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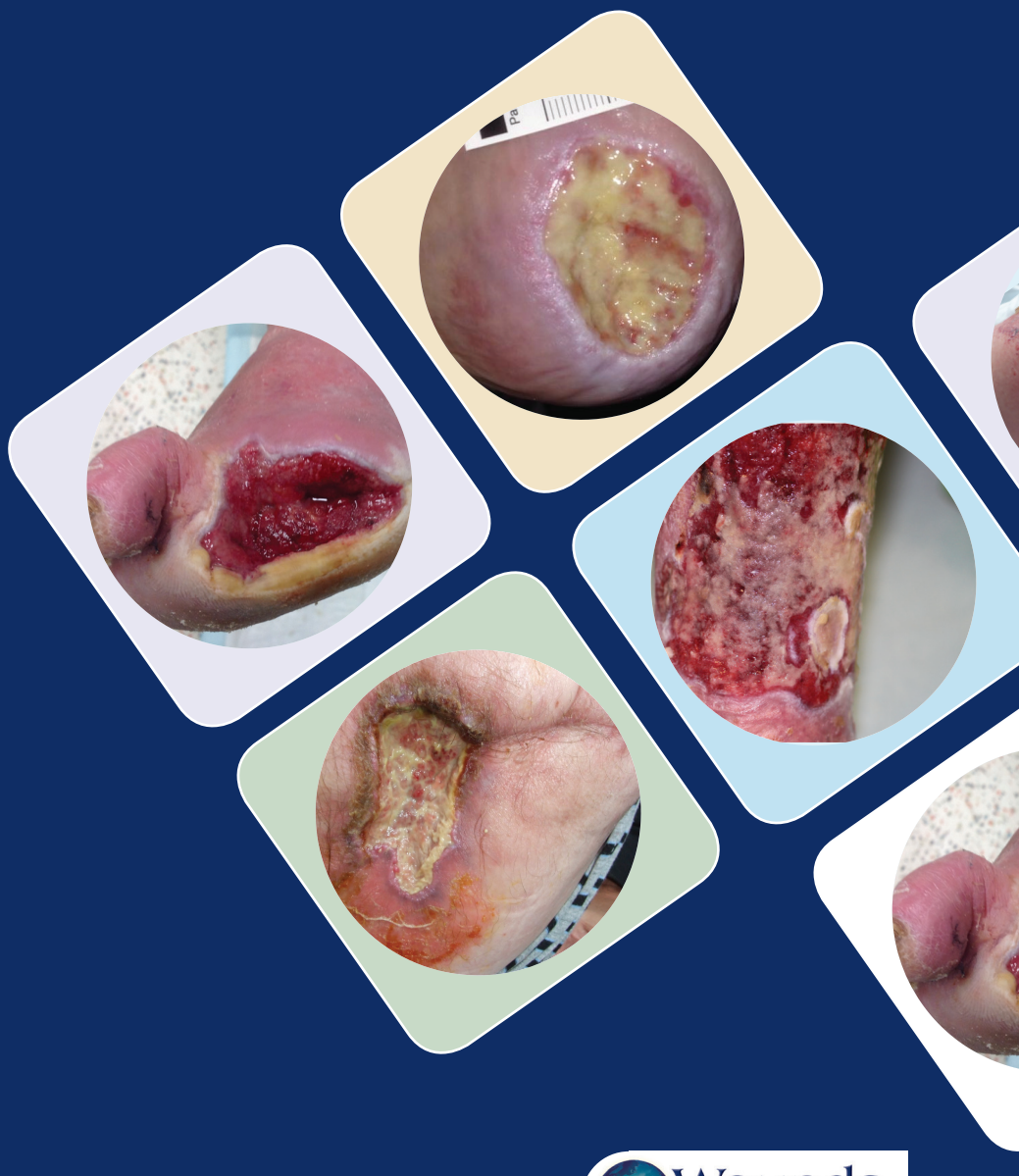
Retrospective case studies evaluation: IODOSORB® in biofilm-based wound care

CASE STUDIES SERIES 2018



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Retrospective case studies evaluation: IODOSORB◊ in biofilm-based wound care

FOREWORD

This International Retrospective Case Studies Evaluation presents eight cases that involve the use of cadexomer iodine (IODOSORB◊) as part of the wound management plan of chronic wounds. The cases are from four countries (Australia, Czech Republic, Denmark and the United Kingdom). After individual patient and wound assessment, the clinician selected IODOSORB◊ Gel (also known as IODOSORB Ointment), IODOSORB◊ Powder or IODOFLEX◊ (also known as IODOSORB dressing) (Smith & Nephew) as part of the management process. Each patient was treated with these products, according to local wound management policies.

Wound assessments were conducted at regular intervals. All wounds were assessed for clinical signs of improvement, such as reduction in wound size; improvement in wound bed tissue composition and surrounding skin condition; reduction in exudate levels and malodour; resolution of infection or signs of infection; and improvement to patient quality of life. Any relevant additional treatment and advice were also reported, such as, debridement and periwound skin care.

Cases 1 and 2 describe two ulcers and cover in greater detail the management of wounds complicated by biofilm. Thorough patient history, diagnostics and test results are provided in the cases. Cases 3–8 summarise six complex, long-duration wounds that made healing progress a challenging prospect (a venous leg ulcer [VLU], a traumatic wound, two non-healing amputation sites and a pressure ulcer [PU]).

Overall, clinicians reported high satisfaction using IODOSORB to progress healing in slow-healing wounds. Patients reported high levels of comfort, even in cases where pain scores were initially very high, and reported satisfaction when they felt they could see the relationship between the use of the dressing and the healing progress of their wounds.

In all case studies, presence of biofilm was either proved through microscopic techniques or highly suspected based on the signs and symptoms presented. The role of IODOSORB in relation to biofilm management is explored in the introduction (pages 2–5).

Introduction

BIOFILM IN CHRONIC WOUNDS

Biofilms are defined as an aggregate of microorganisms that often associate to a surface or to each other, and demonstrate an enhanced tolerance to chemical, biological and host attack[1]. *In vitro* biofilm models have demonstrated that microbial biofilms can withstand antibiotic concentrations 100 to 1,000 times higher than that of planktonic counterparts[2-5], which may explain why some chronic wounds complicated by biofilm fail to heal with standard care and why chronic infections persist[6].

Wound dressings that offer the ability to affect microorganisms (whether biofilm or not) present an attractive alternative to oral antibiotics. Wound dressings containing antimicrobials, such as iodine, are widely used in wound management, and topically applied antimicrobials potentially have advantages over systemic antibiotics in addressing wound biofilm. For example, topical antimicrobials may be able to provide high levels of agents required for biofilm efficacy[3]. Furthermore, topical antimicrobials often have multiple modes of action, and unlike antibiotics, they do not require metabolically active biofilm cells to be effective[7].

When looking at the available evidence, *in vitro* models assessing the effectiveness of many antimicrobials used in wound-related products have identified that these treatments often exhibit variable and poor results against microbial cells in biofilm phenotype[8-11]. As such, the levels of evidence pertaining to the performance of many topical antimicrobial wound care products against biofilms is low to poor, with little translation from *in vitro* models to appropriately designed proof-of-concept human trials, randomised controlled trials or case versus control prospective studies[8].

Evidence suggests that biofilms are present in most, if not all, chronic, non-healing wounds with a recent meta-analysis of *in vivo* studies suggesting prevalence could be at least 78%[12]. Additionally, there are no diagnostic markers to help identify the presence of wound biofilm, and visual cues are not accurate to help guide clinicians when to initiate a biofilm-based wound approach[13]. However, low level inflammation, slow-healing wound, slough, and moderate or no improvement with multiple rounds of oral antibiotics and recurrent infection are symptoms indictive of an infected and chronic wound[14].

Box 1: The T.I.M.E continuum[17] provides a framework for wound bed preparation

T: Tissue, understanding when non-viable and unhealthy tissue should be removed

I: Inflammation and infection, with the practitioner identifying and managing both

M: Moisture management, keeping the balance of moisture for assisting replication and migration of healing cells

E: Edge of wound, keeping the wound edges clean, moist and attached for optimal healing

BIOFILM-BASED WOUND CARE

Standard of care in wound management from the late 1990s has regarded wound bed preparation (WBP) as best practice. The term biofilm-based wound care was coined by Wolcott[15,16], and encompasses the principles of WBP within the T.I.M.E continuum[17] (Box 1), but emphasises the following principles:

- Cleansing, debridement and cleansing again with antiseptic solutions
- Debridement that is aggressive in opening up tunnels and treating with one or multiple types of debridement
- Application of topical antimicrobials with proven anti-biofilm efficacy post-debridement
- Systemic antibiotics that are appropriate to the type and length of treatment.

