

# A silver alginate paste dressing in the management of non-malignant wounds with signs of infection in oncology patients: an observational prospective case series

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Oncology patients have a higher risk of developing wound complications associated with procedures and agents used for cancer treatment. This observational case series investigated the clinical benefits of a silver alginate paste dressing in the management of stalled or deteriorating non-malignant wounds showing clinical signs of local infection or considered at high risk of infection in cancer patients. Fifteen patients were managed using the same standard wound care protocol. Wounds were associated with complications of cancer treatment, such as surgery (surgical site complications) or radiotherapy (chronic radiation dermatitis). Data were collected at inclusion and at the end of week 1, 2, and 4. During follow-up, six wounds healed, two improved, four showed small improvements and three wounds did not change or deteriorated. The silver alginate paste showed efficacy to control clinical signs of infection from the first week. A careful and individualised use of this silver alginate paste in stalled or deteriorating wounds showing signs of local infection can help promote healing.

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**T**he development of complications and the resulting wound healing delay is a frequent issue in oncology patients.

This is associated not only with the patient's general condition and comorbidities, but also with specific significant risk factors linked to anticancer therapies, such as radiotherapy, chemotherapy, immunotherapy and surgery (Xue et al, 2012).

Chemotherapeutic agents adversely affect wound healing by inhibiting cellular metabolism, cell division and angiogenesis. Chemotherapy can inhibit the inflammatory response in the early stages of wound healing. Neutropenia induced by cytostatic agents is greatest 1 week after medications administration, which increases the risk of infection. Coagulation disorders linked to anti-neoplastic therapies (excessive bleeding or excessive clotting) also have a negative effect on the healing process (Lik, 2019).

Very rarely, acute radiation dermatitis induces skin necrosis and chronic wounds. In contrast, chronic radiation dermatitis evolves months to years after exposure to radiation therapy. Unlike

acute radiation dermatitis, chronic radiation dermatitis is unlikely to self-repair and tends to persist indefinitely. Long-term effects of radiation therapy include variable degrees of cutaneous atrophy, which weakens the skin and predisposes it to erosions, chronic wounds and an increased risk of infection. Furthermore, wound healing on previously irradiated areas takes a longer time, and closed wounds are often fragile and unpredictable (Di Carlo, 2020).

Surgery is an important treatment modality for cancer, which is used with curative, adjuvant or palliative purposes. Even if during recent years the extent of cancer surgery has become more conservative, cancer patients are still particularly at higher risk of developing surgical site complications.

Surgical site complications can be further classified as surgical site infections (SSI) and non-infectious wound complications. Common non-infectious wound complications in oncology surgery include haematomas, seromas, wound dehiscence and necrosis. These complications lead to longer hospital stay, additional procedures, and increased

risk of infection (Fraser et al, 2016). SSI is the second most common healthcare-associated infection in Europe and the US (World Health Organization, 2018).

Antibiotic resistance represents a challenge when treating SSI as a result of the increasing number of multidrug resistant microorganisms, such as extended spectrum  $\beta$ -lactamase bacteria and vancomycin-resistant enterococci (Hernaiz-Leonardo et al, 2017).

In general, bacterial colonisation does not impact negatively the process of wound healing in chronic wounds (Bowler et al, 2001). However, factors affecting the host response to bioburden, such as biofilms or altered blood circulation, may contribute to a delay in healing (Park et al, 2017; Rahim et al, 2017). In addition, it is well documented that cancer patients with wounds may have disturbances of their body image and alterations in their quality of life (Gerlach, 2005).

Over the last decade, a wide variety of advanced wound dressings have been developed, including many silver dressings. These contribute to healing improvement by decreasing the bacterial load. Silver ions are active against a broad spectrum of bacteria, yeasts and viruses, including many antibiotic-resistant bacteria (Leaper, 2012; Swathy et al, 2014).

