TECHNOLOGY UPDATE:

The role of ALLEVYN™ Ag in the management of hard-to-heal wounds


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Hard-to-heal wounds are challenging to treat and have a significant impact on a patient's quality of life and healthcare resources [1,2,3]. For clinicians, hard-to-heal wounds pose the dual challenge of providing cost-effective management, while improving patients' wellbeing and concordance with treatment [1,4,5]. This paper examines the impact of hard-to-heal wounds on patients and reviews the clinical efficiency and cost-effectiveness of a topical antibacterial dressing containing silver sulfadiazine (ALLEVYN™ Ag, Smith & Nephew) in the management of patients with infected hard-to-heal wounds.

INTRODUCTION

The prevalence and costs of chronic wounds is increasing globally. This is reflected in the incidence of venous leg ulcers, which affect approximately 1% of the population worldwide[6] and up to 2.5 million patients per year in the US alone[7]. Pressure ulcers have an overall prevalence rate of around 10%, although this is often higher in individual facilities[8]. The number of diabetic foot ulcers is expected to reach some 380 million by 2025, representing 7.1% of the adult population worldwide (www.idf.org). Venous leg ulcers alone typically consume 1–3% of healthcare budgets[9].

DEFINING HARD-TO-HEAL WOUNDS

In the majority of cases, wounds close following a predictable sequence of overlapping stages[6]. However, in some wounds, despite the best efforts of clinicians using standard therapies, closure is prolonged or never achieved[6]. The challenge for clinicians is to predict when a wound is likely to become hard to heal.

Typically investigators have defined hard-to-heal ulcers as wounds that have[10,11]:

- **Been present for over 12 months**
- **A bioburden of more than 10^5cfu/g**
- **A wound area of more than 10cm^2.**

A review by Margolis et al[12] identified that a venous leg ulcer larger than 10cm^2 and more than 12 months old has only a 22% chance of closure by 24 weeks[12]. Others have shown wound closure rates of 30–35% in 'visually clean' venous leg ulcers at 12 weeks using a standard care regimen[13,14,15], while marginally improved closure rates of 55% at 12 weeks have been achieved where active therapy has been used[13].

There is a lot of data to show that older ulcers are more difficult to heal. There may be multiple reasons for this and the full picture is not clear, but as a consequence costs will be greater[16].

Such low rates of closure place a premium on:

- **Reducing bioburden**[6,17]
- **Effective debridement**[18]
- **Optimising the wound environment for closure** [19].

These must all be achieved while maintaining adequate pain control[20].

White and Cutting[21] state that bioburden in a wound may be one of the most important barriers to wound closure. Bioburden refers to the bacterial load present on the surface of the wound or in the tissue. It is thought that the higher the load, the greater the risk of infection or delayed closure[22]. The bacterial diversity and density may also play a role in the delayed closure process[23], with the presence of specific bacteria linked to closure outcomes (including *Pseudomonas aeruginosa*, *Staphylococcus aureus* and β-haemolytic *Streptococcus*)[23].

The presence of biofilms in the wound bed has been suggested as a major contributory

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factor to the failure of some acute surgical wounds to close. The presence of biofilms is also implicated in some chronic wounds becoming hard to heal[24]. Biofilms are different from normal bacterial colonies in that they are usually composed of mixed microbial species in mutually supportive complex communities attached to the surfaces of a wound and distinct from their planktonic counterparts[24].

In addition, studies have shown that elevated levels of pro-inflammatory cytokines found in some hard-to-heal wounds can lead to the degradation of newly formed extracellular matrix (ECM) and other proteins, such as growth factors and receptors[25,26]. As a result, the wound becomes stuck in the inflammatory stage, and fails to progress to the proliferative phase[27]. Some studies assume that these changes are due to a defect or disorder in the host's ability to regulate the inflammatory processes. Other studies have shown that biofilms can 'hijack' the host response to infection by producing a high level of virulence factors that can either dampen or re-orient the innate and adaptive immune response that usually maintains the inflammatory process[28].

Other contributors to delayed closure include patient-related elements such as diabetes, obesity, hyperglycaemia, tissue hypoxia, old age and restrictions in mobility, all of which need to be addressed as part of a comprehensive assessment, along with other wound-related factors such as wound size and depth, anatomical location, duration and wound-bed condition[6].

