Performance and safety of transparent postoperative dressings with silicone adhesive in daily practice on fragile skin

Objective: Currently there is limited real-world research on the adhesion qualities, pain and clinical performance of specific silicone adhesives products, and their role in maintaining skin integrity and preventing medical adhesive-related skin injuries (MARSI). This paper presents a clinical evaluation of performance and safety parameters of two silicone adhesive dressings on lacerations or surgical wounds and the surrounding skin in daily practice on fragile skin.
Method: An observational, prospective, multicentre, uncontrolled post-market clinical observational study with Leukomed T skin sensitive and Leukomed T plus skin sensitive (both BSN medical GmbH, Essity Group) was undertaken at three sites across Germany between June 2021 to November 2022. Inclusion parameters were acute wounds (surgical or laceration) in patients with at least one fragile skin condition. Endpoints included: the percentage of adhered dressing area seven days after application of the dressings; and evaluation of any signs of skin damage and erythema following dressing removal. Furthermore, self-reported patient pain, comfort during dressing wear, and the health professionals' ease of dressing handling with gloves were assessed.
Results: A total of 42 patients with fragile skin and surgical wounds (35 patients) or lacerations (7 patients) were recruited. Mean age was 78 years. There were no signs of erythema following dressing removal and no MARSI (skin stripping, blister, skin tears, maceration, irritant contact dermatitis or allergic dermatitis) occurred at removal after seven days of wear time. Data demonstrated a reliable wound coverage with sufficient adhesion without negatively affecting the periwound skin and wound improvement was observed in 94% of patients. The vast majority of patients reported minimal pain at removal, reduced wound pain and high satisfaction with wearing comfort. Health professionals found the dressings easy to apply and remove, even with gloved hands.
Conclusion: The results of this real-world evidence showed effective and well-tolerated use of transparent dressings with silicone adhesive in patients with fragile skin. The dressings may reduce the risk of skin damage including MARSI, while providing patients a high wearing comfort and allowing an almost pain-free dressing change.
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Leukomed T skin sensitive • Leukomed T plus skin sensitive • MARSI • pain management • silicone adhesives • skin tears • undisturbed wound healing • wound • wound care • wound dressing • wound healing

The global population is ageing with the World Health Organization (WHO) estimating by 2030, 1 in 6 people in the world will be aged 60 years or over.[1] WHO also estimate that by 2050 this will double to approximately 2.1 billion and will continue to increase.[1] Ageing negatively affects skin integrity and wound healing, as well as delaying the immune response.[1,2]

At a biological level, cell replacement continuously declines, and the barrier function, mechanical protection and thermoregulation are compromised, alongside decreasing sweat and sebum production.[2] Integral to these changes are the reduction of natural moisturising factors and lipids in the stratum corneum, resulting in skin becoming drier and at risk of skin tears and medical adhesive-related skin injuries (MARSI).[3]

MARSI has been defined as skin damage related to the use of medical adhesive products or devices, such as tapes, wound dressings, stoma products, electrodes, medication patches and wound closure strips.[4] MARSI includes: mechanical injuries (skin stripping, tension injuries, blistering, skin tears); dermatitis (caused either by irritant contact or allergic reaction); maceration; and folliculitis. MARSI can affect any age group but is particularly prevalent in those individuals with fragile skin, and when there is incorrect application and removal techniques of adhesive dressings/devices.[5]

The prevalence and incidence of MARSI are often underestimated and under reported. International data on MARSI are currently limited; however, what is available suggests that they range up to 37.2%.[6,7]

A prospective cohort study, consisting of a sample of patients aged ≥65 years who were admitted to a

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long-term care facility and required the use of medical adhesive tape, concluded that devices used to treat pressure ulcers (PUs), vascular access dressings, stoma equipment, nasogastric tube fixation and adhesives applied to abrasion sites were responsible for causing skin injuries in 24 (15.4%) of the 155 older people evaluated.[8] A survey among clinicians revealed that MARSI was estimated to affect over a quarter of individuals with postoperative wounds within 12 months in Australia.[9]

Health professionals are also affected by MARSI. Wei et al.[10] conducted a cross-sectional survey in China. Their data showed 41.9% of medical personnel using protective adhesive dressings under personal protective equipment (PPE) during the COVID-19 pandemic experienced MARSI, experiencing severe pain and skin damage upon dressing removal.