Askina® Calgitrol® (B. Braun) is a range of silver wound care products that includes Askina® Calgitrol® Paste, a silver alginate wound paste (SAWP). A previous clinical assessment of the Askina silver alginate dressing showed an improvement in the clinical and bacteriological status of chronic wounds (Trial et al, 2010). In an *in vitro* assessment, the silver alginate dressing absorbed and released more moisture than four other comparator antimicrobial dressings (Aramwit et al, 2010). In partial-thickness burns this SAWP was found to be superior to a 1% silver-sulfadiazine dressing regarding wound healing time, pain improvement, number of wound dressings required and nursing time (Opasanon et al, 2010).

The SAWP formulation was also evaluated in a small case series of patients with infected diabetic foot wounds. A 2-week treatment showed reduction of clinical signs of infection, effective exudate management, and improved wound progression (Chadwick, 2013).

However, published reports about the use of silver alginate pastes for the management of infected wounds or those at risk of infection wounds in cancer patients could not be found.

## Aims

The main objective of this research was to

investigate the clinical benefit of a specific SAWP dressing (Silver Alginate Askina® Calgitrol® Paste, B Braun Medical) on wound healing progression when used for the local management of infected or at risk of infection non-malignant wounds in cancer patients.

Secondary objectives included:

- To assess the effect of the SAWP on local clinical signs of infection
- To use the generated evidence to explore the feasibility of further clinical research.

## Materials and methods

This clinical work was designed as an observational prospective case series with the aim to assess the test product in oncology patients under standard wound treatment at the Research and Wound Care Unit of the Institut Curie, Paris, France. All included patients had complex wounds showing delayed healing and clinical signs of infection, or high risk of infection. This research did not include patients presenting with malignant or fungating wounds. All included patients were treated with a SAWP.

The test product is a calcium alginate matrix combined with ionic silver. It is described as highly conformable because the paste formulation allows for close contact with the wound bed. The SAWP has registered indications for the management of partial to full thickness wounds; pressure ulcers (categories II–IV); venous, arterial and neuropathic ulcers; second degree burns; and donor sites. It may be used under medical supervision for the management of infected wounds.

After cleansing with saline solution, the SAWP was applied directly to the wound bed, then covered with gauze or other similar absorbent dressing. Mechanical debridement was performed only if clinically indicated. The SAWP is supplied sterile in a tube with a long cannula, which facilitates application into tunnels, sinuses, cavities and awkward-shape wounds, and was applied as a thick layer to the entire surface of the wound bed in most cases. Dressing changes were performed daily or every 2 days depending on the wound status.

Initial data recording included patient demographics and associated factors promoting wound breakdown, such as malnutrition, pressure or tension on the wound edges, and in particular the presence of factors related to cancer treatment, e.g. whether the wound was located on a previously irradiated area.

Wound and clinical evolution data were recorded at the initial assessment and follow-up visits (end of week 1, 2 and 4). Local signs

**Table 1. Demographics, type of wounds, location and prior evolution.**

Patient number	Age (years)	Sex	Wound type	Wound as a complication of	Anatomical location	Wound evolution before inclusion
1	45	F	At risk of infection	Surgery	Thorax	Stalled
2	78	F	At risk of infection	Radiotherapy	Head	Stalled
3	71	F	At risk of infection	Venous insufficiency	Lower limb	Deteriorating
4	71	M	Infected	Radiotherapy	Thorax	Stalled
5	76	F	Infected	Surgery	Thorax	Stalled
6	67	F	At risk of infection	Surgery	Thorax	Deteriorating
7	71	M	Infected	Surgery	Head – neck	Stalled
8	67	M	Infected	Surgery	Head – neck	Stalled
9	72	F	At risk of infection	Surgery	Thorax	Stalled
10	70	M	At risk of infection	Surgery	Abdomen	Stalled
11	80	F	Infected	Surgery	Thorax	Deteriorating
12	61	F	At risk of infection	Surgery	Thorax	Stalled
13	69	F	At risk of infection	Surgery	Abdomen	Stalled
14	44	F	At risk of infection	Surgery	Thorax	Deteriorating

**Table 2. Average wound duration prior to inclusion versus outcome.**

	Wounds that healed	Wounds that did not heal
All patients (n=15)	29 days	165 days
Excluding outlier venous leg ulcer (n=14)	NA	90 days

of infection were clinically assessed and detailed as: periwound erythema, presence of purulent exudate, level of exudate, unexpected wound changes, darkening of the wound bed, development of new lesions on the periwound skin, sudden wound deterioration, and pain.

