Management of malignant fungating wounds with a bioactive microfibre gelling technology dressing: an evaluation

KEY WORDS

- Case Studies
- Oncology Wounds
- Bioburden
- Odour Reduction

Aim: In this article, we aim to raise awareness of some of the clinical concerns surrounding the management of oncology wounds, particularly malignant fungating wounds. We will also provide practical wound management recommendations for healthcare professionals to consider when managing this wound type. We aim to assess the potential of a 100% chitosan with Bioactive Microfibre Gelling (BMG) dressing (MaxioCel), to support wound management and work in partnership with industry to deliver clinical education on the management of oncology wounds, including malignant fungating wounds. **Method:** A 10-patient case study series was undertaken four weeks, using the chitosan BMG dressing. **Results:** The chitosan BMG dressing facilitated a significant improvement in wound tissue type and managed exudate well, improving periwound skin and reducing malodour. A reduction in patient-reported pain levels also was noted throughout the evaluation process. **Conclusion:** The introduction of BMG fibre technology demonstrated good outcomes in this patient group, in a short period of time. Importantly for this patient group, the BMG dressing was able to remain *in situ* during radiotherapy treatment allowing uninterrupted management of the wounds

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According to Cancer Research UK between 2016–2018 there were 375,400 new cases of cancer (Cancer Research UK, 2023). Patients with cancer often suffer from acute or chronic wounds caused by either the disease itself or the effects of cancer treatment. These wounds present many challenges for the patient, thier family and multidisciplinary team treating them.

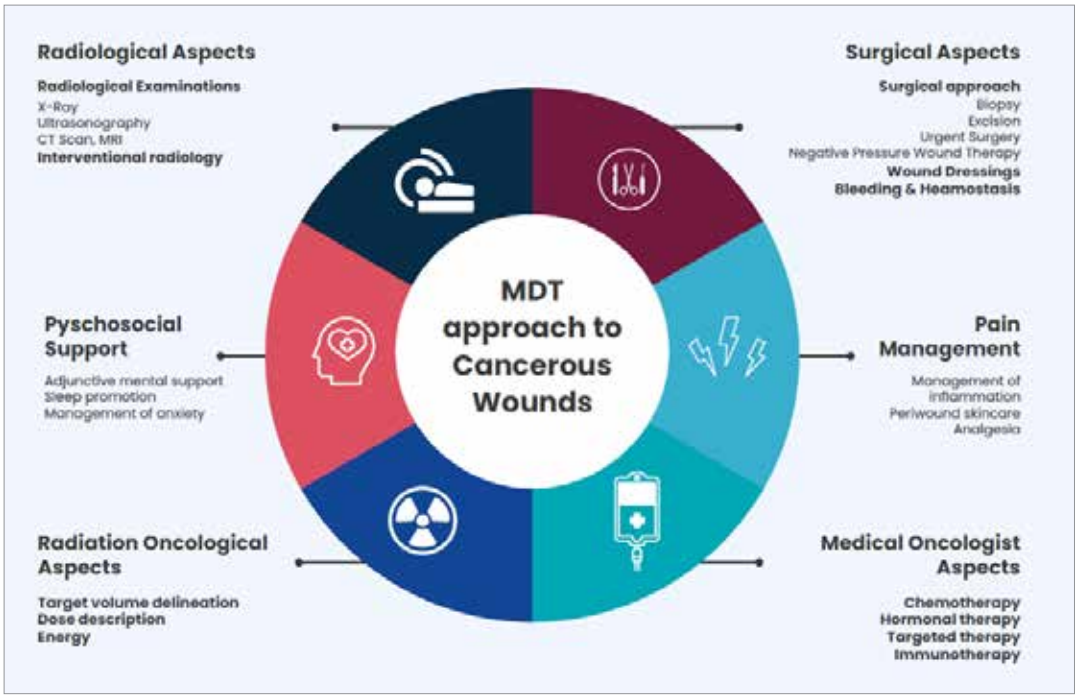
Cancer itself can cause wounds in the form of multiple skin lesions or malignant fungating wounds (Naylor et al, 2001). Malignant fungating wounds are often non-healing wounds, which are caused by the aggressive proliferation of malignant cells and tumours that infiltrate the epidermis, blood vessels and underlying structures in advanced cancer patients (Grocott et al, 2013). Malignant fungating wounds can result from primary, secondary or recurring malignant disease (Alexander, 2009) and often become infected, although data on this is limited (Vardhan et al, 2019).

The wounds can be odorous, produce large amounts of exudate, bleed easily, cause psychosocial distress and are a constant reminder to the patient and family of progressive cancer (Schultz et al, 2002). The symptoms attributed explicitly to malignant fungating wounds are unique to this population (Tilley et al, 2016). Malignant fungating wounds are predominantly developed during the last months of life and indicate the impending end of life (Alexander, 2010).