Skin tears are traumatic wounds caused by mechanical forces and are a type of MARSI, when caused by medical adhesive removal. They can affect any age group, but in particular older people, neonates and chronically ill patients. Classified as acute wounds, they should heal within 7–21 days. While the severity of skin tears can vary by depth, they do not penetrate through the subcutaneous layer.[11] Research on the prevalence, incidence and economic impact of skin tears is limited. However, studies by Strazzieri-Pulido et al.[12] and LeBlanc[13] report incidence rates ranging from 2.2–92.0%, with the highest rates observed in long-term care facilities. Similarly, Van Tiggelen and Beeckman[14] reported prevalence of skin tears to be estimated at between 1.1–41.2%, with studies in long-term care reporting between 3.0–41.2%, whereas prevalence was slightly lower in acute care settings, varying from 1.1–19.8%.

MARSI can be treated in a clinical environment provided there are clear guidelines and protocols in place.[15] However, the prevention of MARSI can reduce pain and discomfort during dressing removal, reduce additional costs to the health system and minimise the length of hospitalisations.[16] Assessment of skin before applying a wound adhesive is essential; however LeBlanc et al.[17] and Da Silva et al.[18] reported, although there are instruments for assessing skin tears, as yet there are no validated instruments for other MARSI types. It is clear more research is required in this area to allow for evidence-based guidelines to be developed and implemented into practice. Savine and Snelson[6] argue that to improve care around MARSI requires an exploration of and learning from the key drivers underpinning PU prevention that led to this area of care becoming a priority for healthcare environments.

Prevention of MARSI should include principles of good skin care, including: avoidance of washing the skin too much; using a pH-balanced soap substitute; daily moisturisation of the skin; prevention of dehydration; appropriate use of emollients; awareness of environmental hazards; and careful handling of the skin, i.e. when drying the skin lightly patting without rubbing.[4]

Choosing the right adhesive is crucial for managing skin integrity. The three main types of adhesives used are silicone, acrylate and hydrocolloid. Adhesion to the skin varies among medical adhesives, each employing a different mechanism. Acrylate adhesives work by filling the gaps between the adhesive backing/device and the skin's irregular surface, with bond strength increasing over time. In contrast, silicone-based adhesives are softer and gentler, maintaining a constant level of adherence, whereas adhesion of hydrocolloids can weaken over time, dependent on its water content.[4] There is limited research surrounding the area of MARSI; however, most publications recommend silicone adhesives should be used to maintain skin integrity and prevent MARSI, such as skin tears.[11,19]

In this paper, the results of real-world evidence of two transparent film dressings with silicone adhesives are presented, and their clinical performance and safety within the intended use in patients with fragile skin conditions reported.

Methods

An observational, prospective, multicentre, uncontrolled post-market clinical observational study with the investigational medical devices with silicone adhesives (IMD-SA) Leukomed T skin sensitive and Leukomed T plus skin sensitive (BSN medical GmbH, Essity Group) was undertaken. Leukomed T skin sensitive and Leukomed T plus skin sensitive are wound care products and are especially suitable in patients with fragile or sensitive skin. Leukomed T skin sensitive is a transparent film dressing with silicone adhesive and is intended for fixation of wound dressings and as additional fixation of devices, as well as for coverage of acute wounds, such as closed surgical wounds, cuts and abrasions. Leukomed T plus skin sensitive is a transparent island dressing with silicone adhesive and contains an additional low-adherent wound pad. It is intended for acute

Fig 1. Flowchart of participant distribution in the study in chronological order based on data management activities

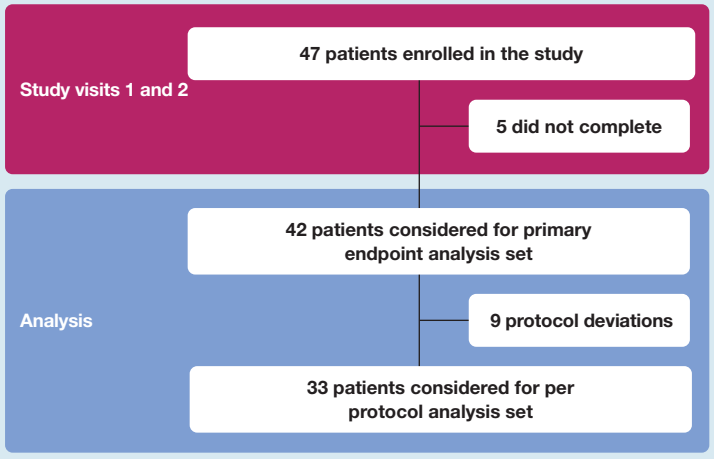


Table 1. Overview of reported reasons for fragile skin in primary endpoint analysis (PES) and per protocol set (PPS; multiple entries possible)