IMPACT OF WELLBEING ON WOUND CLOSURE

In addition to the clinical challenges, there is increasing evidence to support a relationship between psychological and socioeconomic factors (such as a patient living alone or with poor nutritional status) and delayed wound closure[28]. Living with a wound is associated with increased anxiety and poor quality of life[3,29].

To capture patient experiences, a large-scale survey was conducted in 15 different countries with over 2,018 patients and reported in a variety of studies [30,31,32]. Data from focus group work was consistent in showing that pain is one of the symptoms that patients find particularly distressing. Pain can impact on a patient's ability to cope, along with feelings of loss of control, 'uncleanliness' and a reduced sense of self-identity, which may also affect sexuality[31]. In addition, the wound may affect the patient's ability to perform everyday activities, which can lead to social withdrawal and loss of financial independence[31].

Many patients who live with a wound over a long period of time indicate that symptom management is very important. Symptoms such as pain, odour and exudate can affect the way patients conduct their lives and they may worry that the wound will deteriorate, never heal or become infected. While patients report that their priority is for the wound to close, the ability to improve patient wellbeing appears to rely on appropriate symptom management, allowing them to get the most out of their daily living. For many patients, managing the symptom most important to them, rather than closure, can be the next step in care management[33].

The emphasis is on the need to address patient concerns through a holistic approach. Listening to patients can help clinicians gain their confidence and trust, leading to a partnership in which, for example, the patient feels able to discuss concerns about medication and clinicians can offer evidence-based advice to the patient on topics such as wound dressings and compression bandaging. A treatment plan can then be mutually agreed[4]. The quality of the relationship between the patient and the clinician can impact positively on treatment outcomes, improve quality of life and help to reduce costs by improving concordance with treatment[1,4,16].

In addition, access to care and referral to clinicians with the appropriate knowledge and skills is vital for an early diagnosis and ensuring that appropriate treatment strategies are used to either achieve closure or manage the symptoms effectively. The importance of educating staff so that they know how to develop wound-care protocols and access resources cannot be underestimated. Such factors will vary in different parts of the world according to national and local standards and priorities for healthcare delivery[6].

CLINICAL APPROACHES FOR HARD-TO-HEAL WOUNDS

Management of wounds should focus on identifying problems early and using appropriate strategies and interventions to facilitate closure. According to several reports[34,18] hard-to-heal wounds are often treated using one strategy at a time. Due to an increase in antibiotic-resistant strains of

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bacteria, wound dressings containing topical antibacterials such as silver, iodine, honey or polyhexamethylene biguanide (PHMB) are popular choices, irrespective of the quality of the *in vivo* efficacy data, since they have a broad theoretical spectrum of antibacterial activity[35,36,37].

However, a lack of knowledge regarding the appropriate and timely use of these products could put patients at risk of delayed closure, while untreated local infection can lead to systemic sepsis [38]. Using antibacterial dressings to stop local infection spreading may avoid unnecessary complications and costs, such as extended hospitalisation and, therefore, it is important to recognise and accurately identify the signs and symptoms of at-risk wounds[39].

THE ROLE OF SILVER DRESSINGS

When the antibacterial properties of silver are used in wound-care products, it is the silver ions rather than the atoms that exert their effect. The theory is that on contact with wound fluid, silver atoms are slowly released from the dressing as positively charged ionic silver (Ag+)[40]. These silver ions kill pathogens in a variety of ways:

- **Binding to the bacterial cell wall, weakening it and causing leakage from the cell and death of the bacteria[41]**
- **Binding to bacterial cell oxidative enzymes, inhibiting their activity[42]**
- **Binding to bacterial cell DNA to interfere with cell division and replication[43].**

How far a dressing's antibacterial effect is influenced by the amount of silver contained in a dressing and the rate of release of Ag+ remains unclear[36,44].

One Cochrane review reported on three studies (n=847) using absorbent sustained-release silver dressings in venous leg ulcers, but failed to show faster closure rates at four weeks[36]. Similarly, the VULCAN study did not show a difference in closure rates over 12 weeks for venous leg ulcers treated with a silver dressing when compared with an absorptive dressing[45].

However, the goal of using a silver dressing is not to close the wound, but rather to help reduce the bioburden and thus prepare the wound bed for closure. Therefore, large studies into the ability of a dressing that is intended to kill bacteria being used to close wounds, many of which may not have significant bacterial burden, would appear to be inappropriate. Indeed, very few studies report on bioburden, with the exception of one that examined a 0.9% cadexomer iodine dressing (Iodosorb™, Smith & Nephew), which was found to significantly reduce *S. aureus* levels over a six-week period in venous leg ulcers[35].