An interdisciplinary approach with continuous consultation between various specialists can support patient management (Furka et al, 2022). Patients experiencing an oncology or malignant fungating wound require a comprehensive treatment solution to alleviate severe symptoms (Figure 1).

The prevalence and challenges of malignant fungating wounds

Non-healing fungating wounds without effective therapy are a severe socio-economic burden for



Figures 1. Developed from: Furka, Andrea et al. "Treatment Algorithm for Cancerous Wounds: A Systematic Review." Cancers vol. 14,5 1203. 25 Feb. 2022,

all onvolved, including patients, caregivers, and health services (Furka et al, 2022). Cancer patients with wounds may have difficulty with symptom management, disturbances of body image, decreased feelings of self-worth and alterations in their quality of life (QoL). Such wounds often affect every aspect of an individuals life for example, work, socialisation, and relationships. This can be due to prolonged healing times, the repeated need for medical attention in the form of dressing changes, alongside pain, infection, and odour (Olsson et al, 2019).

Chronic wounds affect up to 2.21 per one thousand individuals and significantly impact rates of morbidity (Martinengo et al, 2019; Sen, 2019). It is much more challenging to assess the prevalence of malignant fungating wounds, a subset of chronic wounds as there is no registry monitoring the incidence of the wounds.

A survey of 269 nurses in Switzerland, run over a six month period, found the prevalence of malignant wounds in patients with metastasised cancer was 6.6% (Probst et al, 2009). However, this was a nurses survey, not a prospective prevalence study and the overall number of samples were small, all of which means it may not represent the world population. Furthermore, the prevalence of malignant wounds is thought to be underreported due to feelings of shame, fear and embarrassment (Alexander, 2009).

A systematic review of literature published between 1995 and 2020 (Tilley et al, 2021) found that malignant fungating wounds can develop from any type of malignancy, the most prevalent are associated with breast cancer (66%), followed by head and neck tumours (24%), the groin, genitals, and back combined account for 3%, and all other sites account for 7%. According to Tilley et al (2016), malignant wounds are a global health problem, and their incidence is expected to rise as the ageing population grows due to improvements in treatment.

Cancer wounds have a dynamic bacterial flora when compared with chronic wounds (Fromantin et al, 2013). Symptoms of malignant fungating wounds are already a result of an imbalance created by bacterial species, type, and total bacterial load (Vardhan et al, 2019). There is greater difficulty in diagnosing infection in malignant wounds since they often emit malodours, exudates, and necrosis, and their clinical signs are not indicative of bacterial imbalances (Fromantin et al, 2023).

A Cochrane review in 2014 found relatively little evidence for using topical agents and dressings to improve the QoL in people with malignant fungating wounds (Adderley and Holt, 2014). Malignant fungating wounds rarely heal unless the tumour is treated with radiotherapy, chemotherapy, immunotherapy, or surgery which is all the more

Table1: Clinical benefits and mode of action of MaxioCel Dressings	
Clinical Benefit	**MaxioCel mode of action**
Haemostat	The positively charged chitosan fibres of this BMG dressing attracts negatively charged blood cell membranes, initiating the agglutination of red blood cells and platelets (Chen et al. 2017). This promotes the activation of thrombin, which activates the clotting pathway, leading to thrombus formation to activate haemostasis
Antimicrobial / Antibiofilm action	Oncology wounds can become infected and run the risk of increased and repeated infections which was seen during this evaluation. The positively charged chitosan fibres attract, disrupt and kill bacteria within the dressing therefore reducing the bacterial load which is a barrier to healing. Biofilms adhere to the gel matrix when the dressing is changed the biofilm is removed
Odour Management	The Bioactive Microfibre Gelling (BMG) dressing demonstrated the ability to reduce odour by facilitating removal of the devitalised tissue and slough
Exudate Management	BMG technology and the dressings vertical wicking action allows for increased absorbency and strength. This resulted in effective exudate management and peri wound skin protection together with longer dressing wear time which improved patients quality of life due to reduced dressing changes and clinic visits. The dressing was also able to be removed in one piece
Pain Reduction	Chitosan has been shown to have the ability to prevent the release of, and to help absorb the bradykinin that is released at the wound site and causes pain by directly stimulating primary sensory neurons (Okamoto et al, 2002)
Promotion of Wound Healing	The BMG dressing aids autolytic debridement in helping to remove slough and necrotic tissue. BMG Chitosan fibres have demonstrated cell migration similar to a positive control, demonstrating no toxicity and reflecting its contribution to supporting wound healing (Edwards-Jones, 2023)
Reduction of inflammation	The inflammatory response is essential for wound healing. However, in many wounds,chronicity is associated with wounds remaining in this inflammatory phase with inflammatory proteins and other cytokines beginning to interfere with the healing process, this can lead to wound stasis and pain. Chitosan has a positive effect in reducing chronic inflammation. The BMG dressing has been shown to significantly reduce levels of matrix metalloproteinases (MMPs).

challenging due to the advancement of cancer and only given for palliation (Leadbeater, 2016).

