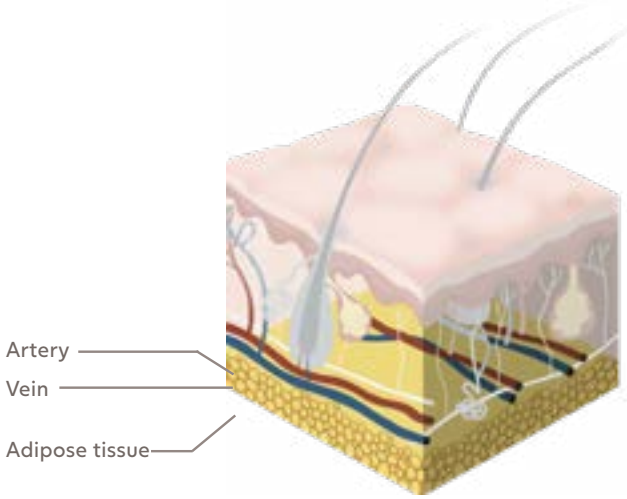

FIGURE 13. Subcutaneous tissue.

5. Medical adhesive-related skin injuries (MARSI)

5.1 Categories of MARSI

Injuries related to the application or removal of adhesives are divided into the following categories: mechanical, dermatitis and other [22]. In Table 8 a brief description of each type of injury is provided and in Figure 14 photographic examples are shown.

TABLE 8. Categories for medical adhesive-related skin injuries. Adopted from McNichol et al. [22] and Fumarola et al [57].

Mechanical
Skin stripping: Trauma that can occur after removing an adhesive incorrectly. Skin stripping removes one or more layers of the stratum corneum. Lesions are typically shallow and irregular, skin may appear shiny, and lesions may be red (erythema) or show blister formation [55, 58]. See Figure 14 A.
Tension injury or blister: Skin injury caused by shear force as a result of stretching or movement of the skin in the presence of a solid, rigid, unbending, non-stretching adhesive, or because of inappropriate application (strapping) of the adhesive [59-61].
Skin tear: An acute wound caused by trauma, cuts or scrapes, or skin friction that may become chronic. They can be partial thickness in which the epidermis separates from the dermis or full thickness in which the epidermis and dermis separate from the hypodermis [62]. See Figure 14B.
Dermatitis
Irritant contact dermatitis: An inflammatory skin response to chemical irritants that can cause dryness, scaling, cracking, redness, swelling, and increased skin permeability. The affected area is well-defined and corresponds with the area of exposure. The condition disturbs the skin's pH balance, which normally protects the skin from pathogens and damage by certain chemical compounds. Irritant contact dermatitis is non-allergic and commonly resolves shortly after the chemical exposure is cleared. However, the reaction may persist for weeks after exposure to the irritant. [63, 64]. See Figure 14C.
Allergic dermatitis: An immunological reaction in the area exposed to an allergen, for example, an adhesive component. Allergic contact dermatitis causes vesiculation (small blisters) an inflammatory response (redness, itchiness) in the area exposed and beyond, which, in turn, increases skin permeability. This type of skin irritation may be associated with other underlying allergies [63, 65]. See Figure 14D.
Other
Maceration: Softening and wrinkling of the skin after prolonged exposure to moisture, such as accumulation of mucus or prolonged entrapment of moisture under the adhesive. Maceration increases skin permeability and makes the skin more susceptible to infection and damage from friction and irritants. Prolonged exposure to moisture also breaks down the affected skin and loosens the adhesive. Maceration can be painful and impair wound healing. See Figure 14E.
Folliculitis: An inflammatory reaction on the skin around the hair follicles caused by a bacterial infection. Small elevations of the skin around the hair follicle that may contain pus. See Figure 14F.

The most common medical adhesive-related skin injuries in total laryngectomy patients are skin stripping, irritant contact dermatitis, allergic dermatitis and maceration [26].

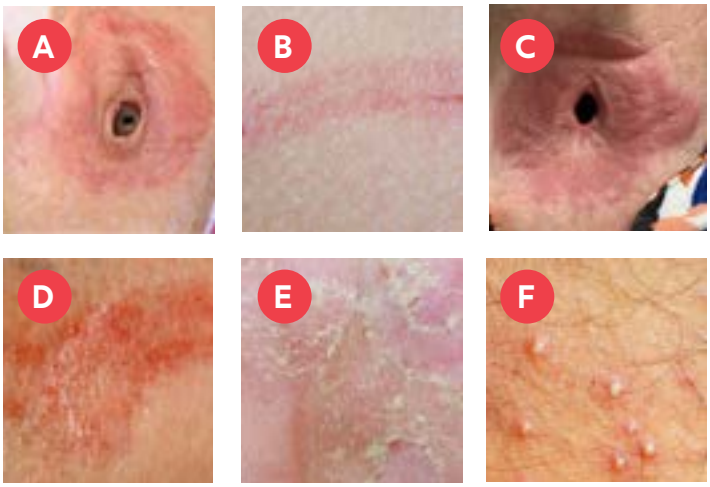

FIGURE 14 A-F. Laryngectomy stoma with skin stripping after forceful and rapid removal of the adhesive (A); example of skin tear (B); laryngectomy stoma with irritant contact dermatitis with a well-defined area of exposure to the adhesive, area is swollen and this condition is likely very painful (C); example of allergic dermatitis (D); example of maceration and desquamation on the sole of the foot (E); and example of folliculitis with small elevations around the hair follicle that contain pus (F).