Fragile skin condition	PES (n)	PPS (n)
Age >80 years	14	12
Repeated taping	16	14
Medical conditions	10	6
Dry skin	9	4
Dermatologic conditions	6	5
Photodamage	1	0
Malnutrition	2	1
Tape/dressing/device removal damage	2	1
Radiotherapy	1	0
Dehydration	1	0
African-American ethnicity	0	0
Prolonged exposure to moisture	0	0

wounds with low-to-moderate exudate levels, such as closed surgical wounds.

The study was conducted on three sites across Germany between June 2021 to November 2022. The study areas included one inpatient geriatric ward, one ambulant dermatological clinic and one ambulant orthopaedic clinic.

Ethical approval and patient consent

Ethical approval was obtained before the study from Ärztekammer Bremen, Germany (registration number: NCT04775316) and all investigators completed good clinical practice training. This clinical investigation was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki. Written informed consent was received from all patients before being included in the study and all data was stored securely by the study team according to good clinical practice. All patients provided written informed consent for publication of photographs and data in this study.

Table 2. Non-healthy periwound skin conditions in the per protocol set (PPS)

	Visit 1 (Day 0)	Visit 2 (Day 7)
Macerated	1	0
Excoriated	1	0
Redness	7	0
Itching	0	0
Eczema	1	0
Oedema	8	1
Rash	2	0
Blisters	0	0
None	18	32

Study design

Inclusion and exclusion criteria are summarised below:

Inclusion criteria:

- All sexes
- ≥65 years of age
- Mentally and physically able to participate in the study
- Signed informed consent to participate in the study
- Fragile skin conditions: based on clinical judgement and presence of at least one fragile skin condition (refer to Table 1 for details)
- Acute wound (surgical wound or laceration) indicated for treatment with the investigational medical devices for a period of seven days.

Exclusion criteria:

- Wound infection
- Alcohol or drug addiction
- Known sensitivity or allergy to any components of the study product
- Patients participating in any other clinical study investigating drugs or medical devices.

A seven-day treatment time was chosen based on the approved wear time of the dressings and as an effective period to support undisturbed wound healing.

Primary and secondary objectives

The primary objective of the study was to assess the percentage of adhered dressing area seven days after dressing application.

Secondary objectives were to: assess for any signs of skin damage or skin reactions (MARSI) after dressing removal; assess for the presence of erythema (redness) of the skin 30 minutes after dressing removal; record self-reported patient pain using a visual analogue scale (VAS) scoring system (scale ranging from: 0 to 10, where 0=no pain and 10=worst possible pain) to assess pain level at dressing removal and comfort during dressing wear time. The ease of dressing re-application, and ease of dressing handling with gloves at application and removal was assessed by the health professionals.

Data collection

Following wound assessment all patients included in the study received either a transparent film or island dressing with silicone adhesive as their postoperative dressing. Patients were assessed at the first postoperative dressing change and seven days after application. Wounds and dressings in situ were photographed at baseline and on day 7 to allow for any changes to be observed.

During the study initiation visit, the principal investigator (PI) and all staff members of the study sites received training related to data collection, e.g., safety reporting procedures and timelines, informed consent process and regulatory requirements including good clinical practice. The training was provided by the clinical

trial manager and/or clinical research associate, who gave a comprehensive overview on all relevant topics. Training was provided for appropriate and correct application and removal of the investigational medical devices.

Sampling

The original study sample was calculated to be 75; however, because of the COVID-19 pandemic fewer patients were recruited and the study was terminated prematurely.