In our Trust there was an unexplainable increase of 94.4% of referrals for malignant fungating wounds in a year following COVID-19 pandemic. This may be chance, or due to the COVID-19 pandemic, resulting in late cancer diagnosis or delayed referral. A potential gap in the education around the management of oncology wounds may also be a potential causative factor. As a tissue viability team, we wanted to raise awareness of some of the clinical issues surrounding the management of oncology wounds, as well as practical wound management recommendations working as part of a multidisciplinary team (MDT), which could serve as a guide for healthcare professionals in future management of this wound type.

The Challenge of Dressing Selection

According to the radiotherapy skin guidelines of the Trust, silver dressings (antimicrobial) are not appropriate to use while patients are undergoing radiotherapy. Even though there is limited evidence in the use of antimicrobial in malignant fungating wound management (Finlayson et al, 2017), antimicrobial dressings are widely used in clinical practice and recognised to have a role in the reduction of odour (Gethin et al, 2023).

In addition, finding an option for patients to undergo radiation therapy while wearing a dressing was a challenge, since radiographers are not trained to dress a complex wound after radiotherapy [AQ1: not sure what you are trying to say here, feels like two unrelated sentances]. If the radiotherapy dose was calculated with the dressings on, there was no

Table 2: Baseline demographics of the patients recruited for this evaluation.

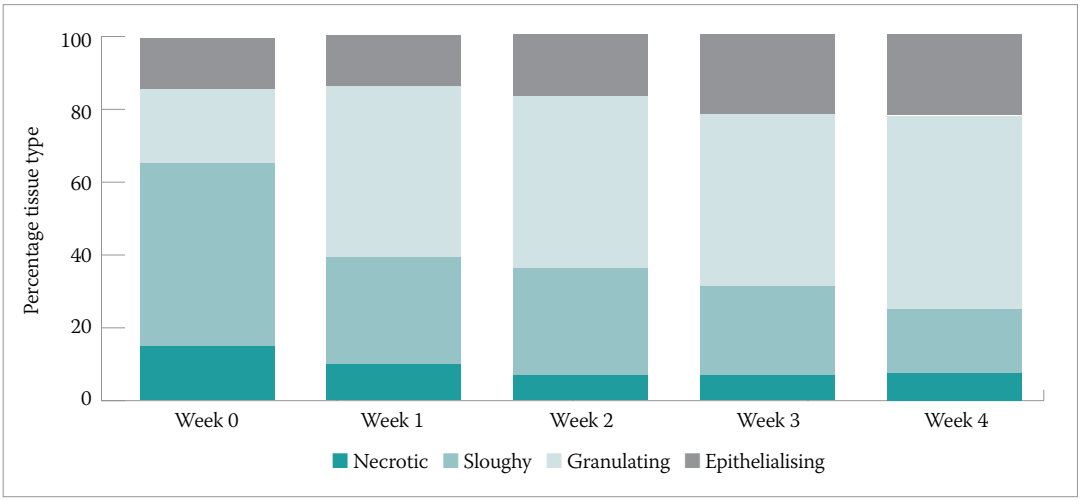
Patient	Wound Type	Wound Location	Wound Duration	Presenting Factors	Previous Dressing Used
1	Malignant fungating tumour	Left side of neck	12 months	High exudate levels, VAS Pain score of 5, slight excoriation to periwound, 30% slough, 50% granulation, 20% over granulation.	Silflex®, Flaminal®, Eclypse®.
2	Malignant fungating tumour	Left breast	7 months	Static wound, very high exudate levels, excoriated periwound, 50% necrosis and 50% slough. Pain level of 8 on VAS.	Aquacel® AG Extra, Flaminal®, CliniSorb®, Zetuvit® Plus.
3	Malignant fungating tumour	Sacrum	25 years	Static wound, moderate levels of exudate, eczematous periwound, 50% slough, 25% granulation, 25% epithelialisation, Pain level of 7 on VAS.	CarboFlex®, Gamgee® padding, Micropore®.
4	T Cell Lymphoma	Left arm	7 months	Static, high levels of exudate, excoriated painful periwound, 80% necrosis, 10% slough, 10% granulation, Pain level of 8 on VAS.	Aquacel® AG, Flaminal® Forte.
5	Fungating nodule disease, squamous cell carcinoma	Left side of neck	1 month	Deteriorating, high levels of exudate, macerated and excoriated periwound, 10% necrosis, 90% slough, pain level of 2-4 on VAS.	Flaminal® Forte, Silflex® Contact, Aquacel® Extra, PolyMem®.
6	Differential squamous cell carcinoma, malignant fungating wound.	Lower mandibula	13 years	Static, very high levels of exudate, dry/ eczematous periwound, 5% necrosis, 35% slough, 60% granulation, Pain levels of 4-7 on VAS.	Kaltostat®, Kliniderm®, Aquacel® Ag®.
7	Malignant fungating wound	Breast	18 months	Deteriorating, moderate levels of exudate, macerated periwound, 80% slough, 20% granulation, pain levels of 5 on VAS.	Mepilex® Border, Flaminal® Forte.
8	T Cell Lymphoma	Left side of back	6 weeks	Static, low exudate levels, 5% granulation, 95% epithelialisation, pain level of 4 on VAS.	Kliniderm®, Aquacel® Ag.
9	Fungating Ulcer	Groin	16 months	Deteriorating, high exudate levels, 5% necrosis, 60% slough, 35% granulation, healthy periwound. Pain level of 7 on VAS.	Aquacel® Ag, Flaminal® Forte.
10	Lymphoma	Multiple sites: arm, leg	9 years	Deteriorating, moderate exudate levels, 100% slough, maceration to periwound, pain level of 3 on VAS	Flaminal®, Aquacel® Ag.