5.2 Risk factors, causes and prevention

5.2.1 Intrinsic and extrinsic risk factors

Several risk factors have been identified for MARSI in the literature. They are typically divided into intrinsic and extrinsic risk factors. The factors listed in this section may not provide a complete overview and new research may uncover additional risk factors. It is therefore important to always consider the patient's general health status and any treatments they have received and medications they are taking. Knowledge of these risk factors helps identify patients that are more likely to develop MARSI.

Intrinsic risk factors:

- Age: Skin changes with aging include for example epidermal thinning, loss of moisture, and loss of elasticity which makes older adults more susceptible to skin injury [55, 66].
- Race/ethnicity: differences in skin structure and function among different race and ethnic groups may cause a difference in susceptibility to skin injury [67].
- (Pre-existing) Dermatological conditions: eczema, dermatitis, chronic exudative ulcers, epidermolysis bullosa [22, 57].
- Underlying medical conditions: diabetes, infection, renal insufficiency, venous hypertension, peristomal varices [22, 57, 68, 69].
- History of contact dermatitis [70].
- Late post-surgical ambulation [70].
- Prolonged hospital stay [71].
- Low Braden scale score [71].

- Dry skin [71].
- Hypoalbuminemia [71].
- Chronic venous insufficiency [72].
- Moderate to severe edema [57, 73].
- Hyperthermia [57, 73].
- Malnutrition [57].
- Dehydration [22, 57].

Extrinsic risk factors:

- Drying of the skin (for example due to harsh (non pH-balanced) cleansers or low humidity) [22, 57].
- Prolonged exposure to moisture [57].
- Certain medications (for example chemotherapeutic agents, long-term use of corticosteroids, anti-inflammatory agents and anticoagulants) [22, 57].
- Immunosuppression [74].
- Radiation therapy [57].
- Photodamage or exposure to ultraviolet light [22, 57].
- Repetitive adhesive tape removal [22, 71].
- and repeated adhesive tape application [22].

Due to the nature of their underlying condition and their typically more advanced age, many TL patients may have medical conditions such as diabetes, may suffer from malnutrition or dehydration and will most likely have been exposed to radiotherapy and/or chemotherapy [75-77]. All these factors can negatively impact their peristomal skin condition and susceptibility to MARSI.

5.2.2 Preventable causes of MARSI

Aside from the risk factors listed in the section above, a number of preventable causes of MARSI have been identified [22, 78, 79]. These include improper choice of adhesive tape (i.e. tape with excessive adhesion for purpose, tape with insufficient stretch), improper application technique (tension ('strapping') on application, applying in wrong direction, applying to wet/moist skin, use of alcohol based skin barriers which are drying to the skin, not allowing skin barriers to dry, not trimming hair, excessive use of tackifiers or glues, leaving occlusive adhesive tapes or dressings on too long, improper removal technique (i.e. quick removal, removal at high angle, insufficient support of the skin at the peel line, lack of use of adhesive removers when indicated), repeated adhesive tape/dressing changes.

5.2.3 Medical adhesive-related challenges specific for TL patients

Most of the clinical evidence around peristomal skin complications and medical adhesive-related skin injuries stems from clinical research in adjacent clinical areas such as colostomy or urostomy. Whereas these learnings are often also applicable to TL patients, there are some specific differences that deserve attention:

Speaking: Many TL patients speak with the use of a voice prosthesis which requires occlusion of the HME, or the use of a handsfree speaking valve, to direct pulmonary air into the esophagus and pharynx. An airtight seal of the adhesive is an important requirement for effective TE speech. This has the following implications for adhesive selection and application:

- Higher levels of adhesion (tackiness) are required to withstand the pressure generated when speaking and application technique should involve prevention of wrinkles.
- Material flexibility and shape of the adhesive should be considered to achieve a good fit with the peristomal skin area and minimize wrinkles and air tunnels.
- Lower moisture vapor transmission rates (permeability) of adhesive materials are required to prevent/reduce 'blow-through' during speech.
- Patients using TE speech may experience neck distension during speech, especially when using a handsfree speaking valve. An adhesive with a more firm/rigid adaptor may be helpful in supporting the neck tissues and limiting the extent of the distension. Furthermore, voice rehabilitation sessions with a speech language pathologist may be beneficial to reduce speaking effort, optimize finger pressure used to occlude the HME for speaking and manually support a bulging neck area.

Mucus: TL patients cough up mucus (Airway Surface Liquid – ASL) via their tracheostoma. This is ideally cleared away immediately, but in some instances, mucus may accumulate and/or seep underneath the adhesive see Figure 15). The pH of ASL averages about 6.6 and can be more alkaline in patients experiencing pulmonary disease (80). The prolonged presence of ASL may affect the acid mantle of the peristomal skin which may cause skin maceration and skin irritation and it negatively affects the airtight seal of the adhesive

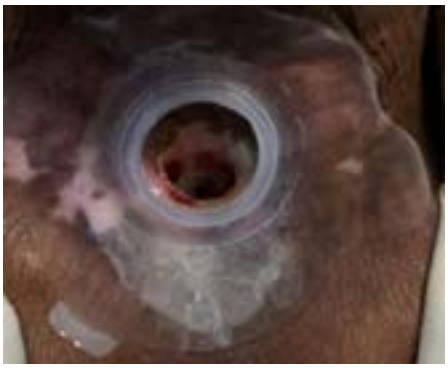

FIGURE 15. Mucus accumulation underneath the adhesive causing the adhesive to come off and possibly causing maceration.