Biofilm-based wound care is a systematic, simple and clear approach that emphasises the importance of debridement and the use of a proven anti-biofilm topical antimicrobial.

Debridement involves the removal of necrotic and contaminated tissue and matter from a wound, and the choice of debridement method (e.g. sharp, autolytic, enzymatic, mechanical) or cleansing must take into account safety and ethical considerations[18]. The physical removal of tissue through debridement or vigorous physical cleansing plays a key role in reducing biofilm burden in chronic wounds[19] to allow healing to occur.

Debridement should be performed regularly because no form of debridement or cleansing is likely to remove all biofilm, especially as biofilm may also penetrate deeper into tissue structures[20]. A study by Schwartz et al (2014) showed that the mean percentage of bacteria killed from baseline was 75% by hydrodebridement and 93% by sharp debridement ($P<0.05$), which represents a 1 $\log_{10}$ reduction to the total microbial load in both techniques[21]. In addition, research has identified that bacteria and/or biofilm can regrow and form mature biofilm within a matter of days[22], so expert opinion suggests that debridement should be performed at least weekly[23].

Although debridement is one of the most important treatment strategies against biofilm, it is important to consider that debridement does not remove all biofilm. It is, therefore, crucial to choose and use an effective and proven anti-biofilm antimicrobial alongside debridement. The antimicrobial used to manage biofilm should have strong anti-biofilm effects in clinically relevant *in vitro* and *in vivo* test models against mature biofilm.

Once a wound shows improvements in wound metrics and/or evidence of reduced infective symptoms, it is likely that a significant enough reduction in microbial load has occurred for clinicians to introduce advanced therapies, such as negative pressure wound therapy (NPWT). In high-risk patients with multiple co-morbidities recovering from a complex chronic wound complicated by biofilm that has responded to a biofilm-based wound care approach, it may also be beneficial to prevent biofilm re-formation and/or further wound infections, by continuing topical antimicrobial therapy using more traditional topical antimicrobials[14,24]. This concept of a prophylactic approach to using topical antimicrobials in this manner is not new in the realms of managing high-risk wounds, but clinicians should consider the economic impact of this decision against patient benefits.

INTRODUCING IODOSORB

IODOSORB® (cadexomer iodine) is a sterile antimicrobial dressing that removes barriers to healing[25-28]. As a dual-action wound management product it offers the benefits of a broad-spectrum, *in vitro* slow-release antimicrobial agent[25,29] in combination with de-sloughing[26,30] and fluid-handling properties[31-33].

The cadexomer particle is a 3D cross-linked polysaccharide starch matrix enclosing 0.9% iodine that is released only when the matrix is in contact with wound fluid. In the presence of wound exudate, the polysaccharide beads absorb slough and debris, and swell. As they swell, there is a slow, sustained release of iodine into the wound[25,29]. Iodine penetrates the cell wall of microorganisms and disrupts protein and nucleic acid structure and synthesis and kills the exposed bacteria[34,35] within the biofilm community. By reducing bacterial load and associated pain, the IODOSORB range can improve patients' quality of life.

IODOSORB's micro-bead technology utilises iodine as a broad-spectrum antimicrobial[25,28,36,37-42] and delivers it in effective, sustained low concentrations[29], rather than high and short-burst doses that may be cytotoxic (as with older formulations such as povidone iodine)[43]. This effective mode of action allows the required concentration of iodine (0.9%) to have minimal cytotoxicity *in vitro* and to not induce cell toxicity in patients[31]. As the iodine is released, the colour of IODOSORB changes from brown to white, indicating dressing change is required.

IODOSORB is available in three formulations:

- A gel (IODOSORB Gel or Ointment)
- A powder (IODOSORB Powder)
- A dressing (IODOFLEX or IODOSORB dressing/paste).

IODOSORB can be used for the treatment of chronic exuding wounds, particularly when infection is present or suspected[44]. The IODOSORB Gel and IODOSORB Powder formats can help minimise trauma at dressing changes[28], aiding patient concordance and reducing pain[33,36,45], and can be used in unusual shaped wounds and cavity wounds[28].

IODOSORB'S ROLE IN BIOFILM MANAGEMENT

Antimicrobials, such as IODOSORB, have a broad spectrum of activity against microbial cells *in vitro* [25,28,36,37-42]. Their multi-faceted action at multiple sites within microbial cells reduces the likelihood of bacteria developing resistance[46]. The use of antiseptics, in conjunction with appropriate WBP can play an important part of an overall management plan:

- To prevent wound infection or recurrence of infection in patients at greatly increased risk of infection
- To locally treat infection
- To treat spreading wound infection and wound infection accompanied by systemic symptoms in combination with systemic antibiotics[47].

Mature biofilm exhibits an enhanced tolerance to treatment and this has resulted in a shift towards sharp debridement and adjunctive use of antimicrobial and other anti-biofilm compounds[16,19,22]. IODOSORB has demonstrated superior efficacy against microbial biofilms *in vitro* and in animal models when compared to other topical antimicrobials used in wound care dressings[9-11]. Malone et al (2017) tested the effectiveness of cadexomer iodine on the microbial load of diabetic foot ulcers (DFUs) complicated by biofilm *in vivo*[27] using an array of molecular, microscopy and zymography approaches. This group have, so far, been the only research group to identify that a topical

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antimicrobial used in wound care (cadexomer iodine) is able to kill biofilm cells in human chronic wounds and subsequently reduces protease levels[27]. On average, IODOSORB® could reduce the total microbial loads by 1–2 $\log_{10}$ (P=0.02), which matches other debridement techniques[21], with a resulting decrease in matrix metallopeptidase 9 (P=0.05) and matrix metallopeptidase 2 (P=0.19) — proteases that are expressed in response to infections[48].

OVERVIEW OF CASES

Case 1 reports on an infected venous ulcer present for 3 months and Case 2 reports on an infected post-amputation wound. Case 3 details a patient who had become increasingly housebound due to a recurring VLU, who was able to return to daily activities after treatment with IODOFLEX. Case 4 describes a non-healing traumatic wound that, as several of the cases summarised highlight, was adequately prepared for NPWT through management with IODOFLEX. Cases 5 and 7 report on two non-healing wounds on amputation sites, complicated by diabetes and surgical site infection respectively, and Case 6 describes a non-healing VLU that had increased in size over time so that it covered nearly the entire gaiter area of the leg in a patient with multiple co-morbid conditions. Finally, Case 8 summaries a chronic PU, which had been present for longer than 2 months.

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CASE 1: USING IODOSORB◊ ON AN INFECTED CHRONIC VENOUS ULCER ON THE RIGHT MEDIAL MALLEOLUS

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INTRODUCTION

A 30-year-old male with Spina bifida and paraplegia was referred to the Liverpool High Risk Foot Service with a chronic non-healing wound to the right medial malleolus. The wound had developed after the patient knocked his ankle while in his wheelchair. The wound had been present for 13 weeks and was not responding to standard wound care, which consisted of twice-weekly community nurse visits for wound cleansing with normal saline, the sporadic application of a silver dressing as a primary antimicrobial dressing, non-adherent foam as the secondary dressing and the application of two-layer compression. The patient sought advice from a local GP, who arranged a referral to the community nurse team for wound care, who arranged a referral to an acute tertiary facility high-risk foot service.

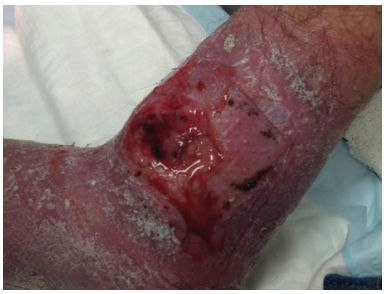

Figure 1: Baseline

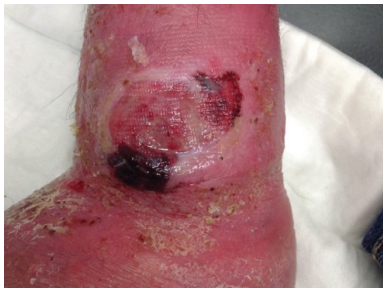

Figure 2: Review 1

Baseline: The wound measured 30mm (length) x 30mm (width) x 20mm (depth) (Figure 1). The wound bed contained a dense fibrin material with no signs of granulation tissue. The local area was warm and there was excessive haemopurulent exudate from the wound, suggesting presence of infection. The patient noted these symptoms had only been present in the past 2 days, and that the odour from the wound had worsened over the previous few weeks.