need for the dressings to be removed while treating the patient with radiotherapy.

A new chitosan bioactive microfibre gelling (BMG) derssing, MaxioCel, was recommended to our Trust for evaluatation in our patients and to determine if it can overcome the challenges staff face with dressing changes during radiotherapy. We wanted to ensure that patients are getting the full benefit of a dressing's properties by not having to take them off every day, which is not necessary in most cases. These properties included haemostatic, antimicrobial, antibiofilm action; odour and exudate management; supporting a reduction in inflammation and wound pain and promotion of wound healing (Table 1).

chitosan bioactive microfibre gelling (BMG) technology

MaxioCel is a chitosan wound dressing with BMG technology. The gelling mechanism of BMG fibres enable the dressing to maintain a cohesive structure with increased fluid absorption capacity. The



Figures 2. Percentage tissue type

dressing, with vertical wicking, is intended for the management of moderate-to heavy wound exudate with fluid-locking ability that prevents saturation, and consequently periwound skin maceration.

Due to the absorption of bradykinin and proton ions that are released within an inflammatory site chitosan has also been found to have analgesic properties (Mo et al, 2015). Additionally, the reduction in exudate due to dressings absorption capability also improves periwound skin, which helps reduce the pain experience, and increases comfort levels for patients.

Grade A Chitosan is proven to have an antimicrobial effect against a range of common and uncommon wound pathogens [AQ2: provide references]. MaxioCel works in multiple ways against bacteria, including breaking down the cell wall and killing bacteria within the BMG fibres. MaxioCel's BMG fibres are positively electrostatically charged, naturally attracting negatively charged pathogens and trapping, disrupting, and killing them within the dressing fibers. This dual action affect against wound bioburden supports the application of MaxioCel as an ideal first line primary dressing for protecting wounds and granulation tissue.

METHOD

A patient evaluation was undertaken to assess the impact of chitosan BMG derssing over a four-week period at the Christie hospital, Manchester. All patients consented to take part in the study, signing Trust's informed consent forms as well as company consent forms. Consent was also given for use of imagery taken during the evaluation period which was supported by the hospital's medical illustrations department. [AQ3: use of the data was also given?]

Patient recruitment was initially across the hospital trust and upon discharge the evaluation continued across the wider community..

RESULTS

Wound types included: fungating tumours to the neck (2) breast (2) sacral tumour (1) submandibular (1) groin (1) and three patients with lymphomas (3). The Table 2 details the baseline demographics of the patients recruited, including wound types, location, duration, presenting factors and previous dressings used, to provide an overview of the clinical challenges faced

By conclusion of the four-week evaluation period the patient's wound status was assessed as: healing (7), almost healed (2), non-healing (1). The average wound area reduced from 51cm^2 on initial assessment, to 44cm^2 at final assessment.

The wound tissue type improved throughout the evaluation period, with increased re-epithelialising and granulatation tissue incresing from 34.5% at presentation to 68.5% at final assessment. There was also a decrease in sloughy and necrotic tissue from 65.5% at presentation to 25.5% by final assessment (Figure 2).