Movement: the tracheostoma is located at the base of the neck and therefore the adhesive baseplate can be affected by movements of the head and neck. Patients may experience discomfort from the adhesive during neck movement.

Appearance: The tracheostoma at the base of the neck is in a visible location and hence the appearance of devices used in the area is of importance.

6. Provox Adhesives

Provox Adhesives are available in 3 materials: hydrocolloid, hydrogel and medical grade acrylic. Furthermore, the Provox Luna Adhesive is equipped with patented SecureFit connector technology, and two adhesives are designed in a concave shape for deeper set tracheostomas, one of which has a firm base and stabilizing bars to provide support to the neck during (handsfree) TE speech.

6.1 Material characteristics and technical details

In Table 9 the material characteristics of Provox Adhesives are detailed. Please refer to section 3.2 for details on material characteristics of hydrocolloids, hydrogels and medical grade acrylics in general.

TABLE 9. Technical details Provox Adhesives

Provox Adhesive*	Technical details (data on file)
Provox OptiDerm**  Skin-friendly adhesive for everyday use	**Carrier:** Polyethylene. Perforated. **Adhesive:** Hydrocolloid. Synthetic rubber base with a proprietary mixture of: • Tackifiers – to create the (initial) adhesion to the skin surface • Antioxidants – to prevent ageing of the material due to UV light and temperature • Absorbents – to absorb moisture (this is the specific component called hydrocolloid) **Liner:** Paper with siliconized surface. One piece. **Connector:** Standard 22 mm connector **Application:** The adhesive material (hydrocolloid) is pressure-sensitive and reaches maximum adhesion after about 15 minutes. Hydrocolloid material responds well to pre-warming prior to application which helps increase initial adhesion to the skin surface. **Removal:** Once the hydrocolloid material absorbs moisture, it becomes a gel and loosens from the skin surface, making it easier to remove. Use Provox Adhesive Remover wipe underneath adhesive – starting from finger lift tab. Or use a lint-free cloth with water (distilled, sterile or drinking quality), apply at the edges underneath the adhesive and allow time for the adhesive to absorb the water and loosen. **Permeability:** MVTR = 1900 g/m^2/24hr **Sizes:** Comes in 3 sizes: Round, Oval, and Plus.
Provox FlexiDerm**  Flexible adhesive with strong adhesion	**Carrier:** Polyethylene. Perforated. **Adhesive:** Medical grade acrylic **Liner:** Paper with siliconized surface. One piece. **Connector:** Standard 22 mm connector. **Application:** The pressure sensitive medical grade acrylic material reaches maximum adhesion after ~1 hour and does not benefit from pre-warming prior to application. **Removal:** Use Provox Adhesive Remover wipe on top of perforated carrier to saturate material and loosen adhesive prior to removal. Then use adhesive remover wipe from the side to gently remove adhesive - starting from finger lift tab. **Permeability:** MVTR = 550 g/m^2/24hr **Sizes:** Comes in 3 sizes: Round, Oval, and Plus.
Provox Luna Adhesive** Soothing adhesive for overnight skin rest and recovery	**Carrier:** Polyurethane. Non-perforated. **Adhesive:** Hydrogel with integrated polypropylene non-woven reinforcement layer to maintain integrity of the adhesive. Soft and high tack, designed especially for skin contact with and for use on breached or damaged skin. The hydro-active adhesive has the following characteristics: • Highly breathable – hydrogels have significantly more breathability than other materials such as silicones, acrylics, or hydrocolloids owing to a high moisture vapor transport rate (MVTR), which is a measure of breathability. • Moisturizing – the hydrogel is formulated with ~30% pharmaceutical grade, vegan glycerin which helps to maintain skin moisture levels as well as the integrity of the adhesive, making it less prone to breaking or tearing. • Water soluble – hydrogels are water soluble and can be rinsed or soaked off the skin. This makes the adhesive easy to remove, but also less suitable for prolonged exposure to external fluids (e.g., showering). • Wound cooling effect – the high-water content of hydrogels provides a cooling effect. • Absorption of bacteria – hydrogels are capable of absorbing bacteria within their polymer structure which may help prevent the accumulation of excess bacteria within the top layers of the skin. • Transparent – hydrogel materials are transparent which allows for observation of potential wound or skin defects underneath the adhesive and is discreet. • Thin and flexible – the adhesive is thin and flexible which adds to patient comfort. **Liner:** Polyester with siliconized surface. Three-piece. **Connector:** SecureFit. Diameter 19 mm. Soft and flexible material. Low profile. **Packaging:** High moisture barrier packaging to preserve water content. **Application:** Pressure sensitive material. Does not benefit from pre-warming prior to application. Must be applied to clean and dry skin, free of skin barriers, creams, oily residues, etc. **Removal:** Use lint-free cloth with saline or water (distilled, sterile or drinking quality) to remove. **Permeability:** MVTR = 1300 - 1500 g/m^2/24hr **Sizes:** Available in one size only. Clover-shaped (see Figure 16).