At presentation to the high-risk foot clinic, a full history of the patient and his wound were undertaken. Given the chronicity of the wound, despite standard care and treatment with topical antimicrobials, the suspicion of biofilm involvement was high. In addition, the patient had also presented with acute infective flare up, which also suggested likely bioburden involvement[1].

Diagnostics: After curettage and cleansing of the wound, two tissue biopsies were obtained from the wound edge. One tissue biopsy was sent for routine microbiology, culture and sensitivity, and the other was processed for DNA sequencing and scanning electron microscopy (SEM). Pedal pulses were not palpable; however, handheld doppler ultrasound examination identified biphasic waveforms of the dorsalis pedis and posterior tibial arteries. Previous ankle brachial indices (ABI) of 0.8 identified no arterial disease.

A plan was developed where the patient was treated on a biofilm-based wound care approach due to suspected involvement of biofilm as the cause of delayed healing. The wound bed contained dense fibrin, which required aggressive curettage. The wound bed was further cleansed with chlorhexidine and cetrimide.

The topical application of IODOSORB® Gel was used to provide a sustained antimicrobial action against the biofilm with frequent wound cleansing and debridement or curettage. To address the acute infective flair of the skin and soft tissue, the patient was prescribed ciprofloxacin because they were allergic to penicillin.

The cleansing and dressing regimen was performed three times per week. The patient was also provided with a two-layer compression system. An aggressive approach was used in an attempt to gain control of a chronic wound complicated by biofilm. Excessive exudate will cause greater release of cadexomer iodine from the cadexomer starch matrix, resulting in the requirement to 'top up' the topical antimicrobial therapy. Product change intervals were increased to account for this exudate.

Review 1 (2 weeks from baseline): The wound had decreased in depth by 100% (from 20mm to 0mm). Wound length and width remained similar (26mm x 28mm, respectively). The wound bed exhibited better-quality tissue, with signs of healthy granulation (Figure 2), reduced malodour and reduced exudate. A 2mm tissue biopsy was obtained from the wound edge for exploration of treatment effects. Dressing changes were prescribed for every 2 days because IODOSORB had released all available iodine and had turned white at each dressing change.

FINAL COMMENTS

After initiating an aggressive biofilm-based wound care and compression approach for 2 weeks, the clinician had identified significant improvements to the wound. Wound depth had reduced by 100%, and there were signs of healthy granulation tissue formation and advancing wound edges.

Using SEM, tissue biopsy confirmed that the patient's wound had biofilm presence (Figure 3). A post-treatment analysis of the tissue — in addition to data from DNA sequencing and SEM that also correlate with clinical findings (Figure 4) — confirmed that the biofilm-based approach, as well as appropriate compression, achieved a clinically effective outcome in terms of improved wound metrics. Treatment of the wound with aggressive and frequent debridement, wound cleansing and the application of IODOSORB resulted in a 1 $\log_{10}$ reduction to the total microbial load of a chronic wound complicated by biofilm within 2 weeks. The clinical significance of achieving a 1 $\log_{10}$ against a wound complicated by biofilm was the improvement noted in wound metrics.

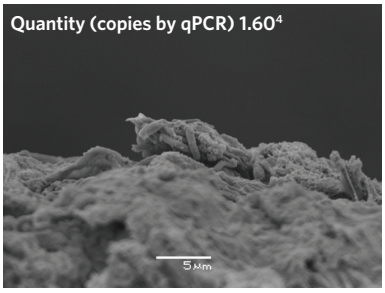

Figure 3: SEM pre-treatment tissue biopsy from the patient. Note the gram-negative rods of *Pseudomonas aeruginosa* forming aggregates and protective extracellular polymeric substances. Quantitative polymerase chain reaction (qPCR) allowed the microbial load to be calculated, identifying 1.64 per mg of tissue

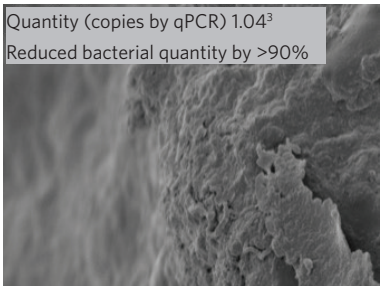

Figure 4: SEM post-treatment identifies significant reduction of biofilm and total microbial load

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CASE 2: USING IODOSORB◊ ON AN INFECTED POST-AMPUTATION WOUND

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INTRODUCTION

A 64-year-old male with type 2 diabetes had recurring right plantar first metatarsal head ulceration. He was recieving treatment for a chronic diabetic foot ulcer (DFU) when he developed an acute severe diabetic foot infection with underlying septic arthritis and soft-tissue gas gangrene (Figure 1).

The patient reported having had the DFU for 8 weeks, but in the week before presentation, the DFU had developed surrounding erythema with discharging purulence. At presentation, he reported feeling unwell and febrile. Clinical observations identified the patient was tachycardic and hyperthermic, and a full blood count revealed elevated white cell count, erythrocyte sedimentation rate and C-reactive protein. The patient was commenced on intravenous (IV) metronidazole and ciprofloxacin due to a penicillin allergy. Intraoperative tissue and bone cultures reported a polymicrobial infection: *Streptococcus dysgalactiae* (Group C/G), *Streptococcus algalacticae* (Group B), *Staphylococcus aureus* and mixed anaerobes.

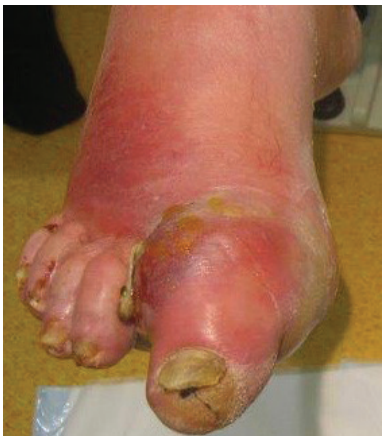

Figure 1: Baseline

The patient was diagnosed with a severe diabetic foot infection with radiographic images confirming underlying septic arthritis using Infectious Disease Society of America (IDSA) guidelines for diabetic foot infection[1] (infection of the joint with cortical erosions in keeping with osteomyelitis) of the first metatarsal phalangeal joint.

Amputation: A hallux amputation with resection of bone down to the middle of the proximal phalanx was performed. During admission, the patient had developed a further allergy to the IV antibiotics and was switched to oral linezolid. The patient was discharged from the vascular surgery unit post-amputation with follow-up at the high-risk foot service. The patient continued on linezolid for an additional 5 days' post-discharge. The post-operative dressing regimen consisted of a non-silver Hydrofiber™ dressing as the primary contact and a high-absorbency pad as the secondary dressing. A controlled ankle motion (CAM) walker was provided to reduce the load around the amputation site.

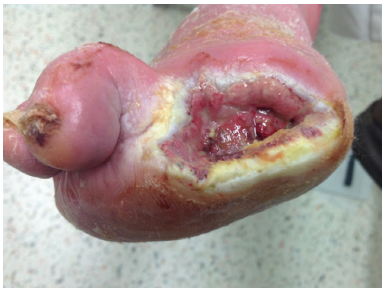

Figure 2: Post-amputation

Four weeks' post-discharge, the healing of the acute surgical wound on the right hallux amputation site had stalled. The wound bed was producing hypergranulation tissue with a gelatin-type material coating the surface (Figure 2). In addition, the peri-wound appeared macerated.

Exudate became purulent (from serous), and the amount of exudate had increased significantly. There were additional signs of acute infection denoted by surrounding oedema, warmth and erythema (moderate infection as defined by the IDSA[1]). A tissue biopsy was obtained for microbiology, culture and sensitivity, as well as analysis with scanning electron microscopy (SEM) in order to ascertain whether biofilm was involved. The patient was re-commenced on oral linezolid. The wound care plan consisted of weekly outpatient visits to the high-risk foot department for wound debridement, cleansing with normal saline and wound dressing; a non-silver Hydrofiber™ dressing and high absorbency pad were used. After 7 days of oral linezolid, the acute infective symptoms had resolved, and oral antibiotic therapy was stopped. The standard wound care plan was continued.