Other factors such as the dressing's capacity to manage exudate, promote autolytic debridement or maintain an optimum wound environment also need to be considered when selecting a silver dressing[44].

Infected wounds are more painful and may be associated with high exudate levels[46]. This can lead to malodour and periwound maceration and leakage, requiring more frequent dressing changes. Treatment of the wound infection, by reducing bacterial load and reducing the inflammatory stimulus to the nervous system, should also result in a reduction in pain, malodour and exudate[46].

ALLEVYN™ AG

ALLEVYN Ag (Smith & Nephew) is described as a highly absorbent antibacterial foam dressing range that has been designed to manage exudate and provide an effective bacterial barrier[40]. It comprises a triple-layered structure of hydrocellular foam containing silver sulfadiazine, a perforated wound contact layer and an outer highly breathable top layer.

Silver sulfadiazine (SSD) is a silver compound that was first developed in 1968 and is effective against a variety of pathogens[47]. It has been used by clinicians as a topical antibacterial agent for burns and other wound types, including venous leg ulcers[48,49,50]. As exudate is absorbed into the dressing and away from the wound, the SSD within the central layer is released as positively charged ions at a bactericidal concentration for up to seven days[51].

In vitro, ALLEVYN Ag has been shown to have a broad spectrum of bactericidal activity against Gram-positive and Gram-negative bacteria, antibiotic-resistant strains, anaerobes, fungi and yeast[52,53].

Clinical evidence for ALLEVYN Ag

In an international study, Kotz et al[2] reported on data generated from 24 participating centres in the USA and Europe. The performance of a number of dressings, ALLEVYN Ag Adhesive, ALLEVYN Ag Non-Adhesive and ALLEVYN Ag Sacrum (Smith & Nephew), was studied for up to six dressing changes in patients with wounds of various aetiologies (median duration 8.7

weeks). The primary objectives of the study were to assess dressing acceptability and dressing performance. Secondary objectives included examining changes to the wound over the course of the treatment period (median 21 days). Treatment settings included wound clinics, hospitals, patients' homes, nursing homes, medical/nurse practices and long-stay health centres.

A total of 126 patients (47% males; 53% females) were recruited and data was captured using a case report form. The suitability of the dressings was assessed in 111 patients and were found to be acceptable for 88% of patients. For the majority of patients, the dressings were found to be either satisfactory or exceeded expectations in exudate management, bacterial barrier, ease of use, durability, patient comfort and convenience[2].

Over the course of the study there was a significant reduction in the percentage of patients presenting with any clinical signs of infection between the first and final assessments ($p<0.001$). There was a median wound area reduction of 61% ($p< 0.001$) with 34 patients (27%) achieving complete closure at the end of the evaluation. There was also a significant reduction in exudate levels between the initial and final assessment ($p<0.001$), with improvement in the appearance of the wound and condition of the surrounding skin[2]. The average wear time was reported as 3.8 days.

This may be attributed to routine practice in the majority of cases, rather than the need to change the dressing because of exudate saturation or other reasons, such as the dressings becoming detached.

These findings are further supported by a recent non-randomised, prospective study by Lantis and Gendics[54]. The study set out to provide a new benchmark for the treatment of patients with infected hard-to-heal venous leg ulcers. The primary goal of the study was to assess the *in vivo* effect of ALLEVYN Ag Non-Adhesive in reducing the total bioburden from 10^5cfu/g or more to less than 10^5cfu/g — the secondary endpoint was to track wound closure and other markers of wound progression.