Provox XtraBase**  Strong adhesive with reinforced concave base for extra support	**Carrier:** Polyethylene. Perforated. **Adhesive:** Medical grade acrylic. Same as Provox FlexiDerm Adhesive. **Liner:** Polypropylene with siliconized surface. One piece. **Connector:** Standard 22 mm connector. Incorporates a firmer, concave base. **Application:** The pressure sensitive medical grade acrylic material reaches maximum adhesion after ~1 hour and does not benefit from pre-warming prior to application. **Removal:** Use Provox Adhesive Remover wipe on top of perforated carrier to saturate material and loosen adhesive prior to removal. Then use adhesive remover wipe from the side to gently remove adhesive - starting from finger lift tab. **Permeability:** See above, same as Provox FlexiDerm. **Sizes:** Comes in one size only.
Provox StabiliBase**  Strong adhesive with firm concave base, providing support and strong adhesion.	**Carrier:** Polyethylene. Perforated. **Adhesive:** Medical grade acrylic. Same as Provox FlexiDerm Adhesive. **Liner:** Polypropylene with siliconized surface. Three-piece. **Connector:** Standard 22 mm connector. Firm, concave base with stabilizing bars for deeper set stomas and neck support during (handsfree) TE speech. **Application and Removal:** See above. Same as Provox FlexiDerm. **Permeability:** See above, same as Provox FlexiDerm. **Sizes:** Available in one size only.
Provox StabiliBase OptiDerm**  Skin-friendly adhesive with firm concave base, providing support for deep stomas	**Carrier:** Polyethylene. Perforated. **Adhesive:** Hydrocolloid. Synthetic rubber base with a proprietary mixture of: • Tackifiers – to create the (initial) adhesion to the skin surface • Antioxidants – to prevent ageing of the material due to UV light and temperature • Absorbents – to absorb moisture (this is the specific component called hydrocolloid) **Liner:** Polypropylene with siliconized surface. Three-piece. **Connector:** Standard 22 mm connector. Firm, concave base with stabilizing bars for deeper set stomas and neck support during (handsfree) TE speech. **Application and Removal:** See above. Same as Provox OptiDerm. **Permeability:** See above, same as Provox OptiDerm. **Sizes:** Available in one size only.

*Provox Adhesives do not contain any materials of human or animal origin, and are latex- and phtalate-free (see various-statements.pdf (atosmedical.com) for more information).

**Due to differences in registration and regulatory status, product availability may differ between geographies. Please contact your local Atos Medical representative with any queries about product availability in your region.

6.2 Shape

The flat Provox OptiDerm and FlexiDerm Adhesives come in 3 sizes (Round, Oval and Plus) to address variations in stoma configuration and patients' needs and preferences. The flat Provox Luna Adhesive comes in one size and is clover-shaped; each leaf of the clover moves independently to improve fit to the stoma and reduce air tunnels and wrinkles in the adhesive. See Figure 16.

6.3 Connector

Provox Luna Adhesive is equipped with a SecureFit connector which is soft, flexible, and low-profile. The patented SecureFit technology provides a secure connection for Provox Luna HME. The soft and flexible material and the low profile and smaller diameter of the connector are designed for comfort, for example when sleeping.



FIGURE 16. Simulation of improved fit of clover-shaped design with independent movement of the leaves (Provox Luna Adhesive).

7. Clinical evidence

Peristomal adhesives enable the use of HMEs and as such indirectly contribute to pulmonary rehabilitation. They are important contributors to adherence to HME use and to the efficiency of TE speech. Clinical studies primarily focus on pulmonary outcomes, but some data is available in the literature related to laryngectomy peristomal adhesives. Most users change their adhesive once every 1-2 days [2, 11, 13, 81, 82]. Dermatological problems from adhesives have been reported for 20-60% of total laryngectomy patients [4, 13, 20]. The availability of a variety of adhesives in different materials and sizes is found to improve acceptance of HMEs and to help resolve problems with skin irritation and/or loosening of the adhesive [82, 83]. When problems with skin irritation or redness arise, patients often switch to the skin-friendlier hydrocolloid Provox OptiDerm Adhesive [82]. Provox OptiDerm was found to have lower skin irritation rates than non-hydrocolloid Provox FlexiDerm and Provox Regular adhesives (6% versus 12%) [81].

In the following sections, three clinical studies that primarily focused on Provox StabiliBase and Provox Luna Adhesive outcomes are presented in more detail.

7.1 Provox StabiliBase Adhesive - Clinical study

Hilgers et al. [84] conducted a multicenter, prospective clinical trial in the Netherlands. The study included 65 laryngectomized patients with prior HME and adhesive experience and aimed to investigate possible differences between Provox StabiliBase and Provox FlexiDerm/Provox XtraBase for parameters related to patient preference/satisfaction, dermatological outcomes, and device life. The study started with one week use of Provox FlexiDerm or Provox XtraBase (for baseline data collection) followed by 3 weeks of use of Provox StabiliBase. All study participants used HMEs daily, 9 used a handsfree speaking valve daily and 9 used a handsfree speaking valve occasionally. Sixty-one participants completed the baseline assessment, 34 used Provox FlexiDerm and 27 used Provox XtraBase. Fifty-eight participants completed the study.

Results showed that overall preference for Provox StabiliBase was 76% (p<.001). This preference appeared to be driven by stoma depth (a significant proportion of patients with a deep(er) stoma preferred Provox StabiliBase; p=.041), ease of application (38% found Provox StabiliBase easier to apply; p=.034), fit to the stoma (62% felt Provox StabiliBase fit better to the stoma; p<.001), and less air leakage through the adhesive (33% reported less air leakage through the adhesive with Provox StabiliBase; p<.001). Skin irritation was not found to differ between the baseline adhesive and Provox StabiliBase.

Adhesive lifespan was found to be longer for Provox StabiliBase (average 44.8 hours) versus the baseline adhesive (average 28.8 hours) (p<.001).