At 6 weeks' post-discharge, the patient developed acute infective symptoms once again. At this point, biofilm involvement was suspected. The tissue biopsy obtained 2 weeks previous was now available and identified dense microbial aggregates in thick, extra-polymeric substances consistent with biofilm architecture.

The patient was recommenced on oral linezolid, and the biofilm-based approach shown in Figure 3 was initiated.

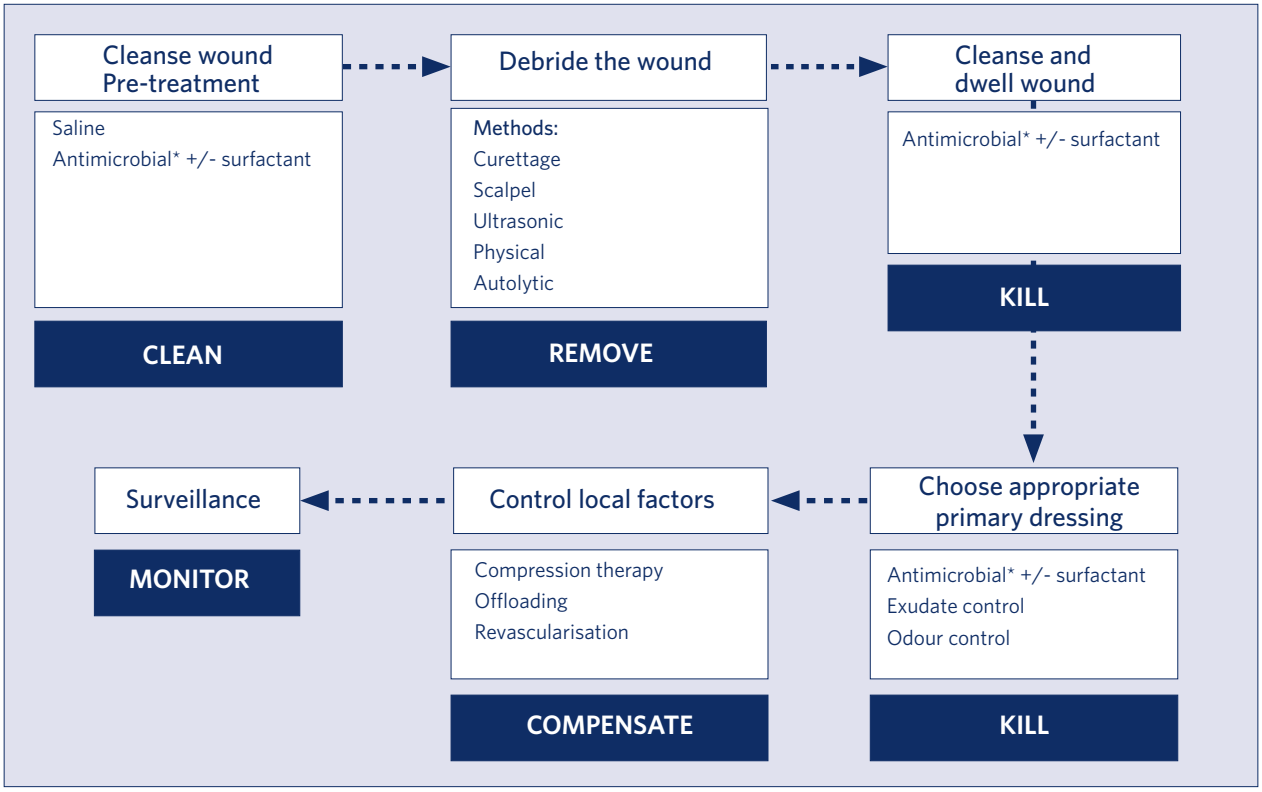

Figure 3: A local approach to managing wounds complicated by biofilm, adapted from[2]
*e.g. IODOSORB®

Ongoing review: The patient was seen in clinic three times per week. The wound was cleansed with saline to remove residual dressings, loose non-viable tissue and surface contaminants. Aggressive curettage of the wound bed was performed, followed by cleansing and a 15-minute dwell using a topical antimicrobial solution (chlorhexidine and cetrimide). This step was performed using a concentrated antimicrobial to help 'mop up' any residual microorganisms and non-viable tissue exposed by debridement. IODOSORB® Gel, a proven topical antimicrobial against biofilm[1], was applied every 2 days. A non-adherent pad capable of absorbing high levels of exudate was applied as a secondary dressing. The patient was placed into a non-removable CAM walker.

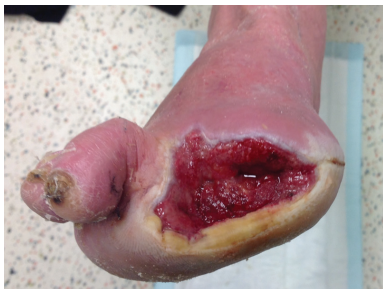

Figure 4: Week 8

Oral antimicrobial therapy was continued for a further 3 weeks, in addition to the aggressive biofilm-based treatment regimen (Figure 3). After 8 weeks' post-discharge, the wound had significantly improved, and infective symptoms had resolved (Figure 4).

Given the large tissue deficit, negative pressure wound therapy (NPWT; PICO® system, Smith & Nephew) was initiated to augment wound closure. The patient was commenced on NPWT, and at week 12, the post-amputation wound site had nearly healed (Figure 5).

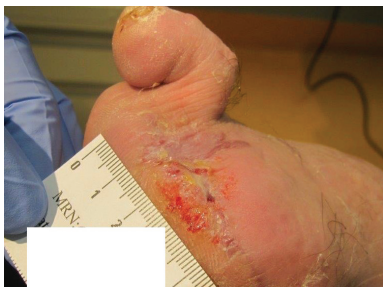

Figure 5: Week 12

FINAL COMMENTS

The patient presented with a complicated, chronic wound that had consistently become re-infected after amputation. The challenges were severe and wide-ranging, including underlying septic arthritis, development of allergy to IV antibiotics, and the identified presence of dense microbial aggregates in thick, extra-polymeric substances consistent with biofilm architecture. An aggressive and multi-modal approach was required, including oral antibiotic therapy; repeated debridement, cleansing and soaking; and the use of IODOSORB® to provide proven topical antimicrobial action[2]. Despite previous deterioration of the wound condition, at week 8 post-discharge, the wound had significantly improved, and infective symptoms had resolved. IODOSORB was an integral part of these improvements, as prior aggressive, multi-modal therapy with other dressings had not brought about lasting results. After integration of IODOSORB to the regimen, the wound had sufficiently improved to the point that NPWT could be commenced, thereby allowing the wound to move significantly towards final healing.

REFERENCES

1. Lipsky BA, Berendt AR, Cornia PB, et al. 2012 Infectious Diseases Society of America clinical practice guideline for the diagnosis and treatment of diabetic foot infections. *Clin Infect Dis* 2012; 54(12): e132–73

2. Malone M, Goeres DM, Gosbell I, et al. Approaches to biofilm-associated infections: the need for standardized and relevant biofilm methods for clinical applications. *Expert Rev Anti Infect Ther* 2017; 15(2): 147–56

CASE 3: CHRONIC PRESSURE ULCER ON THE BASE OF THE LEFT HEEL TREATED WITH IODOFLEX◊ PRIOR TO NPWT

Author: Jane Hampton, Consultant Nurse (Wound Care), Department of Health and Care, Aarhus Municipality, Denmark

INTRODUCTION

An 85-year-old female presented with a pressure ulcer (PU) on the base of the left heel, which had been present for 10 weeks. The patient had multiple concurrent conditions, including dementia, osteoporosis and chronic obstructive pulmonary disease. The patient lived alone and spent most of the time in bed. She was hoisted from the bed to the wheelchair in the afternoons, where she sat for 1–2 hours. She had been given a heel protector to wear after the PU had developed, and the wound was previously managed with a hydrogel and adhesive foam, per local protocols, before being referred to the tissue viability nurse because the wound had failed to progress.