Of the 33 patients screened, 24 patients were recruited. All had venous disease confirmed by ultrasound with a mean ankle brachial pressure index (ABPI) score of 1.1 (median: 1.2; range: 0.8–1.4), a mean ulcer duration before treatment of 70.6 weeks (median 47.7 weeks), and mean ulcer area of 20.1cm^2 (median 12.3cm^2). All wounds were critically colonised with a bioburden of greater than or equal to 10^5cfu/g. In addition, all patients had at least three clinical signs of infection (mean 5.5 per patient), with the majority of patients exhibiting increased exudate (79%), pain (83%), local peri-ulcer erythema (75%) and oedema (92%). All of the

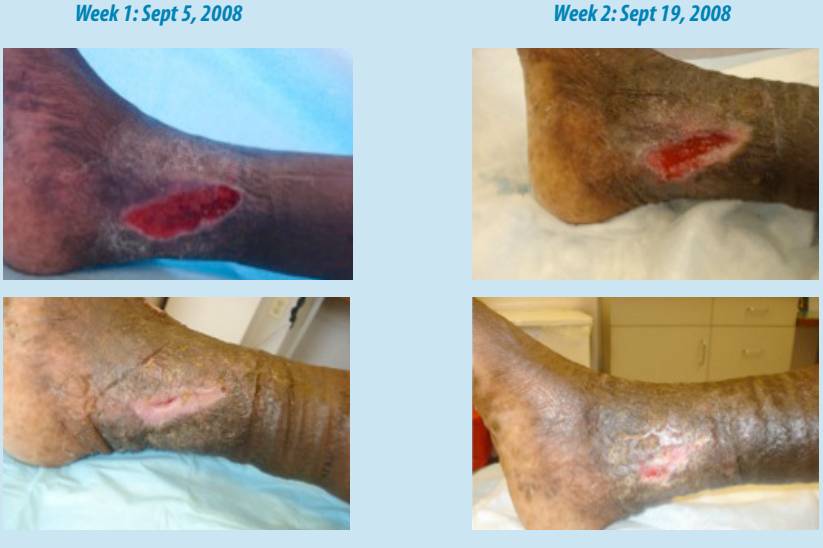

Figure 1 – This patient reported significant reductions in wound complications, including reduction in periwound erythema and oedema.

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Useful links and further reading

ACTICOAT™ and ALLEVYN™ AG Made Easy

Webcast: Improving clinical and economic outcomes in hard to heal wounds

Hard-to-Heal Wounds: a holistic approach

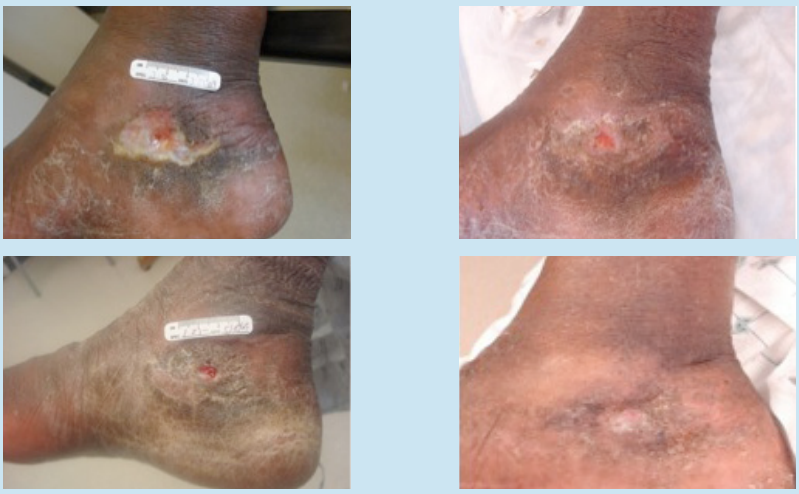

Figure 2 – This patient had a reduction in maceration, periwound erythema and oedema with complete closure of the wound at 12 weeks.

patients experienced non-progression of their ulcer[54]. The most prevalent species at initial biopsy was *Enterococcus faecalis* (9/24), while 79% (19/24) of patients had *S. aureus* at some point during treatment of which 62% (15/24) had a methicillin-resistant strain.

During the study, all patients had ALLEVYN Ag applied to their wounds under compression, using a multilayer bandaging system (PROFORE™, Smith & Nephew). All wounds were assessed on a weekly basis or until wound closure *[Figs 1 and 2]*. Debridement was performed at each weekly dressing change.

Biopsies and semi-quantitative swab cultures were taken to assess bioburden. At week eight, the level of bioburden had reduced to less than 10^5cfu/g tissue in 13 patients (54%) compared with 10 patients (42%) at week two. There was also evidence of a significant reduction ($p<0.001$) in the level of bioburden after eight weeks. All clinical signs of infection were resolved at a median time of 91 days with the median number of clinical signs of infection reduced from 5 at baseline to 0.5 (mean 1.6; range 0–7) at treatment discontinuation. There was also a significant reduction ($p<0.001$) in pain in the last week and exudate level at week 12. Ten (42%) patients complained of malodour at baseline, reducing to five (21%) at treatment discontinuation[54].