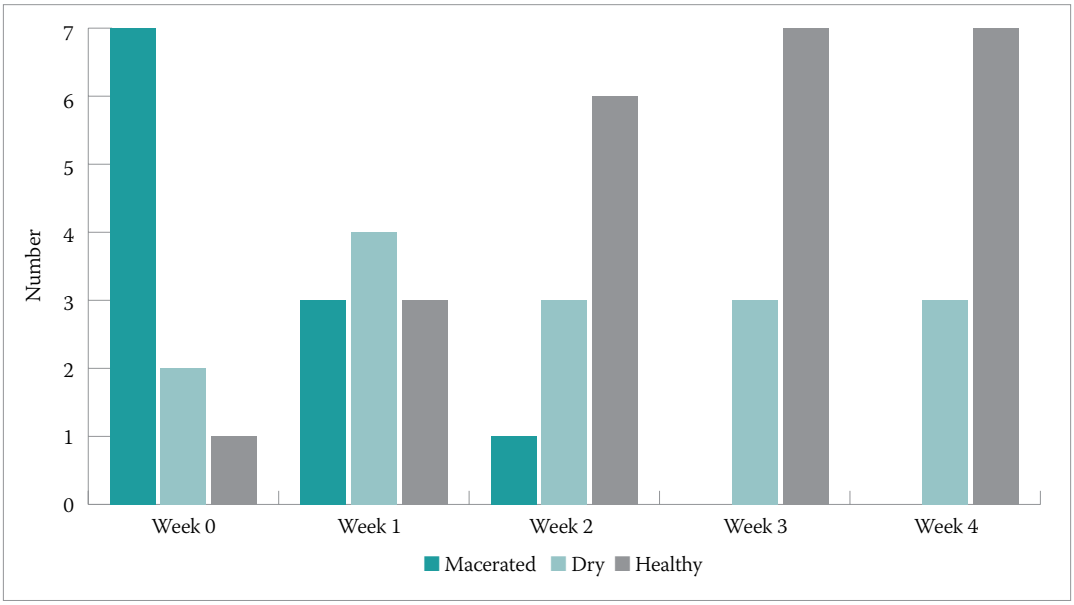
The evaluation found an improvement in periwound skin condition by the conclusion of the

evaluation period, with periwound maceration and excoriation reducing from 70% to 0% in the four week period, and 'healthy' periwound skin increasing from 10% to 70% by the end of the evaluation (Figure 3).

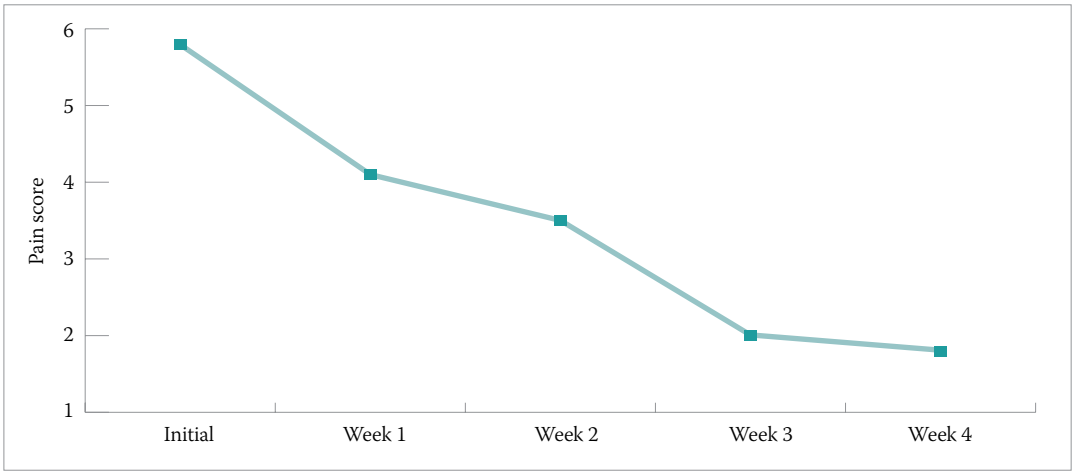
Also worthy of note, all patients in this study experienced a reduction in pain within the first few dressing changes, reducing from an average of 6 on visual analogue scale (VAS) at initial presentation, to 2 at final assessment (Figure 4). In the case of a 49-year-old female with T-cell lymphoma (Case study 2), the wound management objectives included the management of the patients' pain levels while promoting healing. The patient initially reported pain levels of 8 on VAS, causing significant distress and impacting QoL. By the close of the 4-week evaluation, the patient's pain levels had reduced to 2.