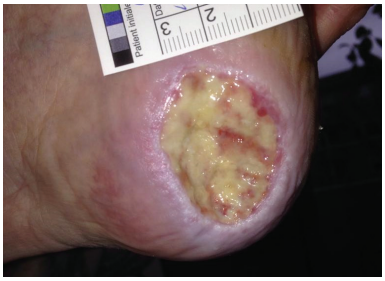

Figure 1: Pressure ulcer at presentation to tissue viability nurse

IODOFLEX◊ was selected as the primary dressing for exudate management and its hydrolytic debridement capabilities. Its ability to absorb and lock-away exudate from the wound allowed for the dressing to be changed twice weekly. The aim was to prepare the wound for negative pressure wound therapy (NPWT; PICO◊ system, Smith & Nephew) by reducing bioburden and 'kick-starting' the healing process. The heel protector continued to be used while the patient was in bed and when NPWT was in use.

Baseline: At presentation to the tissue viability nurse, the wound measured 3.3cm (length) x 0.3cm (depth) x 2.5cm (width), and the wound bed comprised 90% slough and 10% granulating tissue. The surrounding skin was macerated (Figure 1), and there was a moderate level of yellow exudate. There were no signs of local infection, although biofilm was suspected because of delayed healing despite optimal care and presence of excessive slough formation.

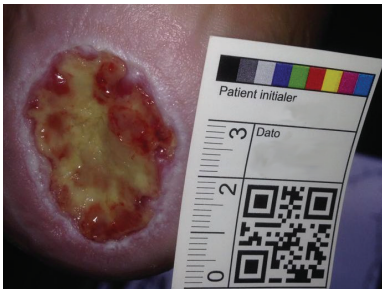

Figure 2: Review 1

Review 1 (6 weeks from baseline): After 6 weeks using IODOFLEX, which was changed twice weekly, the wound had improved and reduced in depth. Although the length and width of the wound remained the same, the wound bed composition had improved, consisting of 60% slough and 40% granulation tissue. The surrounding skin had less maceration (Figure 2).

The clinician found IODOFLEX easy to apply and remove, and it was convenient that the dressing could be cut to size. There were no indications of discomfort from the patient, as the slough was now easier and less painful to remove than at presentation.

NPWT was commenced at review 1 and used for 3 weeks. After NPWT treatment (9 weeks from baseline), the wound reduced in size by 30%, and the wound was now a surface wound. A hydrogel under an adhesive foam dressing was planned to be used for 1 week and changed three times per week. At the recommencement of IODOFLEX◊, the wound measured 3.1cm (length) x 2.1cm (width).

Review 2 (11 weeks from baseline): One week after IODOFLEX® was recommenced, the wound measured 2.7cm (length) x 1.5cm (width) (Figure 3). Periwound maceration had improved, the wound bed contained more healthy-looking epithelial tissue, and the slough was moist and continued to be easy to remove. Dressing change continued twice weekly.

Review 3 (14 weeks from baseline): Three weeks later, the wound size measured 1.8cm (length) x 1.3cm (width). The wound bed comprised 80% granulation tissue and 20% epithelial tissue, and there was no slough (Figure 4). IODOFLEX was stopped, per local protocol, and the wound was treated with an adhesive foam dressing that was changed once a week.

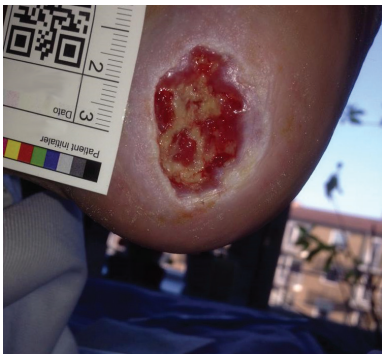

Figure 3: Review 2

FINAL COMMENTS

The clinician was highly satisfied with IODOFLEX due to its ease of use and effectiveness in absorbing exudate and clearing the wound bed of slough. The clinician rated the ability of IODOFLEX to handle exudate and reduce clinical signs of infection as 'very good'. The ability of IODOFLEX to change colour when product change was required was rated as 'excellent'. The clinician would use IODOFLEX in the future on other non-healing wounds, particularly if biofilm involvement was suspected.

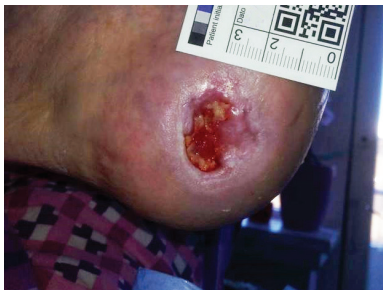

Figure 4: Review 3

CASE 4: IODOFLEX◊ TREATMENT ON A NON-HEALING, PAINFUL TRAUMATIC WOUND ON THE LEG

Author: Jane Hampton, Consultant Nurse (Wound Care), Department of Health and Care, Aarhus Municipality, Denmark

INTRODUCTION

A 67-year-old female presented with a traumatic wound on the gaiter region of the left leg. The patient had cared for the wound herself for 6 weeks before being referred by her GP to a community nurse clinic. The patient had osteoporosis, psoriatic arthritis, chronic obstructive pulmonary disease and venous insufficiency.

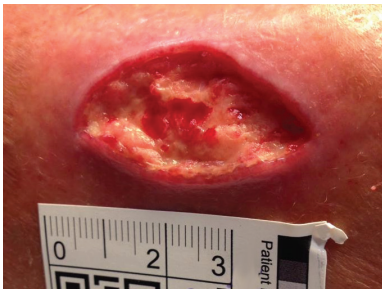

Figure 1: Initial presentation

At the clinic, the patient's wound was managed by applying a hydrogel dressing, a sterile occlusive dressing impregnated with petrolatum, and an adhesive foam. At each dressing change, an analgesic ointment was applied to the wound bed before sharp debridement, but the patient was still in too much pain, so the clinician was unable to remove sufficient non-viable tissue. Dressing changes were performed three times weekly. After 4 weeks, the wound had failed to progress and was still covered with a 'tenacious' layer of slough and necrotic tissue.

Baseline: At presentation to the specialist tissue viability nurse, the wound measured 3.8cm (length) x 2.1cm (width). The wound had a thick layer of fibrinous slough (wound composition 100% slough), the wound edges showed signs of oedema, and there was low-level, yellow exudate. Figure 1 shows the wound after sharp debridement. There were no signs of infection but the wound had failed to heal, so biofilm presence was suspected. The patient reported that the level of pain impacted on her quality of life, and she had begun wearing trousers instead of skirts to hide the 'unsightly' wound.

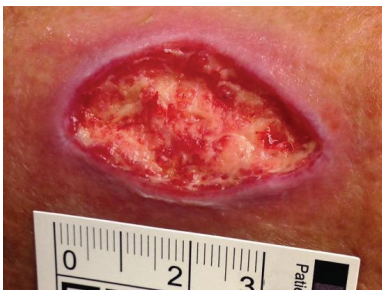

Figure 2: Review 1

As the hydrogel dressing used by the community nursing clinic had failed to remove slough and necrotic tissue from the wound, IODOFLEX◊ was chosen to reduce bioburden and prepare the wound for negative pressure wound therapy (NPWT). Dressing change was scheduled for twice weekly. The IODOFLEX dressing was applied to the wound under a non-adhesive foam and a two-layer compression bandage system.

Review 1 (6 days after baseline): Two dressing changes after initial presentation, the wound measured 3.6cm (length) x 2.1cm (width). IODOFLEX absorbed and contained the exudate, and there was less oedema in the wound edges. The patient experienced considerably less wound pain in general and during debridement. The clinician noted that it was easier to remove slough from the wound bed than at presentation, and there was more granulation tissue (Figure 2). Treatment was continued, with sharp debridement and dressing change twice weekly.

Review 2 (approx 26 days from baseline): The wound had reduced to 3.6cm (length) x 1.9cm (width) and comprised 80% granulation tissue and 20% slough (Figure 3). The depth of the wound had decreased, and the wound was no longer painful. Exudate levels had reduced, there was less oedema around the wound edges, and epithelised tissue was now visible.

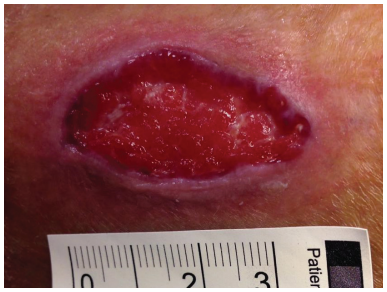

Figure 3: Review 2

NPWT was commenced to aid the healing process and used for 14 days resulting in the wound area reducing (3cm [length] x 1.1cm [width]).The wound was completely healed 7 weeks later, approximately 13 weeks after initial presentation to the specialist tissue viability nurse.