There was a significant reduction in ulcer area from baseline to treatment discontinuation ($p<0.001$), while the median wound area reduction after eight weeks was 93%. Of the 24 patients, 19 achieved at least a 75% reduction in ulcer size within eight weeks from baseline. Patients with ulcers less than or equal to the median size (12.3cm^2) achieved a slightly higher percentage area reduction than those with an ulcer greater than the median[54]. A closure rate of 46% was achieved within an 81-day median treatment duration and a median time to closure of 91 days *[Fig 3]*[54].

These findings are significant for this difficult-to-treat cohort of patients, who rarely fall within the inclusion criteria for randomised controlled trials and compare favourably with previously published wound closure rates with active agents, for example, protease-modulating dressings (41% closure in 12 weeks)[13]; extracellular matrices (55% closure rate at 12 weeks)[14]; and bilayered skin substitutes (63% closure at mean 61 days)[55].

Throughout the Lantis and Gendics[54] study period, debridement was performed on a weekly basis and its frequency may be a contributory factor to the wound closure rate achieved[14]. In addition, the significant reduction in pain and exudate levels may have contributed to a good level of patient concordance — no patients interrupted the treatment protocol for longer than seven days. Dressings were changed weekly (mean 7.2 days between dressing changes), providing evidence for longer wear times, compared to an average of 2.7 per week found in a separate study[16], and efficacy when worn under compression bandaging.

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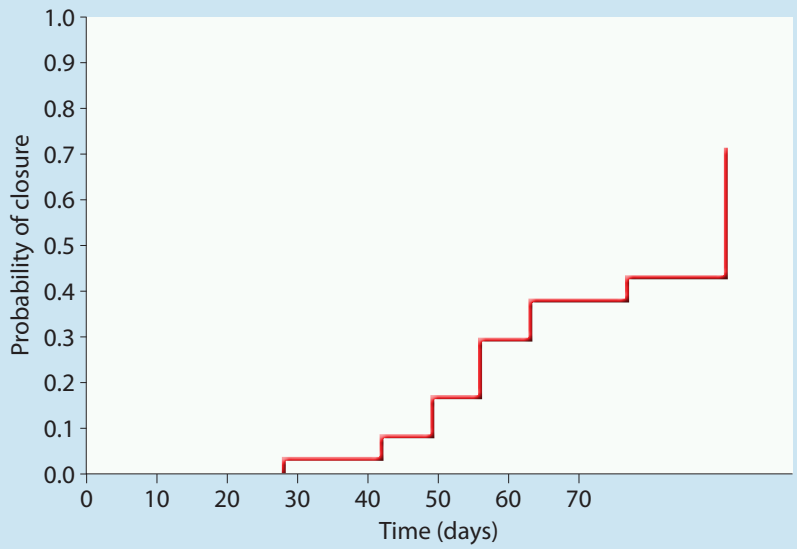

Figure 3 – Kaplan-Meier plot of time-to-closure.

This study provides benchmark data that may support a structured treatment protocol with frequent debridement, together with weekly dressing changes using ALLEVYN Ag in infected, hard-to-heal venous leg ulcers[54].

Cost-effectiveness of ALLEVYN Ag

A cost comparison model *[Table 1]* comparing the wound closure rates achieved by Lantis and Gendics[54] and standard care has subsequently been extrapolated. This table makes a number of assumptions in relation to wound closure rates and frequency of dressing changes in the standard care arm. Furthermore, it assumes that, once the wound is closed, these patients do not incur any further costs and does not factor in follow-on costs associated with further clinic attendance by patients in either arm using standard care versus ALLEVYN Ag.

For the purposes of this cost-comparison model, the study by Skog et al [35] has been used to provide a control baseline, as there was no standard care arm in the study by Lantis and Gendics [54]. The closure rate achieved by Skog et al[35] was 3%. To provide a more conservative measure, a 5% wound closure rate for standard care in hard-to-heal venous leg ulcers is assumed in the model. The dressing change frequency in the study by Lantis and Gendics was every 7.2 days[54]. When calculating costs for the standard care arm, twice-weekly dressing changes have been assumed to reflect standard clinical practice in such wounds[16], with an average of 32 minutes nursing time per visit.