Provox StabiliBase showed to have a positive impact on handsfree speech: patients with neck distension during handsfree speech demonstrated a significant preference for Provox StabiliBase (p<.001) and 43% indicated they could use their handsfree speaking valve for more hours per day with Provox StabiliBase (p<.001).

7.2. Provox Luna Adhesive – Clinical study 1

Ratnayake et al. [20] conducted a multicenter randomized cross over trial in the Netherlands. The study included 53 laryngectomized participants with prior HME and adhesive experience and aimed to investigate changes in adherence to HME use, dermatological and pulmonary outcomes as a result of using Provox Luna (Adhesive and HME) when sleeping. Participants were randomized to A) Usual Care for 4 weeks, followed by 4 weeks of Provox Luna added to their usual regimen or B) 4 weeks of Provox Luna added to their usual regimen, followed by 4 weeks of Usual Care. Final data analysis included 46 participants who completed the entire study.

The use of Provox Luna significantly improved adherence to HME use. During Usual Care 76% of the participants used an HME ≥ 20 hours per day and with Provox Luna added to their Usual Care regimen this was 96% (p=.02). Participant diaries showed that the number of compliant days increased significantly from 22.5 to 27 days (out of 28) when Provox Luna was added to their regimen (p=.002) and that the average hours of HME use per day increased significantly from 21.6 hours during Usual Care and to 23.3 hours when Provox Luna was added to their regimen (p=.003). See Figure 17.

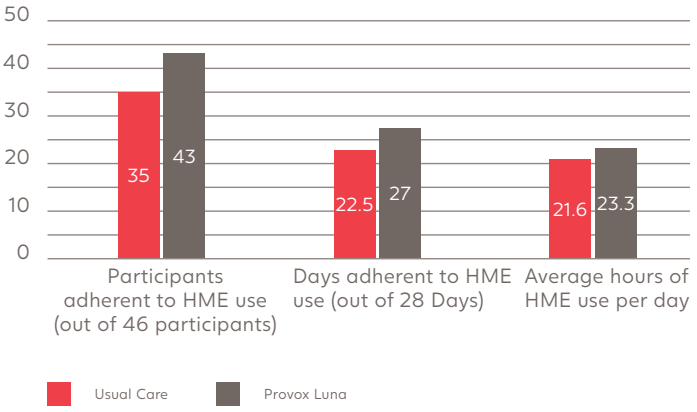

FIGURE 17. Bar chart illustrating the impact of the addition of Provox Luna Adhesive (hydrogel) and HME to the usual HME regimen on aspects of adherence to HME use. As can be seen, more patients are adherent to HME use (left), for more days (middle) and more hours per day (right).

The addition of Provox Luna to the Usual Care regimen had a positive effect on dermatological outcomes. During Usual Care the peristomal skin improved overnight in 3.9 out of 28 nights, and with the addition

of Provox Luna this occurred in 8.1 out of 28 nights (p = .008). The number of days with skin irritation reduced when Provox Luna was added to the regimen, but not significantly. Participants reported a reduction in duration (33%), episodes (30%), and severity (22%) of skin irritation when Provox Luna was part of their regimen. And 28% reported better skin recovery with Provox Luna versus not using an adhesive overnight to 'rest the skin'.

7.3. Provox Luna Adhesive – Clinical study 2

Mayo-Yáñez et al. [40] conducted a randomized crossover trial aimed to investigate possible differences in dermatological symptoms, pulmonary symptoms, sleeping and quality of life between the use of Provox FlexiDerm adhesive day and night and the use of Provox FlexiDerm adhesive during the day only, in combination with Provox Luna adhesive during the night. Twenty-eight laryngectomized HME users participated in the study, divided into two groups. After a wash-out period of 15 days during which the study participants used the Provox XtraFlow with a Provox LaryTube attachment, allowing the peristomal skin to settle, group A used the medical grade acrylic adhesive (Provox FlexiDerm) with Provox XtraFlow HME for 24 hours per day for 25 days. Group B used the medical grade acrylic adhesive (Provox FlexiDerm) with the Provox XtraFlow HME during the day (~12 hours) and the Provox Luna HME and Adhesive (hydrogel) system during the night (~12 hours) also for 25 days. After a wash-out period of 5 days, data was collected, and the participants crossed over to the other usage group. Leaving a total dataset of 28 patients to compare dermatological symptoms between use of Provox FlexiDerm Adhesive only versus a Provox FlexiDerm Adhesive during the day and Provox Luna Adhesive at night.

Results showed that dermatological problems were significantly less frequent when the study participants used the Provox FlexiDerm Adhesive (medical grade acrylic) with Provox XtraFlow during the day and the Provox Luna (hydrogel) Adhesive with Provox Luna HME during the night (46.4% versus 14.3%), see Figure 18. Furthermore, all 13 patients experiencing dermatological problems whilst using Provox FlexiDerm with Provox XtraFlow for 24 hours per day needed to abandon the use of the adhesive for their skin to improve, seven of them every night and six on demand. Of the four participants that experienced dermatological problems whilst using Provox FlexiDerm Adhesive with Provox XtraFlow during the day and Provox Luna Adhesive and HME during the night, three needed to abandon adhesive use to improve the skin, two every night and one on demand.