Data management

The PIs were responsible for ensuring accuracy, completeness, legibility and timeline of data recorded in the electronic Case Report Form (eCRF). Entries were remotely monitored on a regular basis. The assigned monitor conducted source data verification of completed eCRFs against local medical records. Any inconsistencies, missing information or incorrect data were addressed by queries.

Results

In total, 47 patients with at least one skin condition leading to fragile skin were enrolled in the study, of which 42 patients were considered for the primary endpoint analysis set (PES), with 20 (47.6%) inpatients and 22 (52.4%) outpatients. There were five patients who did not complete the study (one incomplete informed consent form, one lost to follow-up, one non-surgical/acute wound not intended to be included, and two due to the use of additional fixations). A drop out rate of 20% was expected, as the recruitment of sites and participants was affected by the COVID-19 pandemic in several ways, e.g., stop-and-go recruitment within a site may lead to deviations from the study protocol due to a lack of study routine and changing staff. Due to protocol deviations, a further nine patients were excluded resulting in 33 patients considered for the per protocol analysis sets (PPS), comprising 11 (33.3%) male and 22 (66.7%) female patients, with a mean age of 78.4±6 years. In the PPS, 31 (93.9%) surgical wounds and two (6.1%) lacerations were treated (Fig 1).

The reported concomitant diseases reflected a population with multiple comorbidities that are typical, for example, of an older population treated in a geriatric hospital ward. Of the 42 PES patients, all had at least had one fragile skin condition (Table 1), with most patients (n=24; 57.1 %) having one and 18 patients (42.9 %) having two or more fragile skin conditions that may lead to MARSI.

During the study, various wound types in a range of locations, including upper and lower limbs, spinal region and torso, were treated with the investigational medical devices. Of the patients, 16 were treated with Leukomed T skin sensitive and 26 patients treated with Leukomed T plus skin sensitive, based on clinical assessment. From the PES, 35 (83.3%) patients presented with a surgical wound, whereas seven (16.7%) had a laceration. In the PPS, 31 (93.9%) patients had surgical wounds and two (6.1%) had lacerations.

Fig 2. Wound pain using the visual analogue scale (VAS 0–10) *p<0.0001

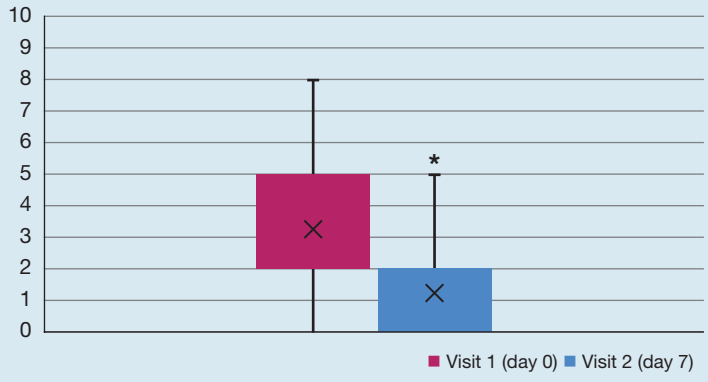
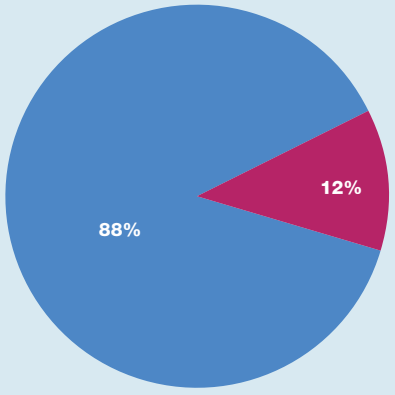
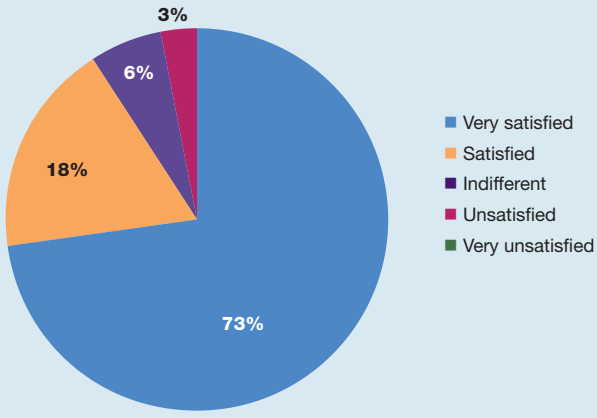