CASE STUDY 1

A 56-year-old female with malignant fungating wound to the left side of her neck that had been present for 12 months. Patient was undergoing radiotherapy. Wound management objectives



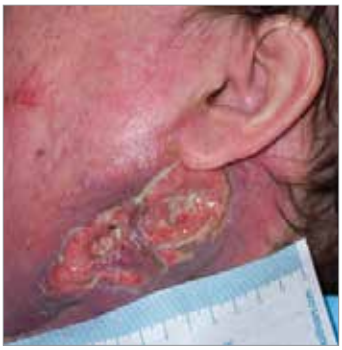
Figures 3. Periwound skin condition change throughout four week evaluation



Figures 4. Change in the patients reported average pain levels (on visual analogue scale) over the 4-week evaluation period

Case study 1

- A 56-year-old female with malignant fungating wound to the left side of her neck that had been present for 12 months
- **Initial assessmen**: 24 April 2022, Wound dimensions:L 8.5cm x W 3cm x D 0.5cm: wound bed condition: 40% slough, 50% granulation 10% overgranulation: exudate level, high: malodour, moderate: pain level: 5 on VAS
- **Previous treatment:** Daily dressings with hydrofibre and superabsorbent. Antibiotic therapy for wound infection. Radiotherapy treatment, slight excoriation to periwound skin
- **Final assessmen**t: 24 May 2022 wound dimensions: L5cms x W0.5cm: wound bed condition: 5% slough, 75% granulation, 20% epithelialisation: exudate level, low malodour: no longer present: pain level, 2 on VAS



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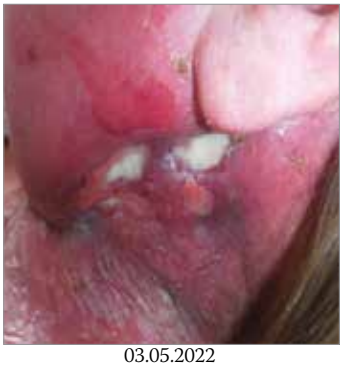

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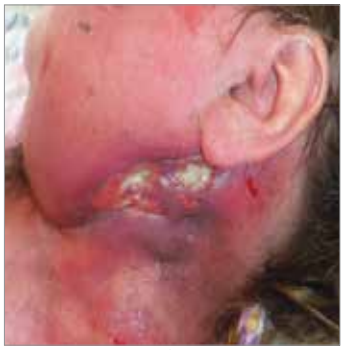

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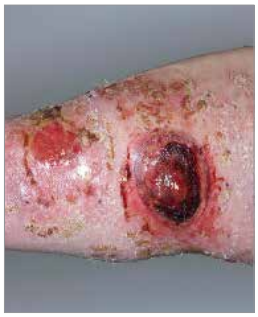
Case study 2

- A 49-year-old female with T Cell Lymphoma to left arm (5cm x 4.5cm) and satellite wound (3.5cm x 3.5cm).
- **Initial assessmen**: 21 April 2022, Wound dimensions: L5cm x W4.5cm x D 0cm: wound bed condition: 80% necrotic 10% slough 10% granulation: exudate level, moderate: malodour, significant: pain level: 8 on VAS
- **Previous treatment:** Foam dressing and enzymatic alginogel tried with no success. Patient's husband changing the dressings at home 2-3 times per day.
- **Final assessmen**t: 26th May 2022 wound dimensions: L4cms x W3cm: wound bed condition: 60% granulation, 40% epithelialisation: exudate level, low malodour: no longer present: pain level, 2 on VAS



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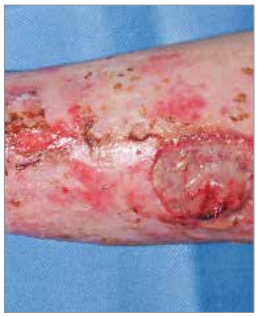

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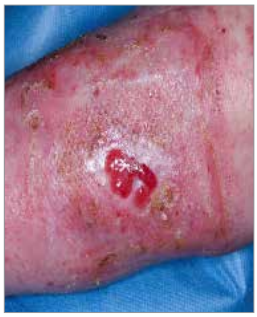

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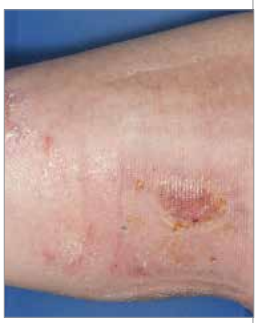

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were to encourage granulation, reduce exudate and associated odour, reduce excoriation during patient's end-of-life care.

Full details can be found in Case study 1. In summary after the four week treatment, the periwound skin was healthy. Community nurses were able to perform dressing changes alternate days, which allowed patient comfort during her end-of-life care. The patient found the dressing extremely comfortable and was very pleased with howit managed both exudate and in particular odour and supported some reduction in wound pain.