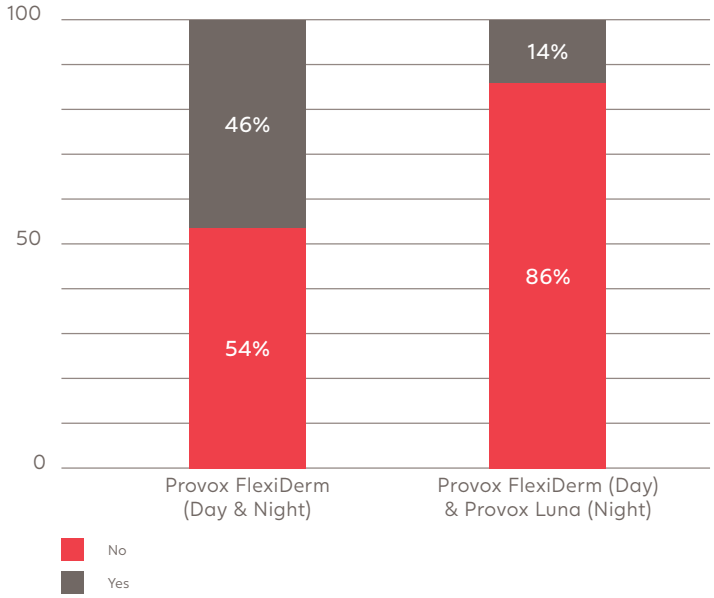

FIGURE 18. Stacked bar chart showing the frequency of occurrence of dermatological problems (itching, irritation, inflammation and/or redness) when using Provox FlexiDerm Adhesive (medical grade acrylic) for 24 hours per day versus Provox FlexiDerm Adhesive during the day and Provox Luna Adhesive (hydrogel) during the night.

8. Prevention of MARSI in TL patients

As indicated in section 5.2.2, several preventable causes of MARSI have been identified. Table 10 lists these causes along with some possible solutions to consider, including some additional causes for MARSI that are specific to the TL population.

Table 10. Preventable causes of MARSI in TL patients and possible solutions.

Preventable cause		**Recommendations and solutions to consider**
Improper choice of adhesive	Excessive adhesion (tackiness) for the purpose/situation.	Always select the most skin-friendly option based on the patients' skin and communication needs. Provox OptiDerm Adhesive and Provox Luna Adhesive are the most skin-friendly options.
	Wrong choice of adhesive	Provox OptiDerm Adhesive is a skin friendly hydrocolloid that is suitable for immediate postoperative use and can be used on an ongoing basis if the tackiness is sufficient for the patients' communication needs. Provox Luna Adhesive is a hydrogel adhesive that can be used overnight on dry skin. Hydrogel contains water and provides a moist environment for the skin to recover. This hydrogel adhesive can also be used on an ongoing basis during the day and night if the tackiness is sufficient for the patients' communication needs. It is best suited for dry skin. See section 3.2 for more details on the materials characteristics of hydrocolloids and hydrogels.
Improper application technique	Applying with tension	Apply the adhesive with the neck in neutral position, do not pull or stretch the adhesive when applying.
	Applying in wrong direction	Start from the center, around the stoma, then outwards starting with the bottom then top and sides.
	Applying to wet/moist skin	Ensure the skin is clean and dry, free of mucus and wound exudate. Cough and clear secretions prior to application. If the skin is wet due to wound exudate, use a moisture absorbing hydrocolloid adhesive such as Provox OptiDerm and ensure the skin is dry prior to adhesive application.
	Applying to greasy or oily skin	Ensure the skin is clean and dry, free from creams, ointments, and adhesive removers.
	Allowing for gaps and wrinkles	Avoid gaps and wrinkles that can allow moisture and mucus to enter between the adhesive and the skin, which can create an air leak during TE speech.
	Using irritating skin barriers (these are drying to the skin)	Use no-sting skin barriers such as Provox Skin Barrier that are suited for peristomal skin and for use around a neck stoma. Skin barriers with strong smells of vapors and skin barriers sprays should be avoided as they can be inhaled.
	Not allowing skin barriers to dry (common cause of irritant contact dermatitis)	Let skin barriers dry fully prior to adhesive application.
	Not trimming hair	Trim/shave all hair in and around the area of application.
	Excessive use of glues or tackifiers	Use tackifiers and silicone glues only when necessary and do so sparingly.
Leaving non-permeable adhesives on too long		Establish a change routine that optimizes for a good and secure seal for the duration of a full day, allowing for scheduled adhesive changes at a convenient time. Patients may define success by the length of time the adhesive stays in place. This can cause skin irritation due to the adhesive staying on too long, disruption due to unscheduled adhesive changes, poor application due to unanticipated adhesive changes under poor and unhygienic conditions, and insecurity due to the adhesive losing the seal at unpredictable times, disrupting the ability to communicate effectively. Scheduled routine changes allow for properly prepared adhesive changes under good and hygienic conditions.
Improper removal technique	Quick removal	Remove the adhesive slowly and gently, starting from the finger-lift tab and from the bottom of the stoma upwards
	Removal at high angle (i.e perpendicular at 90^0)	Peel the adhesive off at a low angle (i.e. close to 1800, not straight up (see Figure 19). This reduces sheer forces on the skin.
	Lack of support to skin at peel line	Support the skin at the peel line (see Figure 19)

Table 10. Preventable causes of MARSI in TL patients and possible solutions.