Pain was assessed using a visual analogue scale of 0–10 (where 0 = no pain and 10 = unbearable pain). The initial pain assessment took into consideration pain associated with previous wound treatment and actual wound-related pain.

Odour was assessed using a four-point scale (1 = none, 2 = slight, 3 = moderate, 4 = intense), as described by Fromantin et al (2014).

At each assessment, data on concomitant treatments (antibiotics and analgesics) were documented, as well as data on the ease of use of the SAWP (application and removal).

Data recording was stopped after the week 4 assessment; however, the SAWP was continued in some patients if clinically indicated. Assessments also included the investigation and reporting of any adverse events.

As the SAWP is CE marked and considered compatible with our institution's standard wound care protocols, ethics committee

approval was not required. Data from patients were treated following regulations of the French Health Data Protection Agency. An information letter was provided to patients on their first day of evaluation. After collection, all data were anonymised.

Data analysis included only descriptive statistics. Given the study design and the population size, comparative tests and statistical significance analysis were not planned.

## Results

Data were collected from 15 patients who were treated at least once with the SAWP dressing. The mean age of the patients was 64.8 years (range 30–80 years), with 11 women and four men. For all patients, the intention of the cancer treatment was curative. At the initial assessment, none of the patients were receiving systemic antibiotics.

Lesions were associated to complications after surgical treatment in 12 patients (breast cancer, melanoma, liposarcoma and colorectal cancer), complications associated with chronic radiation dermatitis in two patients, and one venous leg ulcer. The venous leg ulcer was not cancer related, however, the cancer and the associated treatment affected the VLU healing.

Prior to inclusion, wounds were stalled in 11 patients and deteriorating in four patients. Wounds in five patients showed clinical signs of infection and wounds in the other 10 patients were clinically considered at high risk of infection. *Table 1* presents demographics and wound type information.

**Table 3. Clinical symptoms and signs of wound infection, distribution and evolution at initial, week 1 and week 2 assessments.**

Wounds	Patients assessed	Pain	Periwound erythema	High level exudate	Purulent exudate	Wound changes	Wound bed darkening	Smell	Periwound skin lesions	Sudden wound changes	Total
<b>Initial assessment</b>											
Infected	5	5	3	3	4	0	0	1	1	0	17
At risk of Infection	10	3	1	3	0	1	1	1	1	1	12
<b>Total at initiation</b>	<b>15</b>	<b>8</b>	<b>4</b>	<b>6</b>	<b>4</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>1</b>	<b>29</b>
<b>Week 1 assessment</b>											
Infected	4	3	0	2	2	0	0	0	0	0	7
At risk of infection	10	1	1	0	0	0	0	0	0	1	3
<b>Total W1</b>	<b>14</b>	<b>4</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>10</b>
<b>Week 2 assessment</b>											
Infected	4	0	0	0	1	0	0	0	0	0	1
At risk of Infection	9	0	1	0	0	0	0	0	0	0	1
<b>Total W2</b>	<b>13</b>		<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2</b>
<b>Total</b>	<b>12</b>	<b>6</b>	<b>8</b>	<b>7</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>41</b>

The mean wound duration before inclusion was 114 days (range 15–730 days,  $n=15$ ). Additional data comparing wound duration versus outcome is presented in [Table 2](#).

The SAWP dressings were applied for a mean duration of 32 days (1–58 days).

#### Clinical signs of infection

At the initial assessment, 29 symptoms and signs suggesting infection were identified in all patients (17 in infected wounds and 12 in wounds at risk of infection). These numbers excluded delayed healing, as it was present in all patients. Pain was the second most commonly found clinical sign after delayed healing, followed by high exudate level, purulent exudate and periwound oedema. The average number of clinical signs suggesting infection was 3.4 for the infected wounds (range 2–5) and 1.2 for the wounds considered at risk of infection (range 0–4). The number of clinical signs associated with wound infection decreased to 10 (average 1.75 and 0.4, respectively) at the week 1 assessment. [Table 3](#) presents the distribution of clinical signs by wound type at initial, week 1 and week 2 assessments.