Fig 3. Pain during removal using the visual analogue scale (VAS; % patients)



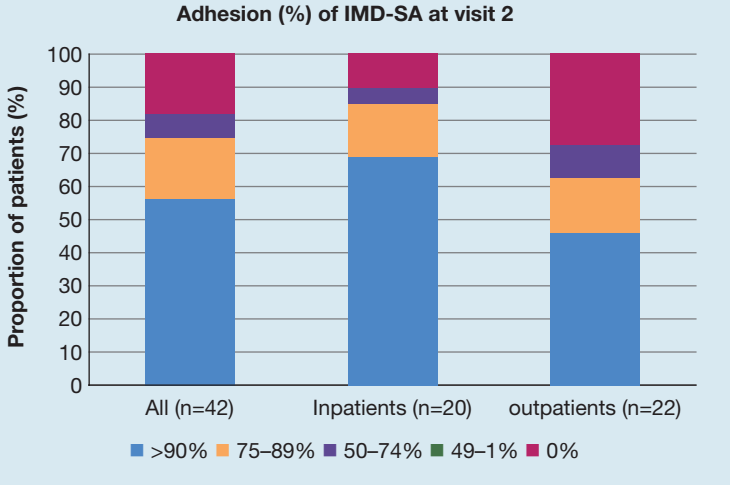
Patients %	VAS 0–10
9%	1
3%	4

Fig 4. Patient wearing comfort



The occurrence of MARSI following removal of the IMD-SA after seven days wear time was assessed. No skin stripping, tension injury/blister, skin tear, irritant contact dermatitis, allergic dermatitis, maceration or

Fig 5. Reported dressing adhesion at the primary endpoint analysis for inpatients, outpatients and all patients. IMD-SA—investigational medical devices with silicone adhesive



folliculitis was observed. Additionally, no erythema was noted 30 minutes after dressing removal.

Furthermore, maintenance of the periwound area was evaluated during the study period. Of the PPS, 14 (42.4%) patients presented with a non-healthy skin condition at the first visit, of which three (9.1%) were reported as having two or more of such skin conditions (Table 2). By day 7, there was an improvement in the periwound area in 93% of patients, and an unchanged periwound area in 7%. There was no reported deterioration of the periwound area.

Pain level during removal and wound pain was assessed during the study period using a VAS. Wound pain reduced significantly from 3.1±2.2 to 1.2±1.6 (mean VAS; $p<0.0001$) over the seven-day period between study visits (Fig 2). Dressing removal was perceived as pain free (VAS 0) by 87.9% of patients and the mean pain intensity at dressing removal was low, at 0.2 (minimum: 0; maximum: 4; median: 0) (Fig 3).

Patients reported on their level of comfort during wear (personal satisfaction with dressing considering wearing comfort and overall satisfaction), of which: 90.9% were 'satisfied' or 'very satisfied'; 6.1% were 'indifferent'; and 3.0% were 'unsatisfied' (Fig 4).

PIs categorised adhesion of each dressing at day 7 based on percentage attachment area of the dressing (Fig 5). Most dressings remained in place with an adhesion of >75%; 85.0% of dressing used on inpatients and 63.7% of dressings used for outpatients. Dressings that did not stay in place for seven days were mostly reported in outpatients (75% of all detached dressings).

All health professionals reported above average (36%) and excellent (64%) ease of handling at application and removal using gloves. They stated handling of the dressing during removal exceeded other dressings they used: 'much better' in 45.5%; 'somewhat better' in 51.5%; and 'the same' in 3.0%.

Case studies 1–3 (Fig 6–8), collected during the evaluation period, illustrate these findings. All images are reproduced with patient consent.

Discussion

Currently there is limited real-world research investigating adhesion qualities, pain and clinical performance of specific products for the treatment of patients with fragile skin. Due to the lack of evidence, most publications state that silicone adhesives should be considered based on the technology itself or expert opinion.[11,19] Similarly, product selection is based mainly on case and observational studies, with limited evidence exploring the prevention of MARSI. LeBlanc et al.[20] recommend using an atraumatic and non-adherent wound contact layer, such as silicone, for skin tear management to limit skin damage and trauma during dressing removal and to minimise pain. Fulbrook et al.[21] explored the use of silicone foam dressings versus silicone contact layer for managing skin tears. They concluded the adhesive silicone foam dressing may be superior, as it produced clinically significant healing of skin tears at three weeks compared with the meshed silicone interface dressing.