	Not using adhesive remover when indicated	Use no-sting adhesive remover wipes free of strong smells and vapors, suitable for peristomal skin and tracheostomas, such as Provox Adhesive Remover. Application method differs based on the adhesive materials. On permeable adhesives such as the acrylic Provox FlexiDerm Adhesive, first apply the adhesive remover on top of the adhesive. The adhesive remover will permeate the adhesive carrier and help dissolve the glue. Then apply the adhesive remover underneath the adhesive whilst gently peeling the adhesive off the skin at a low angle. In this case, the finger with the adhesive remover wipe provides support at the peel line at the same time. Adhesive remover may be used to remove hydrocolloid adhesives such as Provox OptiDerm Adheisve. This adhesive is non-permeable, so the adhesive remover will only be applied during removal, at the edge of the adhesive. Hydrocolloids may also be removed with water. The water must be applied at the edge of the adhesive and sufficient time must be allowed for the hydrocolloid to absorb the water.
	Not using water to remove the adhesive when indicated	Hydrogels are removed with water. They take up water rapidly and the hydrogel will easily release from the skin when water is applied at the edge of the adhesive.
Repeated adhesive changes		Avoid repeated adhesive changes, for example multiple times per day. Identify the cause of the repeated changes and work towards a sustainable routine.
Speaking too soon after application		Medical adhesives are pressure sensitive; apply firm pressure to the surface to activate the adhesive by increasing the surface area contact. Over time, the adhesive (glue) will warm and flow to fill in gaps between the adhesive and irregularities in the skin surface which increases the strength of the bond. The length of time this takes differs for the different materials. Pre-warm hydrocolloids prior to application to help speed this process.
Mucus trapping underneath adhesive		Do not allow secretions (mucus) from coughing to settle at the bottom of the stoma and seep underneath the adhesive. After a productive cough, any secretions must be removed from the area.
Excessive speaking pressure		Excessive and sudden speaking pressure puts strain on the adhesive and can cause premature loosening of the adhesive. Work on regulating and lowering speaking pressure and provide medical treatment for hypertonicity if indicated.
Not supporting the adhesive when removing the HME		Removing the HME from the connector may pull the adhesive away from the skin. This may cause skin irritation and premature loosening of the adhesive leading to repeated adhesive changes. Always support the adhesive with two fingers (one left and one right) when removing the HME.
Touching the adhesive layer prior to application		Minimize touching the sticky adhesive layer. Finger contact may decrease the adhesion capacity of the adhesive. This may cause blow-through and premature loosening of the adhesive leading to repeated adhesive changes. For adhesives with stepwise peel-off liners, using the stepwise method will help to avoid this finger contact.

As is evident from the table above, good skin care, proper adhesive selection and appropriate application and removal routine and technique are all important components of successful adhesive use and help to avoid MARSI.

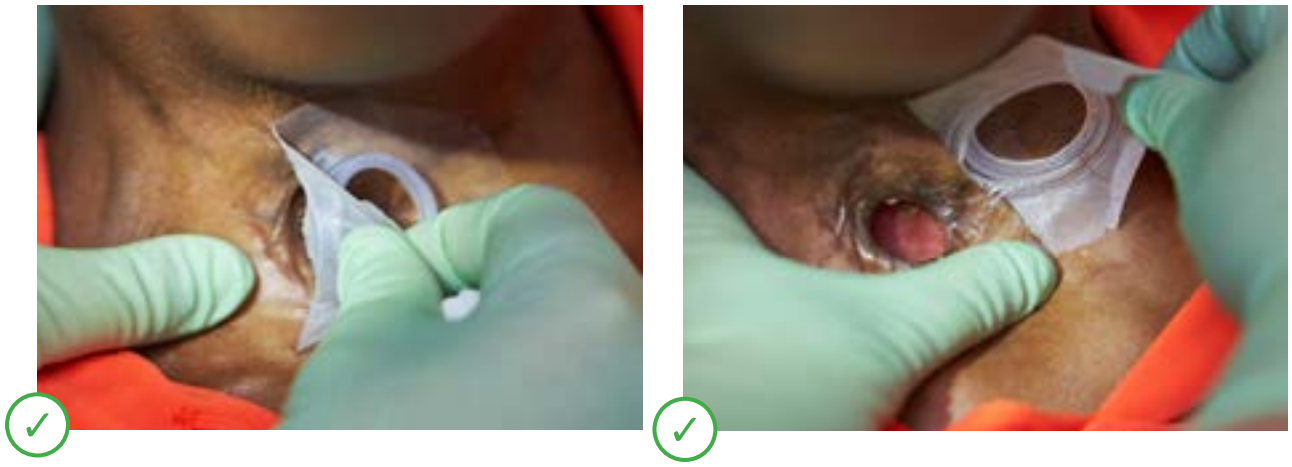

FIGURE 19. A proper adhesive removal technique includes slow and gentle removal with a low-angle peel direction and finger support at the peel line, supported with adhesive remover wipes when indicated.

9. Conclusions

Healthy peristomal skin is a prerequisite for optimal medical adhesive use. It creates the foundation for adherent HME use, which leads to improved pulmonary health and facilitates tracheoesophageal voicing (see Figure 20).