#### Pain assessment

At inclusion, when considering the entire population, the average pain score related to previous treatments was 1.0 (range 0–4). When assessing wound-related pain only, the average

score was 1.67. All patients with clinically infected wounds (5/5), and three patients with wounds at risk of infection (3/10) reported some level of wound pain. The average pain score reported by patients with infected wounds was 3.4 (range 1–5), while patients with wounds at risk of infection reported an average pain score of 0.8 (range 0–4). Only five patients required weak analgesics. After one week of treatment, pain scores improved; the average score was 1.1 for the entire population, 2.0 in patients with infected wounds and 0.4 in patients with wounds at risk of infection.

#### Odour assessment

In general, wounds did not present bad odour. Odour was considered “intense” (grade 4) in wounds of two patients (one infected and one at risk of infection) at the initial assessment only. In both cases, odour was controlled with the proposed wound management.

#### Wound evolution

Complete healing was obtained in six cases (40%) during the observation period, two in patients with infected wounds and four in patients with wounds at risk of infection. In other two patients, wound evolution was considered good (reduction in wound size, healthy granulation tissue and advancing epidermisation). Follow-up for one patient was stopped at day 1 because systemic antibiotics

**Table 4. Wound evolution under treatment with the SAWP and associated risk factors.**

Patient	Wound Type	Time SAWP used	Risk factors for wound complications	Wound evolution after treatment with SAWP
1	At risk of infection	2 weeks	Increased tension at wound edges, previously irradiated area, chemotherapy, hormone therapy	Slow evolution, some mild hypergranulation
2	At risk of infection	4 weeks +	Irradiated zone	Epidermisation between exostosis
3	At risk of infection	4 weeks +	Malnutrition, smoking, venous insufficiency, oedema lower limbs	Good evolution, reduction of wound size
4	Infected	4 weeks	Malnutrition, radiotherapy	Healed
5	Infected	4 weeks	Recurrent breast cancer, malnutrition, previously irradiated area, chemotherapy	Healed
6	At risk of infection	4 weeks +	Total mastectomy with axillary clearance, increased tension at wound edges	Slow evolution – unhealthy granulation tissue
7	Infected	2 weeks	Metastatic melanoma, chemotherapy	No evolution after 2 weeks
8	Infected	4 weeks	Previously irradiated area, oedema	Persistent purulent exudate, osteitis diagnosed, required treatment change
9	At risk of infection	1 week	Total mastectomy with axillary clearance, chemotherapy	Good evolution, reduction of wound size. Left study at week 1 as radiotherapy started, required revision
10	At risk of infection	4 weeks +	Metastatic liposarcoma, radiotherapy, chemotherapy, abdominal wall reconstruction with prosthetic mesh	Slow evolution, some signs of improvement
11	At risk of infection	1 day	Area previously irradiated, treated with artificial dermis	Follow-up stopped, required systemic antibiotics
12	At risk of infection	3 weeks	Total mastectomy with axillary clearance, area previously irradiated, hormone therapy. Reconstruction with DIEP free flap	Healed
13	At risk of infection	4 weeks	Colorectal cancer, left hemicolectomy, increased tension at wound edges	Healed
14	At risk of infection	2 weeks	Mastectomy with axillary clearance, chemotherapy, hormone therapy	Healed
15	At risk of infection	2 weeks	Partial necrosis after DIEP reconstruction, chemotherapy, hormone therapy	Healed

were required. The SAWP was stopped after 1 week for another patient who required immediate radiotherapy; the silver ions contained in the dressing were not considered compatible with radiotherapy. In four patients there was some wound improvement, but the evolution was slow, and finally in two patients, wounds (both infected) did not improve and required surgical revision. Details on wound evolution are presented in [Table 4](#).

#### Wound tissue type evolution

At inclusion, necrosis was present over a very small surface (2% of average wound surface, AWS); slough tissue, which represented a small percentage of AWS (9%), decreased over the next 2 weeks, and was absent at the final assessment.