CASE STUDY 2

A49-year-old female with T Cell Lymphoma to left arm (5cm x 4.5cm) and satellite wound

Table 3. Summary of the properties of chitosan BMG dressing, and the resulting clinical impact for patients in this evaluation

Clinical Bbenefit	MaxioCel mode of action	Patient results
Haemostat	The positively charged chitosan fibres of this BMG dressing attracts negatively charged blood cell membranes, initiating the agglutination of red blood cells and platelets (Chen et al, 2017). This promotes the activation of thrombin, which activates the clotting pathway, leading to thrombus formation to activate haemostasis.	2 patients experienced bleeding from their wounds. The BMG dressing facilitated haemostasis in both cases.
Antimicrobial/ antibiofilm action	Oncology wounds can become infected and run the risk of increased and repeated infections which was seen during this evaluation. The positively charged chitosan fibres attract, disrupt and kill bacteria within the dressing therefore reducing the bacterial load which is a barrier to healing. Biofilms adhere to the gel matrix when the dressing is changed the biofilm is removed.	4 patients demonstrated suspected or confirmed infection present in their wounds at initial presentation.
Exudate management	BMG technology and the dressings vertical wicking action allows for increased absorbency and strength. This resulted in effective exudate management and periwound skin protection together with longer dressing wear time which improved patients quality of life due to reduced dressing changes and clinic visits. The dressing was also able to be removed in one piece.	The BMG dressing effectively managed exudate in all 10 cases for a longer period of time compared to previous dressings and periwound skin was protected from further breakdown.
Pain reduction	Chitosan has been shown to have the ability to prevent the release of, and to help absorb the bradykinin that is released at the wound site and causes pain by directly stimulating primary sensory neurons (Okamoto et al, 2002)	All 10 patients reported a reduction in pain (on visual analogue scale) within the first few dressing changes.
Promotion of wound healing	The BMG dressing aids autolytic debridement in helping to remove slough and necrotic tissue. BMG Chitosan fibres have demonstrated cell migration similar to a positive control, demonstrating no toxicity and reflecting its contribution to supporting wound healing (Edwards-Jones, 2023).	A reduction in wound area was seen in 9 patients, which in turn increased patient concordance. 1 patient's wound was non healing, however objective in this case was to manage wound symptoms during end of life care.

(3.5cm x 3.5cm). The patient expressed that the wound was impacting her quality of life, as the offensive malodour of the wound was causing her embarrassment in the workplace, where she worked in a shared office environment. Objective to manage patient's pain levels, promote healing and protect granulation tissue, manage exudate, and support autolytic debridement.

Full details can be found in Case study 1. In summary within 4 days of begininng treatment using the dressing, pain reduced, the necrotic area became debrided, slough softened, odour reduced, and dressing change reduced from 2–3 times per day to daily, allowing supported self-care. The periwound skin was much improved. Patient requested to continue with dressing beyond the evaluation, she was also receiving immunotherapy treatment.

DISCUSSION

In patients with malignant fungating wounds an aggressive approach of debridement, cleansing and application of topical antimicrobial may not be possible due to patients' levels of pain and discomfort. The chitosan BMG dressing facilitated gentle debridement and minimisation of odour as a result of removing the bacterial load from the wound. Evidence of the dressing facilitating autolytic debridement can be seen in Case study 1,