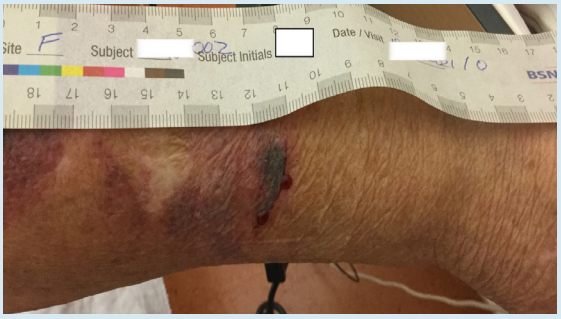
Various authors have reported benefits of using silicone dressings to maintain skin integrity in acute postoperative wounds, demonstrating superiority of silicone dressings in maintaining skin integrity, reducing dressing changes and costs.[22–25] Savine and Snelson[6] reported a case study using silicone adhesive dressings and fixation for prevention of skin damage in two patients with epidermolysis bullosa (EB). EB is a complex genetic disorder that causes extreme skin fragility, with patients at highest risk of skin damage, especially during dressing change. Patients reported a very high wearing comfort and less pain, while health professionals concluded that they would choose the investigated silicone dressings in future patients with EB to minimise skin trauma.

As the global population continues to age with significant increases in the number of older adults expected,[1] this demographic shift will likely lead to an associated increase in individuals who may experience MARSI due to comorbidities that can lead to fragile skin. Using gentle and skin-friendly wound dressings and fixation options with atraumatic removal should be a state-of-the-art approach to prevent additional skin damage during wound coverage and dressing changes.[15]

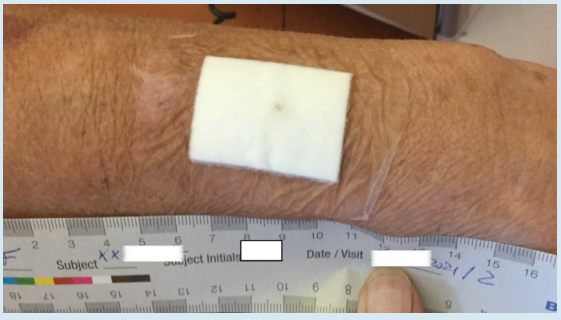
This present study using IMD-SA, with or without a wound pad, aimed to assess the clinical performance and safety of the dressings for intended use in daily clinical practice on fragile skin. The findings demonstrated reliable wound coverage with sufficient adhesion without negatively affecting the periwound skin after seven days of wear time for all patients. The removal of the IMD-SA did not cause any type of MARSI or skin reaction, including erythema, indicating that the IMD-SA can help to prevent the occurrence of MARSI and maintain skin integrity.

The importance of preventing periwound skin damage and its role in wound management has been

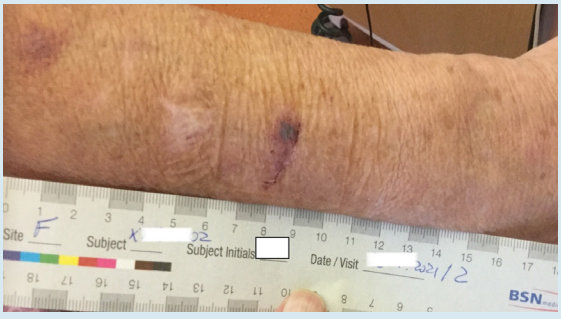
Fig 6. Case study 1: a 73-year-old female patient with a laceration on the left forearm and a high pain sensitivity. The surrounding skin was excoriated and erythema was present. After seven days of wear time the dressing was 90–100% adhered. No medical adhesive-related skin injuries or pain was reported during removal. Non-healthy skin conditions were resolved and an overall wound improvement was observed



Before application (Day 0)