Granulation was the predominant tissue type for all wounds, it represented 82% of the AWS at inclusion. Granulation decreased steadily

as wounds healed, but still was predominant at the final assessment (56% of the AWS). Epithelialisation represented only 7% of the AWS at inclusion. Epithelialised surface increased progressively as wounds healed. [Figure 1](#) presents the weekly evolution of wounds tissue type as a percentage of the AWS.

#### Ease of use of SAWP dressings

For all patients and across all assessments, nurses graded the application and removal of the paste as “easy”. The use of the cannula applicator facilitated the intimate contact of the SAWP with all wound surfaces, especially in cavity wounds.

#### Dressing tolerability

The SAWP was well tolerated in all patients. None of the early treatment discontinuations were associated with tolerability issues with the study product.

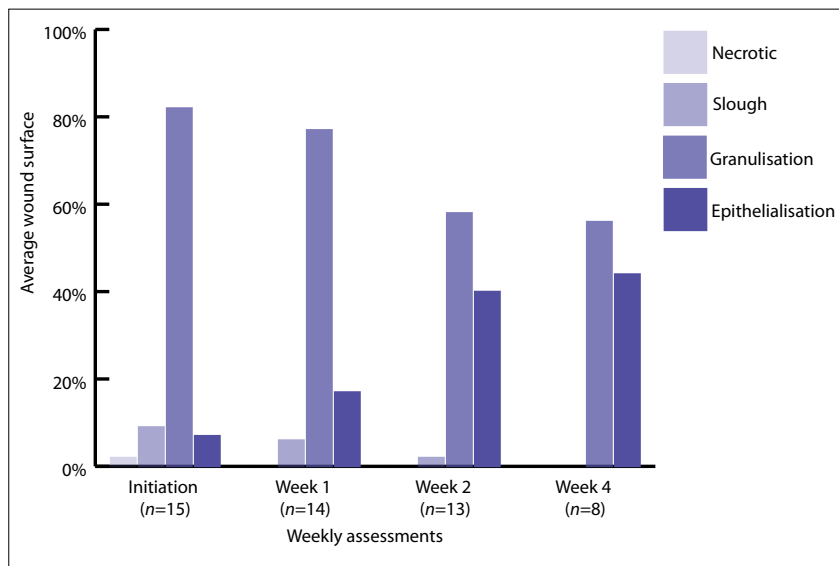


Figure 1. Tissue type evolution.

#### Adverse events

No study-device-related adverse events were reported during this study.

Maceration of the periwound skin was reported in one patient, which was related to the level of exudate and the capacity of the secondary dressing to retain absorbed exudates. Maceration responded well to wound management and resolved within days with no residual problems.

#### Discussion

This is the first study to explore the impact of a SAWP dressing in the management of non-malignant wounds in oncology patients. Cancer patients have multiple risk factors that result in an increased incidence of treatment-related complications.

Based on data from more than 17,000 patients, Olsen et al (2017) reported an incidence of 14.5% for surgical complications after mastectomy, with or without immediate breast reconstruction, a rate more than three times higher than the incidence of complications after clean surgery in the general population.

In our series, use of the SAWP was generally positive, as evidenced by a relatively quick effect on a majority of infection-related clinical signs from the first week of treatment, with almost full control after 2 weeks. Wound tissue type evolution was also consistent with the evolution of other clinical indicators. Local wound care, combining wound cleansing and sequential treatment with the SAWP for a minimum of 2 weeks, helped to optimise the therapeutic strategy.

This therapeutic approach seems appropriate when managing stalled or deteriorating wounds that are clinically infected or at risk of infection. Delayed healing indicates host compromise, and a good clinical response to antimicrobial dressings (healing) confirms the bacterial aetiology, whereas a persistent healing delay should drive us to search for a different cause and to modify the treatment.

During the observation period, six wounds healed completely and two others showed clear improvement. Wounds that healed in full during the study were of a shorter previous duration than those that did not heal (29 days versus 165 days, respectively). This is not surprising as it is well known that previous shorter wound duration is directly related to better healing rates; a longer previous wound duration is commonly associated with an excessive and persistent inflammatory stage (Bosanquet and Harding, 2014).

