Setting a new clinical pathway for faster healing of chronic wounds

The 26th EWMA conference in Bremen, Germany on the 11-13 May 2016, centred around the theme of ‘Patients.Wounds.Rights’. Fitting directly within this was a symposium, sponsored by Urgo Medical, highlighting the burden of chronic wounds to health-care professionals, patients and health-care systems and the crucial need to develop a new pathway to accelerate wound healing. The session was chaired by Dr Karl-Christian Münter. A key highlight of the symposium was the presentation of a pooled real-life data analysis from over 10,000 patients, supporting that the healing time of leg ulcers can be reduced from 210 days to 112 days.¹

Dr Münter introduced the detrimental impact of chronic wounds on health-care professionals, patients and health-care systems across the world. One to two percent of the global population² is affected by chronic wounds and costs £3.1billion per year in the UK.³ Research has found that up to 42% of leg ulcers remain unhealed for more than six months.⁴ These statistics show the critical need to accelerate wound healing time to lighten the load on health-care systems and improve patient health and wellbeing.

What do we need to do within the wound to accelerate healing?—Professor Steven Percival, CEO 5D Health Protection Group Ltd, Liverpool, UK

Many factors affect the wound healing process such as age, gender, stress, disease, obesity, medications, and nutrition. As well as these, local factors like slough, debris, necrosis or excessive levels of Matrix Metalloproteinases (MMPs) may contribute to increasing the risk of local infection and to prolonging the wound healing process.

Professor Percival laid out the key factors that need to be addressed to heal wounds faster:

● Cleaning and keeping the wound clean
● Fully controlling the risk of infection
● Rebalancing the levels of MMPs.

Cleaning and keeping the wound clean

● The presence of microorganisms, slough, exudate and biofilm in the wound maintains an ideal environment for microbial proliferation and biofilm formation. Indeed, wounds with debris, exudate and friable tissue is five times more likely to have critical colonisation.⁵ The presence of such materials can impede wound healing by maintaining a prolonged inflammation leading to the imbalance of proteases and the degradation of growth factors.

Fully controlling the risk of infection

● Managing local infection requires a combined antimicrobial and cleaning action to reduce the bioburden of the wound more effectively by reducing microbial levels and facilitating complete action of Ag+ ions. Moreover, complete cleaning reduces infection risk by helping the removal of biofilms which can stimulate inflammation and slough production, and by removing all materials where microorganisms may attach, disseminate and form biofilm.

Rebalancing levels of MMPs

● Chronic wounds display higher levels of MMPs than normally healing acute wounds. Excessive levels of MMPs impede the healing process by degrading extracellular matrix (ECM) proteins and causing degradation of growth factors, which are essential for healing. Therefore all chronic wounds should be treated for their protease imbalance and would benefit from a protease modulating treatment.

When the risk of infection is present: UrgoClean Ag with complete cleaning action—Dr Michèle Sigal, MD, Dermatologist, CH Victor Dupouy, Argenteuil, France

The first step to reducing the risk of infection must be to identify the possible sources as early as possible and to be

UrgoClean Ag

UrgoClean Ag is a silver dressing with a complete cleaning action. It fights against local infection by reducing the bacterial load within the wound and removing all materials that favour bacterial proliferation and may limit the silver action. These two properties effectively fight against local infection with a combined antimicrobial, antibiofilm and complete cleaning action.
vigilant about local inflammatory signs suggesting risk of infection. When local infection is identified a silver dressing which can both have an antimicrobial and complete cleaning action should be used. Three studies have been conducted by Urgo Medical to determine the efficacy of UrgoClean Ag.  

2008: The UTAG RCT
This was a clinical trial with 102 patients treated either with the TLC healing matrix (control group) or the sequence TLC-Ag healing matrix and TLC healing matrix. The clinical score suggested that heavy bacterial load was significantly lower in the TLC-Ag group than in the control group at week 8 (clinical score of 1.43 versus 2.31 in the control group).

2012: The EARTH RCT
The EARTH RCT recruited 159 patients that were either treated with UrgoClean or Aquacel. The results showed that the poly-absorbent fibre dressing (UrgoClean) achieved a significantly larger reduction of sloughy tissue (65.31% versus 42.62% reduction) and significantly more desloughed wounds (52.5% versus 35.1%) than Aquacel at week 6.

These two RCTs have respectively proven the antimicrobial efficacy of TLC-Ag healing matrix evaluated by improvement of clinical score suggesting heavy bacterial load, and the desloughing properties of poly-absorbent fibres.

2013: UrgoClean Ag study
Following the successful results of the RCTs, a clinical study was conducted to evaluate the efficacy, acceptability and safety of UrgoClean Ag. This involved 37 patients across 17 centres in France over a 4 week period. The researchers found that there was a wound area reduction of 32.5% at week 4 and that heavy bacterial load decreased after a 4-week treatment. It reduced sloughy tissue to the wound bed by 62.5% at week 4 and there was very good/good conformality in 97.4% of cases.