FINAL COMMENTS

IODOFLEX® was easy to use and remove, and conformed to the wound bed easily, and the clinician rated the ability of IODOFLEX to handle exudate and reduce clinical signs of infection as 'very good'. For this painful wound, after using IODOFLEX for 1 week, the patient reported a reduction in pain, potentially due to the reduction in the clinical signs of infection and because the fibrinous slough was easier and less painful to remove. In addition, the patient reported feeling satisfied by seeing improvements to the wound bed and a reduction in wound size over time.

CASE 5: IODOFLEX◊ USED ON AN AMPUTATION SITE PRESSURE ULCER

Author: Debbie Simon, UK Tissue Viability Nurse Specialist, North West Boroughs Healthcare, Community Health Services, Knowsley, UK

INTRODUCTION

A 68-year-old male presented with a pressure ulcer (PU) that had developed on his left leg at the tip of the amputation site after he was discharged home following a below-the-knee amputation procedure. The patient had poorly controlled type 1 diabetes and previous osteomyelitis of the left leg.

The GP had commenced oral antibiotics, and after 5 weeks, there was little improvement to the wound, so the patient was referred to a tissue viability nurse, who diagnosed the patient with a grade 3 PU. The wound was increasing in size, and the fragile tissue was bleeding easily, which was exacerbated because he was also receiving anticoagulation therapy. The wound was dressed with a DURAFIBER◊ Ag (Smith & Nephew) dressing and an adhesive foam dressing, which was started at the hospital before discharge and changed three times a week. As a result of his paraplegia (he also had a below-the-knee amputation of the right leg), he was unaware that the stump dressing was causing pressure and further breakdown of the wound.

Baseline: The wound measured 3cm (length) x 5.5cm (width), with areas of varying depths and pocketing. The wound bed comprised 75% unhealthy granulation tissue, and the medial aspect of the wound was covered in slough. There were moderate amounts of exudate, necessitating dressing changes three times a week. Tissue was friable; and the wound often bled on removal of the dressing (Figure 1). There were no signs of infection but, because the wound was not progressing, biofilm involvement was suspected. The patient found it difficult to keep the affected limb flat, and a cylindrical pressure-relieving cushion was used to try to reduce the pressure on the stump and wound. The patient's quality of life was poor due to his complex medical history and the presence of a PU near his sacrum, which was healing. He reported that being bedridden and away from his family negatively affected his mood.

IODOFLEX◊ was selected because the wound had not progressed and had not responded to antibiotics and the existing dressing regimen. IODOFLEX was selected to reduce the bioburden in the wound bed, thereby progressing the wound to a healing trajectory. The wound was gently irrigated in an attempt to avoid further bleeding of the wound, and ALLEVYN◊ Life was used as a secondary dressing. The dressing was changed three times a week. The patient continued to use the cylindrical pressure-relieving cushion when in bed, and, when the PU on his sacrum healed, he was able to sit out of bed for short periods of time.

Review 1 (1 week from baseline): Three dressing changes after presentation to the tissue viability nurse, the depth of the wound began to decrease (Figure 2). The size

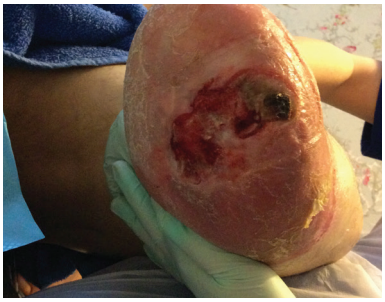

Figure 1: Baseline

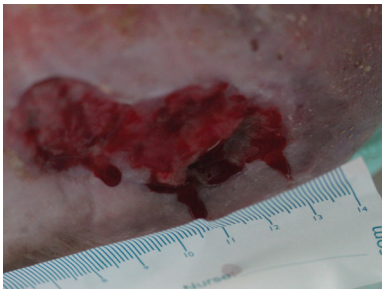

Figure 2: Review 1

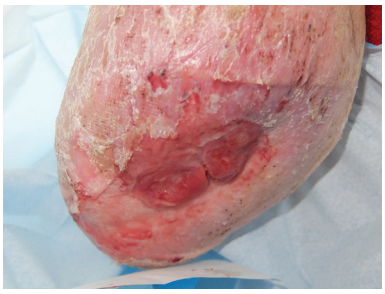

Figure 3: Review 2

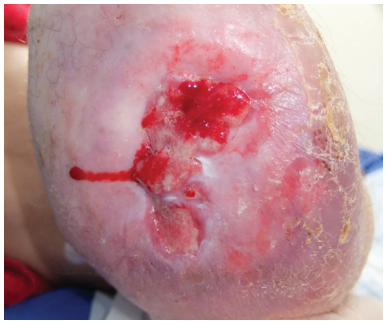

Figure 4: Review 3

of the wound remained unchanged but the wound bed appeared healthier and the slough on the medial side had lifted. The surrounding skin was also less irritated. The tissue remained friable and there was heavy bleeding. IODOFLEX® regimen was continued unchanged.

Review 2 (2 weeks from baseline): The wound was reviewed following three dressing changes. The wound remained the same size but was now a surface wound. As the patient has paraplegia, he is unable to feel pain in the area. At the previous dressing changes, due to heavy bleeding from the wound, exudate was not apparent. As the bleeding subsided (Figure 3), serous exudate was visible. A barrier film was applied to the surrounding skin to prevent maceration. IODOFLEX treatment regimen continued, with dressing change reduced to twice weekly.

Review 3 (3 weeks from baseline): Levels of serous exudate had now decreased. The clinician identified the development of epithelial tissue around the wound edges, which was starting to bridge across the centre of the wound, indicating that the wound was beginning to heal (Figure 4). IODOFLEX was discontinued in accordance with local protocols regarding use of topical antimicrobials, and replaced with a gelling fibre dressing. Two weeks later, the patient was referred back to the clinic due to deterioration of the wound. IODOFLEX was recommenced, with dressing change twice weekly.

Review 4 (9 weeks from baseline): Four weeks after IODOFLEX was recommenced, the wound had reduced in size significantly (2.5cm x 2.5cm) and improved in composition and appearance (Figure 5). The surrounding skin was healthy and the wound surface was granulating. Biofilm indicators were no longer present and the wound was moving towards healing, so IODOFLEX was discontinued.

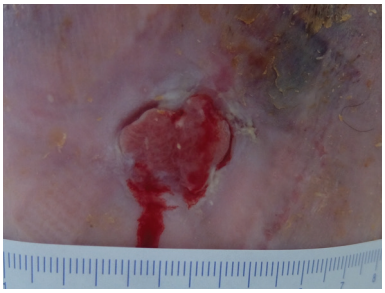

Figure 5: Review 4

FINAL COMMENTS

Wound changes required two nurses because the patient was paraplegic, with one nurse holding the limb while the other changed the dressing. Despite this, the dressing was rated as easy to apply and remove, and clinicians found the experience of using IODOFLEX positive and said they would consider using it again in the future. Additionally, the clinician was impressed with how quickly the wound recovered after IODOFLEX was recommenced when the wound deteriorated. The clinician commented that increased duration of use of IODOFLEX might be necessary in some cases to ensure management of local infection and biofilm.

CASE 6: USING IODOFLEX◊ FOR A PAINFUL RECURRING VENOUS LEG ULCER AFFECTING ACTIVE LIFESTYLE

Author: Debbie Simon, UK Tissue Viability Nurse Specialist, North West Boroughs Healthcare, Community Health Services, Knowsley, UK

INTRODUCTION

An 82-year-old female presented with a recurring venous leg ulcer (VLU). Despite having rheumatoid arthritis, she was usually active and independent until the VLU returned.

After the VLU recurred, she initially attended the local community leg ulcer clinic. A non-adherent primary dressing was applied, and following a ABPI reading of 1.1, she was commenced on 40mmHg compression bandaging with weekly review. Despite appropriate compression, the wound began to deteriorate. A clinic nurse diagnosed the presence of local infection and a silver dressing was used, but there was little visible improvement over 4 weeks' use.

The patient became housebound because the leg was too painful to weightbear, and her GP prescribed morphine to be taken before dressing change. She could no longer drive or carry out her daily tasks, and had become tearful due to the pain and negative impact on her quality of life, worrying that 'this was how [she] may be for the rest of [her] life'. Twelve weeks after presentation to the community wound clinic, the patient was referred to a tissue viability specialist for management of the wound.