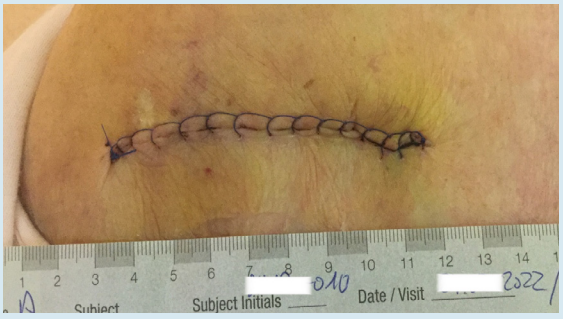


Before dressing removal (Day 7)



After dressing removal (Day 7)

Fig 7. Case study 2: an 88-year-old female patient with a surgical wound on the right shoulder and a normal pain sensitivity. Patient was sensitive for patch allergies. After seven days of wear time the dressing was 90–100% adhered. No medical adhesive-related skin injuries or pain was reported on removal. The patient was very satisfied with the wearing comfort and an overall wound improvement was observed



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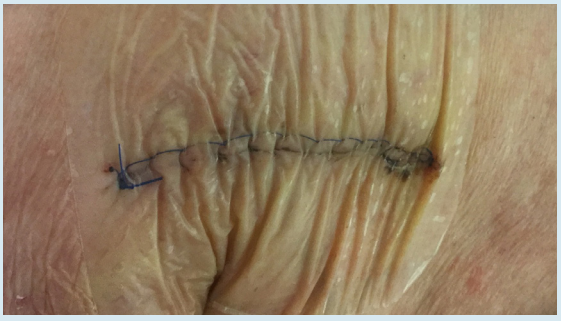
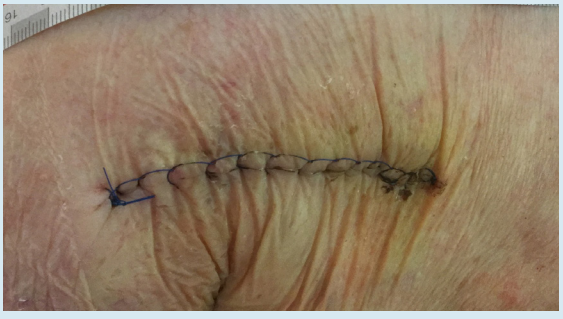


Before dressing removal (Day 7)



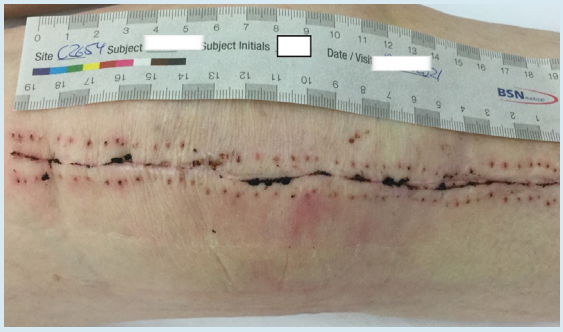
After dressing removal (Day 7)

discussed.[26,27] It was concluded that maintaining integrity of the periwound skin can enhance wound healing by decreasing wound size and reducing the risk of complications, such as infection, as well as improve quality of life (QoL), as pain and discomfort are diminished. [26,27]

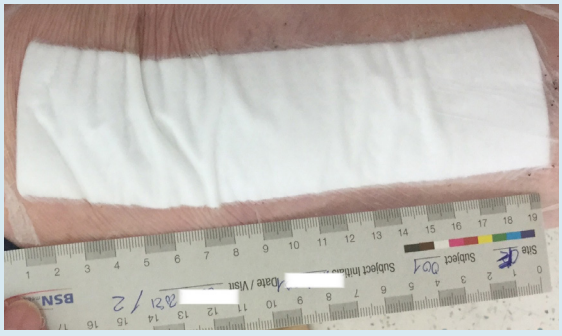
Our results demonstrate that integrity of the periwound skin was maintained and even improved for patients presenting with non-healthy periwound conditions, e.g., erythema and rashes. Furthermore, results showed a significant decrease in wound pain and an overall wound improvement was observed for 93% of patients.