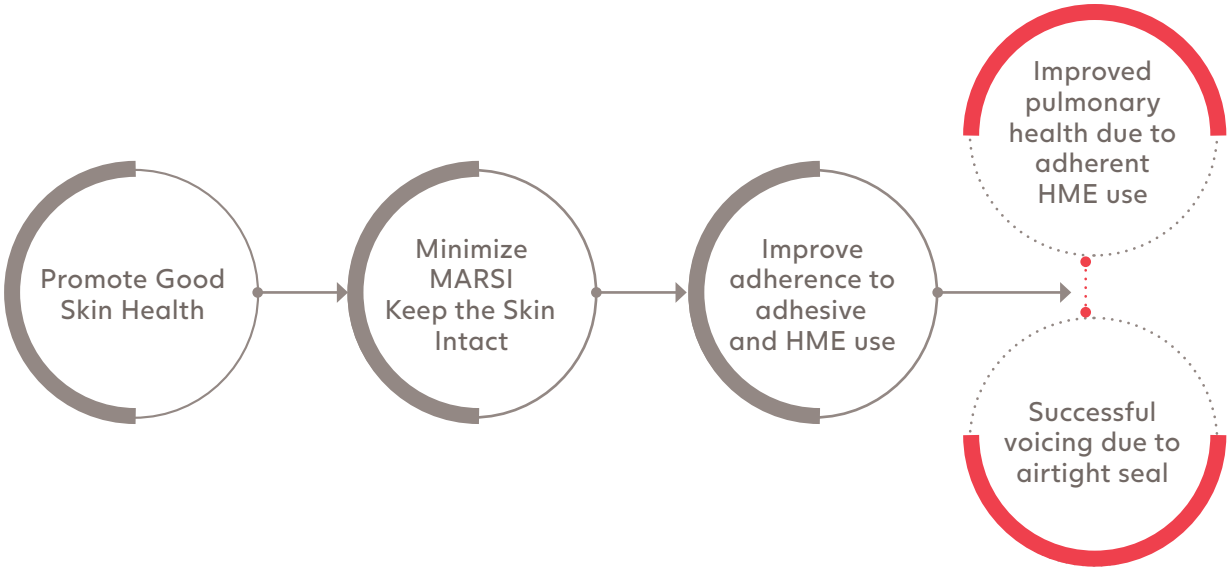

FIGURE 20. Promotion of good peristomal skin health and prevention and timely management of skin problems supports adherence to HME use and an airtight seal benefiting voice and pulmonary rehabilitation.

Minimization of Peristomal Skin Complications and Medical Adhesive-Related Injuries helps keep the skin intact.

This Whitepaper provides knowledge and tools that can help Healthcare Professionals promote good skin health and educate their patients on adhesive selection and proper application and removal techniques.

10. Q & A with the expert



Prof Dr Thomas Rustemeyer

Biography

Thomas Rustemeyer is professor in dermato-allergology and occupational dermatology at the Department of Dermatology-Allergology at the Amsterdam University Medical Centers, the Netherlands. He is supervisor of immunological research of the University, and he is active in supervising patient's care and research addressing fundamental immunological and translational research topics. He is (co)author of more than 300 publications and editor of several textbooks. He is member and/or chairperson of various national land international societies active in dermato-allergology, immunology and occupational health, including governmental and regulatory affairs.

Question:

Are some patients more at risk for skin breakdown? And if so, how can we identify them?

Answer:

This is a very good point – to prevent problems. Not everyone has the same skin condition. Skin tends to get thinner as we age. As people get older their skin becomes more fragile. And the same holds true for people who had radiotherapy at the site and people who use topical steroids that cause thinning of the skin. In addition to age, diabetes can also slow down skin regeneration and weakens the skin. Thus, people who suffer from long-term diabetes also have fragile skin and an increased risk for wound infection. In these cases, you should pay extra attention not to harm the patient by removing the adhesive with too much force or by leaving it on for too long.

Question:

How do you identify whether something is an irritation or an infection of the skin?

Answer:

This is not black and white, because infection follows irritation, and sometimes irritation can follow infection, but this is not so frequent. So, to prevent infection, you need to prevent irritation and therefore these baseplates are so important, even using them as soon as possible after surgery.

Irritation from the adhesive should be sharply demarcated, so where the adhesive is, the irritation should end. An infection is causing a reaction of the immune system, so it tends to be broader and becomes bigger within 1 or 2 days, it's growing as it is an infection.

Question:

Do you have any tips on removing the adhesive?

Answer:

It must be done gently and carefully, so take your time. Do not remove it abruptly and quickly as this will pull off the horny cells which are the skin barrier. In addition, the sheering forces can lead to irritation of the skin. Inform the patient to take their time to remove the adhesive. If possible, in front of a mirror. Gently peel it off millimeter by millimeter. Leave the skin open for a couple of minutes so it can rest and evaporate. Maybe even a little longer, to help the skin settle down. These are the most important things.

I would recommend not to use any creams or body lotions, because they have preservatives in them, and they are often scented. Then you have the fragrances and preservatives on the skin and when you apply the adhesive over that you have a higher penetration of the allergens which in the end may lead to allergic contact dermatitis. One final thing, you could be allergic to the adhesive, but the risk is very little. If a patient tells you and starts to complain that the skin is getting worse and worse, think about the contact allergy. You can simply test it by putting a piece of adhesive, for example on the arm or the back, a patch test, and leave it there for a few days. If the patient also gets itchy, red, and eczematous skin where the skin was normal, then you are most likely dealing with allergic dermatitis. And this irritation can be very well treated by using corticosteroids (from a nose spray) underneath the baseplate. Use nose spray, not cream or ointment, because they are greasy and will prevent the adhesive from sticking.

Acknowledgment

We would like to thank Prof Dr Rustemeyer for reviewing the content of this Whitepaper and for his valuable comments.

Bibliography

Any recommendations in this educational material are a general guide for best practice, to be implemented by qualified healthcare professionals subject to clinical judgement and availability of healthcare resources.

The information presented should not be considered medical advice for specific conditions. A patient's individual circumstances and preferences should always be considered and clinical practice should be in accordance with the principles of protection, participation and partnership.

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