Baseline: The VLU presented as circumferential ulceration around the gaiter area of the patient's left leg. The wound was superficial, and the tissue was friable. The wound currently required redressing twice weekly, and despite having a non-adherent dressing in place, removal was painful and the wound bled easily. The periwound skin was thin and fragile, potentially due to oral prednisolone prescribed by the patient's rheumatologist. The patient had begun declining to have compression bandages reapplied as she could no longer cope with the pain.

The wound exhibited no local erythema or heat. A swab had been taken by the community nurses when the wound first deteriorated and no unexpected bacterial species were detected. Based on the appearance of the wound and using the International Wound Infection Institute consensus[1] on wound healing, local infection was suspected. Because the clinical signs and symptoms had persisted, biofilm involvement was further suspected.

The signs of local infection did not respond to the silver antimicrobial dressing, so the dressing was discontinued, and IODOFLEX◊ was commenced, with a specific goal of reducing the bioburden. Other considerations for IODOFLEX selection included the dressing's high absorbency capability, and the potential for pain-free removal because IODOFLEX can be irrigated from the wound. The dressing was commenced, along with reduced compression delivered via hosiery, with dressing change scheduled three times weekly.

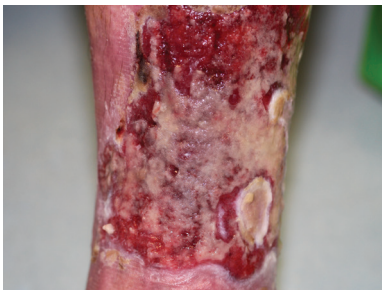

Figure 1: Review 1

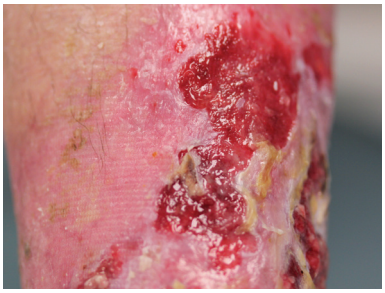

Figure 2: Review 2

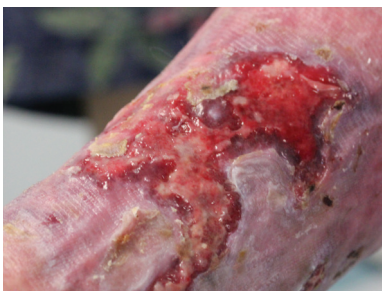

Figure 3: Review 4

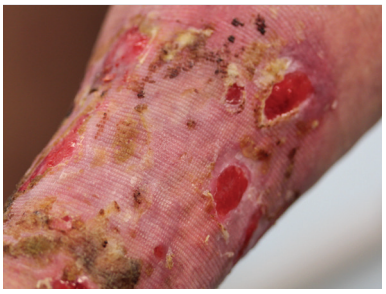

Figure 4: Review 5

Review 1 (2 weeks from baseline): The patient reported that she was able to tolerate compression and was able to elevate her legs with reduced pain. Her mobility had also improved (Figure 1). The wound bed was healthier and the tissue was not as friable. There was a superficial layer of slough on the wound surface, but due to the patient's pain, she was too anxious to have any debridement other than simple irrigation. Therefore, the slough could not be removed. The size of the wound had not changed. The IODOFLEX® regimen was continued, with dressing change twice weekly because exudate levels had reduced and were well managed by the dressing.

Review 2 (6 weeks from baseline): The wound had more epithelised tissue, and the surrounding tissue was pink and vitalised (Figure 2). The patient's mobility and comfort had also improved. As per the local antimicrobial pathway, IODOFLEX was discontinued after 4 weeks' use.

Review 3 (8 weeks from baseline): The wound had deteriorated with the wound bed tissue becoming friable and bleeding easily, and the surrounding skin appearing more macerated. The patient also reported increasing pain. IODOFLEX was recommenced to manage the reformation of suspected biofilm.

Review 4 (12 weeks from baseline): The wound surface area had reduced due to bridging of epithelium across the surface. Bleeding and exudate was minimal, so the dressing was now changed weekly. Paracetamol was taken by the patient for the pain. The patient was fully mobile and had returned to her daily activities. She was able to tolerate application of full compression, and the wound was on a healing trajectory, leading to the decision to discontinue IODOFLEX as per local protocol (Figure 3).

Review 5 (16 weeks from baseline): The wound continued to improve, and the inital wounded area was now nearly completely epithelised. The patient was able to return to weekly management by the community-based leg ulcer clinic (Figure 4).

FINAL COMMENTS

Before commencing IODOFLEX, previous antimicrobials had been ineffective at improving the wound and the wound had been deteriorating. The wound was very painful, and the patient had been advised that there may be some initial discomfort when the dressing was applied and, if she was unable to tolerate it, the dressing would be discontinued. However, she could tolerate the initial discomfort and was happy for the IODOFLEX regimen to continue. Dressing changes became less painful, and the patient reported confidence in the product, in part, because she could see the improvements in the wound. Use of IODOFLEX resulted in wound progression, and the wound responded quickly when the dressing was recommenced.

REFERENCE

1. International Wound Infection Institute (IWII) Wound infection in clinical practice. *Wounds International* 2016. Available at www.woundsinternational.com

CASE 7: IODOSORB◊ TREATMENT ON NON-HEALING WOUND ON LEFT STUMP AFTER RE-AMPUTATION

Author: Jan Stryja, Vascular Surgeon, Head of Outpatient Clinic, Salvatella Ltd, Czech Republic

INTRODUCTION

A 38-year-old, wheelchair-bound, disabled male presented with a non-healing infected, wound dehiscence of 5 weeks on the left femoral stump after re-amputation. The patient, who was diagnosed with Buerger's disease since 23 years of age had originally developed an infected grade 3 pressure ulcer (PU) on the left femoral stump after major amputation of both lower limbs due to ischaemic gangrene. The PU had been managed with standard care, moist wound-healing and systemic antibiotic therapy.

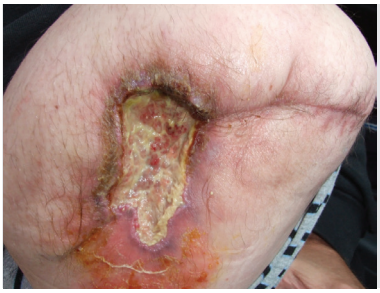

Figure 1: Baseline

The wound had failed to heal after re-amputation due to surgical site infection, with partial wound dehiscence, leading to development of a non-healing wound on the tip of the stump. A 14-day course of negative pressure wound therapy (NPWT; RENASYS◊ GO NPWT system) after sharp debridement was commenced in order to preserve the bone and reduce wound exudate. Antiseptic poultices with polyhexanide, medical manuka honey with alginate dressing, and povidone-iodine dressings were also used as treatments. Oral antibiotics and NPWT had failed to reduce the wound size or improve the signs of infection. The wound remained extremely painful and was coated in slough. Moist wound healing with standard dressings was prescribed in the outpatient setting. The patient's quality of life had deteriorated as a result of the wound because he had become fully dependent on others for help.

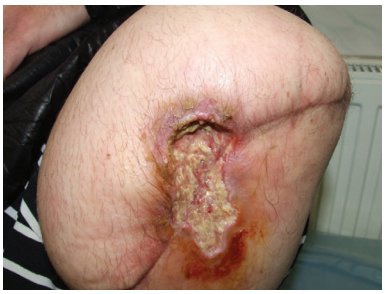

Figure 2: Review 1

Baseline: At presentation to the wound care specialist, the wound measured 10cm (length) x 0.8cm (depth) x 4.5cm (width) (Figure 1). The wound bed was coated by sloughy debris and granulation tissue that was breaking down. The periwound skin was slightly macerated, with erythema and swelling. The wound was producing a moderate level of yellowish, viscous exudate and it was malodourous. The patient's pain was measured using a visual analogue scale (VAS; where 1=no pain and 10=unbearable pain), and his pain score was 9 out of 10.

After superficial wound swabs were taken from the wound, bacteria including *Pseudomonas aeruginosa*, *Citrobacter braakii*, *Citrobacter youngae* and *Finegoldia magna* were identified. Presence of biofilm was suspected due to early restoration of slough on the wound bed after mechanical debridement, stagnation of healing, malodour, swelling and erythema.

IODOSORB◊ Gel was selected for its clinical efficacy in treating infections, and ease of application and use. The aim was to manage viscous exudate, and reduce pain and other signs of infection. IODOSORB Gel was applied to the wound and MELOLIN◊ (Smith & Nephew), a low-adherent absorbent dressing, was used as the secondary dressing. Dressing change was scheduled for three times weekly.