The ability of the adhesive dressings to stay in place for up to seven days can play a significant role in maintaining an optimal healing environment, reducing risk of contamination and minimising disturbance to the wound.[28] Although some dressings did not adhere or only partially adhered after seven days, the majority of the IMD-SA protected the wounds with sufficient adhesion by covering them with an adhesion area of >75%. Limited adhesion occurred mainly in the outpatient group and in challenging clinical situations. For example, on a frequently moved part of the body (hand, ankle), a less than ideal initial application by the health professional or unintentional loosening due to some carelessness when changing clothes can affect adhesion. The importance of involving patients and carers in managing their own wound has been

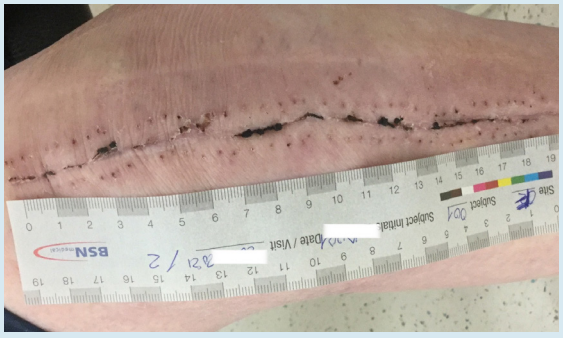
Fig 8. Case study 3: an 82-year-old female patient with type 2 diabetes and a surgical wound on the right knee. The patients fragile skin condition was caused by repeated taping. After seven days of wear time the dressing was 90–100% adhered. There was no medical adhesive-related skin injuries or pain on removal. Wound pain decreased from 3 to 0 (visual analogue scale) and an overall wound improvement was observed



Before application (Day 0)



Before dressing removal (Day 7)



After dressing removal (Day 7)

previously explored.[30–32] These articles state that specific wound care education for patients who are expected to self-care should focus on the wound healing process and strategies for managing patient expectations, including the function of wound dressings.[30–32]

MARSI can cause significant pain and negatively impact a patient's wellbeing and QoL, heightening the risk of wound healing complications.[33] Not educating or involving patients in their care can lead to a greater demand on limited resources and clinician time, increasing the number of outpatient or community-based appointments or extending the patient's hospital stay.[34]

Dressing removal was found to be painless or associated with minimal pain, even in patients with high pain sensitivity. This is particularly important for older patients, individuals with sensitive skin, and those with limited ability to express pain, such as infants, unconscious patients or those with dementia. Most patients rated both the wearing comfort and their overall satisfaction as 'very satisfied' or 'satisfied'. These findings are consistent with Pickles et al.[23] who concluded that using a silicone dressing improved wear time to seven days. Beele et al.[22] determined—in their prospective, randomised controlled clinical investigation comparing two postoperative wound dressings—that silicone-based wound dressings minimised pain and improved patient satisfaction.

This present study explored the suitability and satisfaction with the IMD-SA in daily clinical practice. Health professionals positively rated the ease of handling at application and removal, using gloves, with the vast majority reporting them as above average and excellent. These data underline the good usability of the IMD-SA in daily clinical practice, which is rated as superior to other dressings.

Limitations

This study was a non-comparative observational study inherently lacking a control group, which limits the ability to directly compare its findings with other treatments or products. Also, the presented study was conducted during the COVID-19 pandemic, which influenced recruitment of sites and patient numbers, both of which were fewer than planned. Further research, including larger-scale comparative studies, is needed to substantiate these findings.

Implications for practice

Silicone-based postoperative wound dressings are effective/important dressings and can be used multifaceted for patients with fragile skin. Leukomed T skin sensitive and Leukomed T plus skin sensitive may aid patient comfort due to their being gentle to the skin, reducing pain and discomfort during application and removal, especially for patients with fragile and sensitive skin or those with high pain sensitivity. Overall, the investigated medical devices were shown to be safe and effective in patients with fragile or impaired skin, and demonstrated their ability to maintain skin integrity, reduce complications and enable an undisturbed wound healing.

Conclusion

Overall, it can be concluded that this observational study demonstrated the ability of Leukomed T skin sensitive and Leukomed T plus skin sensitive to be safe and effective wound treatments in patients with fragile skin. Study results demonstrate that these dressings maintain sufficient adhesive properties for up to seven days and enable undisturbed physiological wound healing. Removal was perceived as almost pain-free without causing any new skin damage including MARSI, even in patients with initially non-healthy skin conditions. JWC

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