In conclusion UrgoClean Ag should be considered as part of the new clinical healing pathway because it provides combined antimicrobial and cleaning action to effectively fight against local infection.

Healing chronic wounds faster relieves the burden for patients: UrgoStart, the only dressing proven to accelerate healing—Dr Sylvie Meaume, MD, Gerontologist-Dermatologist, Head of the Clinical Gerontology Department, Wound Care Unit, Hospital Rothschild APHP, University of Paris, UPMC, France

Having a chronic wound can seriously impact a patient’s quality of life. In fact 27% of patients with chronic wounds were considered depressed. They lost working days and experienced social isolation, depression/anxiety and increased stress. Given the negative impact and burden that chronic wounds have on patients, a pathway to speed up the healing process must be developed to enable an earlier return to their normal life.

UrgoStart is proven to accelerate healing by modulating excess MMP levels and enhancing fibroblast proliferation.

The Challenge RCT
Dr Meaume introduced this double-blind RCT which tested the efficacy of TLC-NOSF dressings in the local treatment of venous or mixed leg ulcers. 93 patients had the UrgoStart treatment and 94 patients had a neutral foam dressing. The researchers found that UrgoStart healed wounds twice as fast as a neutral dressing by modulating levels of MMPs and significantly relieving patients’ pain and anxiety.

Why UrgoStart should be the first line treatment for chronic wounds: an analysis of more than 10,000 patients—Dr Karl-Christian Münter, MD, General Practitioner and Phlebologist, Phlebological Practice, Hamburg, Germany

The Challenge Study is one of the most significant studies in wound healing according to Dr Münter, since it is the only double-blind RCT conducted in the wound care field, providing for a dressing the proof of superior wound healing properties.

However, he also highlighted that it is important to develop real-life evidence to corroborate clinical trials. The need for this led to an analysis of real-life data pooled from 8 observational studies, which were conducted in France and Germany with over 10,000 patients. Two indicators were used to evaluate the impact of UrgoStart:

- Time to complete closure
- Time to 50% reduction of PUSH score (an assessment tool based on 3 indicators: wound surface area, exudate level and tissue type).

The results revealed that leg ulcers treated with UrgoStart took 112 days to heal in comparison to the average of 210 days recorded in the SNIIRAM database.

UrgoStart
UrgoStart is proven to accelerate healing. Its unique TLC-NOSF healing matrix modulates excess MMP levels which impede wound healing. UrgoStart has been proven in a double-blind RCT to heal twice as fast as a neutral foam dressing and to significantly improve patient’s quality of life. These results have been confirmed in real-life evidence, on over 10,000 patients: UrgoStart reduces healing time of leg ulcers by 100 days on average.
This shows that UrgoStart reduces healing time of leg ulcers by 100 days on average.

In addition, the data has revealed that there was a shorter time to closure if UrgoStart was used as a 1st line treatment. It has also been observed that the higher the severity score, the higher the time to closure, which suggests that the earlier UrgoStart is prescribed, the shorter the time to closure.

In conclusion, the real-life data reflected the results that were found from the RCTs. The indicators studied suggested that UrgoStart dressings promote healing whatever the aetiology of the chronic wound and its severity level. From these results it can be concluded that UrgoStart is an important first line treatment for all chronic wounds.

Conclusion
It is well recognised and accepted that chronic wounds heavily impact on patients wellbeing, the health-care services budgets and the time of health-care professionals. Therefore it is crucial to develop a clinical pathway which can accelerate wound healing. In order to achieve this we must:

○ Control local infection through wound cleaning and reduction of bioburden of the wound. UrgoClean Ag effectively fights against local infection by combining antimicrobial and cleaning action.

○ Tackle the excess levels of MMPs, which impede healing in chronic wounds. UrgoStart is a dressing proven to accelerate healing and is an important first line treatment for chronic wounds.

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References
1 Kérihuel JC. Practical management of chronic wounds with TLC-NOSF dressings: an evaluation based on more than 10,000 wounds treated by French and German health professionals. EWMA 2016; Free Paper Session.
9 Evaluation of the efficacy, safety and acceptability of the Urgo 310 3084 dressing in the local management of chronic wounds with inflammatory signs from debridement stage; Data on file, 2013
NEW! EWMA document: Management of patients with venous leg ulcers: challenges and current best practice

- MMP modulating dressings are recognised as improving healing of venous leg ulcers:
  ‘Finally, there is some evidence that some modern dressings and procedures that modulate MMPs may be effective in improving healing rates’

- Silver dressings are recommended as a possible therapy in case of local infection:
  ‘Antimicrobial therapy such as silver […] dressings can be prescribed when a VLU exhibits signs of infection.’

- Multicomponent bandages are recommended as the most effective compression system in venous leg ulcers:
  ‘Multicomponent bandages are more effective than single component bandages in achieving ulcer healing, perhaps due to the ability to maintain pressure and stiffness. They are cost-effective as well as effective in reducing healing time, thereby shortening the treatment period.’

Download the full guidance document introduced at EWMA Conference 2016:
http://www.magonlinelibrary.com/page/jowc/resources