Using these assumptions, it is possible to model the costs of once-weekly versus

Parameters	Compression + ALLEVYN™ Ag	Compression only (standard care)	Source
Treatment length (days	84 (12 weeks)	84 (12 weeks)	Lantis and Gendics[54]
Mean time to wound closure (days)	57.3 (eight weeks)	57.3 (eight weeks)	Lantis and Gendics[54]
Wear time (days)	7.2	3.5	Lantis and Gendics [54] Tennvall et al[16]
Duration of community nurse visit (minutes)	30 (US$47/hour)	30 (US$47/hour)	US Bureau of Labor Statistics
Wound closure rate	45.8%	5%	Lantis and Gendics[54] Skog et al[35]

Table 1 – Cost comparison of ALLEVYN™ Ag plus compression versus standard care.

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twice-weekly nurse visits in the standard care arm. The resulting figures show that the once-weekly dressing changes may save US$158 per patient in material costs and a further US$314 per patient in reduced nursing time — a total saving of US$472 per patient over 12 weeks. These costs feature Medicare reimbursement and are taken from the US Bureau of Labor Statistics 2009 (www.bls.gov/home.htm). A clinical evaluation of 25 patients who were treated with ALLEVYN Ag Adhesive and Non-Adhesive in a UK accident and emergency department also illustrates the cost savings associated with the dressing[56]. This study estimated a material cost saving of 40 euros per week. Dressing changes were also reduced by 1.6 per week, resulting in 160 minutes of saved nursing time for each 10 patients treated with ALLEVYN Ag.

It must be noted that neither of these studies were designed to validate the cost benefits of using ALLEVYN Ag in patients with chronic wounds. Therefore, the performance of larger studies with a control arm are necessary if comprehensive conclusions about any cost savings are to be drawn.

CONCLUSION

The management of hard-to-heal wounds relies on a comprehensive approach to care that involves a structured treatment protocol and allows for the practical application of available therapies. Patients with a good level of symptom management and who are concordant with therapy will often go on to achieve closure of their wounds. In wounds where healing is impaired by the presence of bioburden there is a need for clinically effective antibacterial therapies that are easy to use, effective, and that reduce the drain on scarce healthcare resources.

This study featured in this article provided a 'real-world' clinical evaluation of a protocol for the treatment for longstanding venous leg ulcers using a dressing containing silver sulfadiazine[54]. This provides a benchmark for clinicians seeking to reduce the human and financial costs of hard-to-heal wounds.

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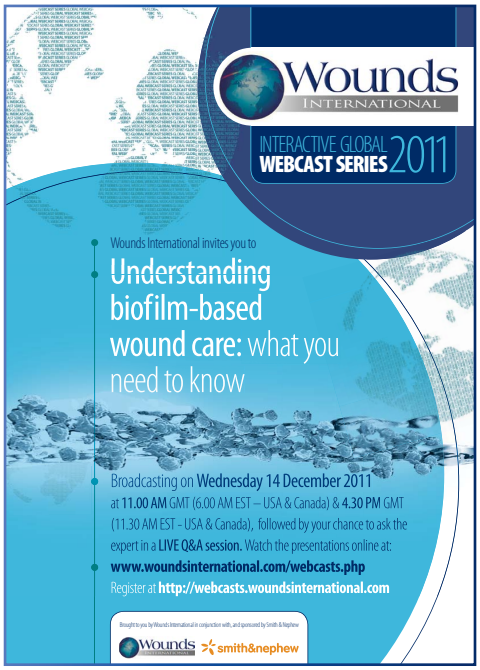

WOUNDS INTERNATIONAL WEBCAST SERIES 2011

Wounds International has launched a new webcast series focusing on topical issues for clinicians worldwide and providing an opportunity to ask the expert. The first webcast was broadcast on 8 June 2011 and was on **Improving clinical and economic outcomes in hard to heal wounds**. Professor Patricia Price and Dr John Lantis discuss the impact of hard to heal wounds on patients and suggest a management algorithm for those with infected venous leg ulcers. For those of you who did not log on to view this live broadcast, you can watch the videos at: **http://www.woundsinternational.com/webcasts.php**

To watch the second webcast in this series with Professor Gregory Schultz and Dr John Lantis speaking on **Understanding biofilm-based wound management: what you need to know**, register at **http://www.webcasts.woundsinternational.com**