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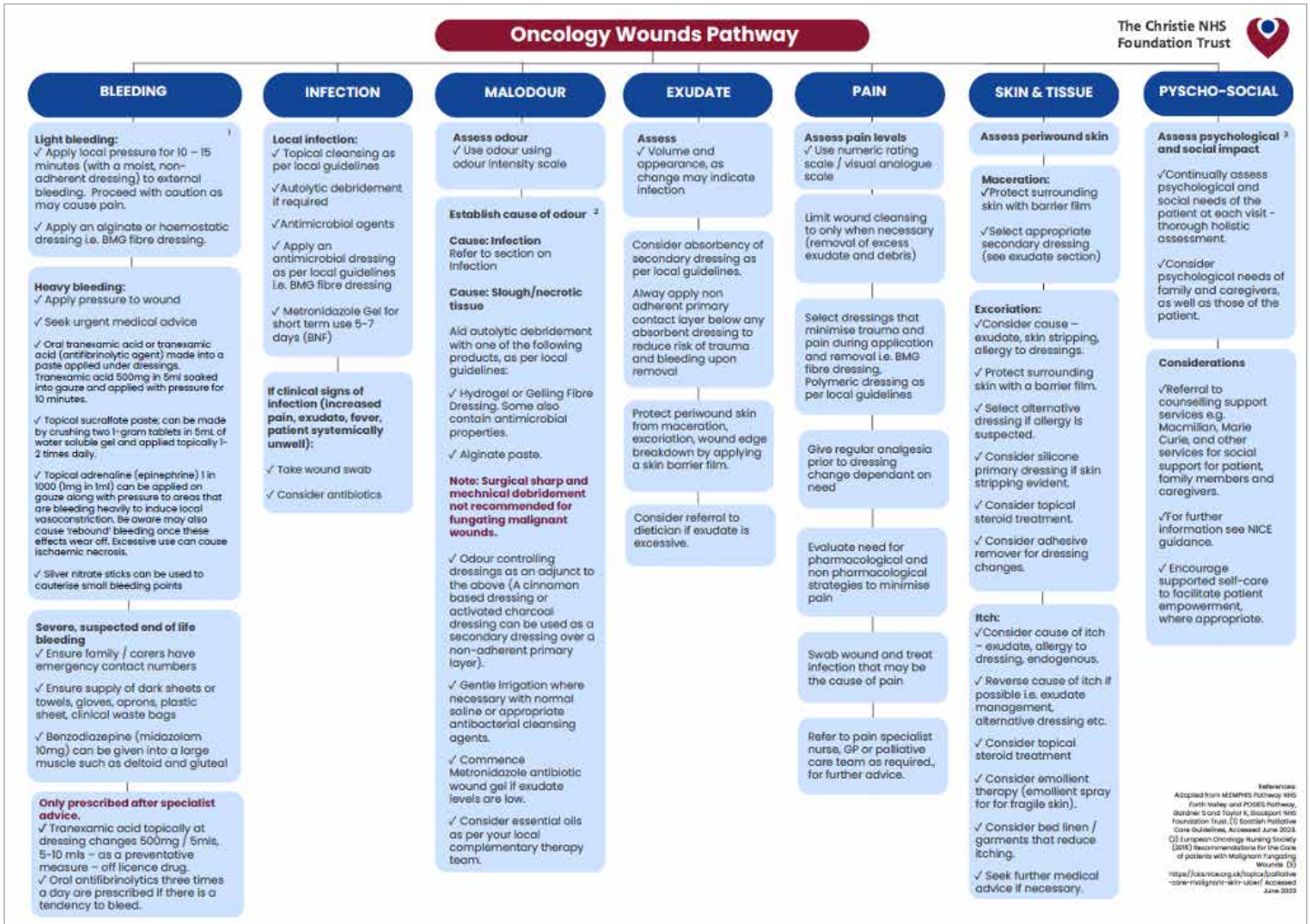

Clinicians should always refer to tissue viability specialist if:-

- Treatment plan was established and shows no signs of progression within 2 weeks. How are you defining progression – it no deterioration progress in this patient group?
- The wound area has decreased less than 20% within 4 week. Is this realistic in this patient group?
- Increases in wound size, pain, exudate, or odour as can be an indication of a worsening wound condition.
- There are underlying structures in the wound like exposed tendon or bone.
- Deterioration of wound edges i.e., rolling or advancing, peri wound maceration.
- The cause Aetiology of the wound is unknown.
- Suspicion or signs of systemic infection – where detrimental biofilm or local infection is suspected, and debridement is indicated but outside of the individual clinician's scope of practice.
- Co morbidity factors e.g., uncontrolled diabetes, vascular status, elevated c reactive proteins
- A decline in the patient's overall wellbeing and health

where the dressing supported the end-of-life care. Working in partnership with both radiotherapy and chemotherapy colleagues and their associated treatment regime also contributed to outstanding results in a relatively short period of time.

Malignant wounds have a myriad of unpleasant symptoms including odour, pain, bleeding, and excessive exudate. The individual with a malignant wound can suffer physical and social distress due to the unacceptable and offensive presence of the wound. Normality is turned on its head and they find themselves in a painful and undesirable situation (Young, 2017). By being able to manage the patients wound pain, promote wound progression across the healing continuum in majority of patient cases, together with end of life care this evaluation demonstrated an enhanced experience for all involved and increased all the patient's quality of life.

By way of sharing our findings and promotion of what we believe is best practice to provide an optimal healing environment and prevent complications that could lead to delayed healing, worsening of symptoms. Working in partnership with Industry we adapted the following pathway to include the use of BMG Fibre technology dressing (MaxioCel) in the management of oncology wounds across our trust.

CONCLUSION

The case study series has been a thought-provoking experience for both patients and staff across all departments and specialities. The impact that the introduction of BMG Fibre technology has had alongside chemotherapy and radiotherapy in such a short period of time has been remarkable.

This technology has been presented at a national virtual oncology conference to support other clinicians managing oncology wounds alongside two virtual symposia. It is hoped that the introduction of a pathway will support other clinicians in management of their patient's oncology wounds and facilitate further discussion and more education and training events around this topic in the future. Further discussions with senior management and procurement are now underway, in the hope of including this advanced wound care dressing within the current trust formulary. WUK

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