Review 1 (3 weeks from baseline): There was no change in the wound size, but the wound bed had improved, with reduction of slough and erythema (Figure 2). The swelling of the surrounding skin had resolved. The patient's pain-relief medication had been reduced, and his VAS pain score had decreased from 9 to 5. He continued to offload the stump and use his wheelchair entirely for movement.

Review 2 (9 weeks from baseline): Dressing change continued three times per week. The wound size had reduced, now measuring 5cm (length) x 0.5cm (depth) x 3cm (width) (Figure 3). The appearance of the wound bed had improved, with reduction of slough, and continued resolution of erythema and swelling of the periwound skin. The patient's pain had decreased from 5 to 3 on the VAS pain score. The patient was able to change the dressing himself and continued to offload his stump and use his wheelchair for movement.

The signs of infection and wound exudate levels had subsided, so the use of IODOSORB® Gel was discontinued as per local protocol, and use of a silver Hydrofiber™ dressing was initiated.

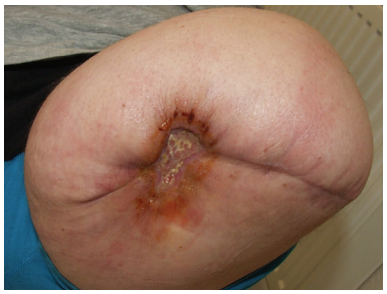

Figure 3: Review 2

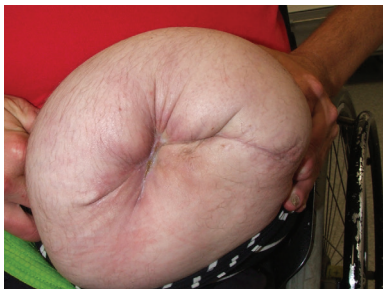

Figure 4: After 7 months of treatment

FINAL COMMENTS

After 9 weeks of IODOSORB use, the infection signs had disappeared so IODOSORB was discontinued and a non-antiseptic topical treatment was commenced. Complete wound closure took a further 7 months (Figure 4), due to the ulcer location and difficulty in getting the patient to effectively offload. However, this considered, the clinician was pleased with the outcome.

IODOSORB Gel was easy for the staff and patient to apply and remove. It appeared to have helped reduce maceration of the surrounding skin and to have absorbed the thick exudate well. The overall patient and clinician experience of using IODOSORB Gel was rated 'good'.

CASE 8: NON-HEALING INFECTED VENOUS LEG ULCER ON THE RIGHT LEG

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INTRODUCTION

A 70-year-old female presented with a non-healing infected venous leg ulcer (VLU) of 5 months' duration on the gaiter region of the right leg. Over the 5 months, the size of the wound had progressively become larger. Treatment during that time had included standard moist wound dressings (e.g. non-silver Hydrofiber™), polyurethane foams and hydrocolloids). Three weeks before presentation to the wound care specialist, the wound had become extremely painful and had a thick layer of slough. The surrounding skin exhibited signs of infection that was spreading.

The patient also had a number of co-morbid conditions: arterial hypertension, chronic venous insufficiency, chronic heart failure, surgical revascularisation of the myocardium, pacemaker implantation and type 2 diabetes. The patient was admitted to the hospital for local and systemic treatment of the infected VLU because outpatient treatment had been unsuccessful. A wound biopsy was taken and malignancy and pyoderma gangrenosum were excluded.

On referral to the surgical department, the wound bed was prepared using sharp debridement. Antiseptic poultices with polyhexanid were applied, and polyurethane foam dressings with silver were used. However, the wound remained coated with slough and was painful, with no reduction in wound size.

Baseline: The wound had been present for 5 months and measured 9.4cm (length) x 0.1cm (depth) x 7.8cm (width) (Figure 1). The wound bed was coated with sloughy debris and necrotic granulation tissue. There was a moderate level of yellow, viscous exudate and malodour. There were also erythema and swelling present in the slightly macerated periwound skin. The patient rated her pain as 9 out of 10 on a visual analogue scale (VAS; where 1=no pain and 10=unbearable pain). The patient's quality of life was adversely affected due to the severe pain, dependency on others, admission to hospital and wound odour.

Swab analysis of the wound revealed the presence of *Pseudomonas aeruginosa*, *Proteus mirabilis* and *Enterococcus faecalis*. Biofilm involvement was also suspected because of stalled wound healing, quick restoration of slough on the wound bed after sharp debridement and the presence of a gel-like purulent coating on the wound. The patient was given amoxicillin and clavulanic acid together with ciprofloxacin, according to the advice of a microbiologist, for 7 days.

The wound bed was prepared using sharp debridement and cleansed with Ringer solution. IODOSORB◊ Powder and IODOFLEX◊ were selected for their clinical antimicrobial properties, ease of application, exudate management, and reduction of pain. The total amount of IODOSORB was used in line with the manufacturer's

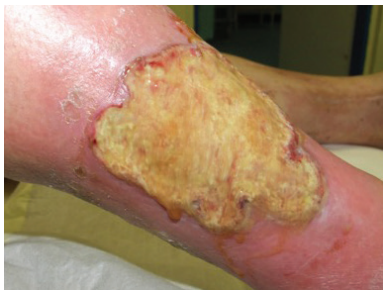

Figure 1: Baseline

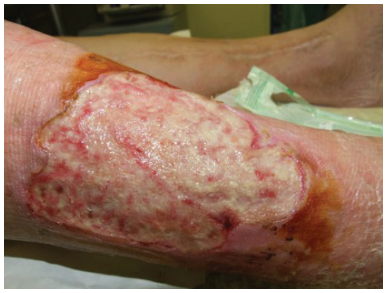

Figure 2: Review 1

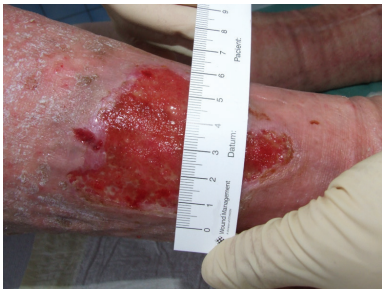

Figure 3: Review 2

instructions (maximum dose 150g/week or 50g per single application). The combination of IODOSORB® Powder and IODOFLEX® was to increase exudate absorption capacity. The dressing was scheduled for change every other day. Analgesics were continued throughout treatment until the VAS pain score had adequately decreased.

Review 1 (1 week from baseline): The wound size had not reduced, but the wound bed had improved, with reduction of slough, and resolution of periwound swelling and erythema (Figure 2). In addition, the patient reported a reduction in pain, giving a score of 6 on the VAS. Antibiotic treatment was discontinued due to improvements in the appearance of the wound. The patient's analgesic doses had been reduced and she was scheduled to be discharged in the following week. Treatment with IODOSORB Powder and IODOFLEX continued, with dressing changes three times per week by the patient. She was also prescribed and instructed in the use of short-stretch compression.

Review 2 (5 weeks from baseline): The wound had reduced in size to 7cm (length) x 0.1cm (depth) x 5.5cm (width). The wound bed had improved, and slough had resolved (Figure 3). The patient's pain had further reduced (a pain score of 4 on the VAS). The patient had been able to change the dressing herself and apply a short-stretch compression bandage without difficulty.

IODOSORB Powder and IODOFLEX were discontinued, due to local topical antimicrobial protocol and because the infection had been controlled, with reduction in wound exudate production. A soft silicone polyurethane foam dressing was used instead.

FINAL COMMENTS

The challenging wound had been present for 5 months before IODOSORB was initiated. It was complex, and wound healing improved while using IODOSORB. Regular sharp debridement of the wound helped to clean the wound and support the antimicrobial effect of IODOSORB. Complete closure has only been achieved after 2 years, due to the complexity of the wound, the presence of type 2 diabetes and the poor vascularisation to the area of scar; however, during this time, there has been no recurrence of infection.

The patient and the clinician were satisfied with the performance of IODOSORB Powder and IODOFLEX in combination in managing the infected, non-healing VLU, particularly in clearing the infection and reducing pain, which was negatively affecting the patient's quality of life. The patient rated the comfort of the IODOSORB Powder and IODOFLEX during wear time as 'very good', and the clinician rated the ability of the products to change colour when product change was required as 'excellent'.

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