Better outcomes were shown in wounds with superficial infection. The SAWP seemed less appropriate for wounds with complicated deep infection (abscess or osteitis), for which revision surgery was necessary.

Swabbing is not part of our standard protocol of care for infected wounds because there is a risk of wrong or delayed bacteriological diagnostic. Swabbing is more likely to collect bacteria colonising the wound surface rather than deeper bacteria, which are generally more responsible for infection. A similar situation has been described for infected malignant wounds, in which the responsible pathogens are deeply located. This explains why the use of some antimicrobial dressings, which normally show efficacy on chronic wounds, is not efficacious on infected malignant wounds (Lund-Nielsen et al, 2011; Fromantin et al, 2014). Based on this, infected malignant wounds were not included in this study. Further research would be needed to define if this SAWP might be beneficial or not in the management of fungating or malignant wounds.

In addition, this work did not include any patients with acute radiation dermatitis. It is important to remember that alginate silver dressings are not indicated for the management of acute radiation dermatitis, particularly stages 1, 2 and 3.

Pain was present in some patients, particularly those with infected wounds. Pain scores were low to moderate at inclusion and during the first week. No wound-related pain was reported after the week 1 assessment. During the first week, weak analgesics were needed for five patients,



and only one required local anaesthesia. Results indicate that the SAWP contributed to pain control in two ways: first through control of infection signs and second through the avoidance of pain during application and removal, which might be linked to this SAWP's physical characteristics (non-sticky and conformable).

The SAWP seems well adapted for application on low to moderate exuding wounds, with the alginate matrix contributing to exudate management. The study confirmed that the SAWP is well adapted to dress superficial, as well as cavity wounds and hard-to-wick wounds, as in all cases, nurses rated the application and removal of the paste as "easy". This is important for wound care delivered in the community, where dressings should be efficacious, comfortable, and easy to use.

Although QoL was not specifically assessed, this study showed that by providing an appropriate wound care protocol, patient comfort can be improved and patient distress decreased. These benefits are important when managing cancer patients, who face heavy treatments and long recovery periods.

Tolerance to the SAWP was good. In addition, no SAWP-related adverse events were reported.

Due to the complex nature of cancer therapy and the impact of wound infection, healthcare professionals must adapt the protocol of care individually to every patient's requirements in order to optimise outcomes and improve patient's QoL.

The population size, the absence of comparator and the predominance of breast cancer patients and wounds at risk of infection in this series can be seen as limitations. However, this work shares similarities with what is currently defined as real-world evidence. The study included a small but representative sample of the type of patients we treat every day in our hospital; patients received standard care and no specific inclusion/exclusion criteria were applied.

Due to the physical characteristics of the SAWP and because part of its action follows the release of ionic silver, in the absence of evidence from well-designed comparative studies, findings from this research should not be generalised to other silver alginate dressings.

These results can be directly extrapolated to clinical practice and could be helpful to plan further research in oncology patients under the form of a comparative trial versus other therapeutic alternatives to confirm these encouraging initial findings.

## Conclusion

The results of this case series showed that the study SAWP is effective, well tolerated and safe for the treatment of infected and at high risk of infection non-malignant wounds, resulting from complications associated with cancer treatment.

A careful and individualised use of this SAWP (and possibly of other ionic silver dressings) for the management of wounds showing signs of local infection can help promote healing.

This SAWP represents a valid and reasonable addition to the list of products available to treat wounds with clinically confirmed or suspected infection.

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## Disclosure

*MN, MC, IK, and IF have no conflicts of interest to declare. B. Braun Medical paid HJ some honoraria for consulting services to support translation, data analysis and editorial services for this article.*

*No ghost-writers were used in writing this article.*

*This article complies with the guidelines on authorship of the International Committee of Medical Journal Editors (ICMJE).*

## Acknowledgements and funding

*This research was sponsored by the Research and Wound Care Unit of the Curie Institute.*

*B. Braun Medical provided the SAWP dressings used during this clinical research free of charge.*