

Evaluation of a New Extracellular Matrix Protein for Wound Treatment on a Hard-to-heal Venous Leg Ulcer: A Case Study Evaluation

Authors: Kaija Uusimäki (MD) and Anna Pöyry (RN), Seinäjoen keskussairaala, Dermatology polyclinic, Hanneksenrinne 7, 60220 Seinäjoki, Finland.

INTRODUCTION

The incidence of chronic wounds varies according to age, health status and co-morbidities such as diabetes, cardio-vascular and neurological diseases. The primary chronic wounds are pressure ulcers, venous leg ulcers and diabetic wounds (Mustoe et al, 2006). Approximately 1–2% of the population will suffer from a leg ulcer during their lifetime (Barwell et al, 2004); prevalence increases with age (Vowden et al, 1997). There are major economic consequences on the health care system as a result of venous leg ulcers (Bouza et al, 2005) and, as a result, their treatment is a heavy economic burden on health services in many countries. Venous ulcers (VLU) are characterised by a cyclical pattern of healing and recurrence. The main treatment is graduated compression (decreasing from toe to knee), either in the form of compression bandages or hosiery. However, it has been shown that a significant percentage (10–20%) of VLU fails to heal despite compression therapy (Barwell et al, 2004). This has set demands for health professionals to increase their knowledge and skills in the daily management of wounds, and to keep up to date with new wound treatment methods so that they can select the best care for each patient. An advanced treatment that has recently been used is *Xelma*® (Mölnlycke Health Care), which has been developed and adapted from a successful periodontal disease treatment.

This advanced product consists of an extracellular matrix (ECM) biocompatible protein – amelogenin, which when applied to the wound bed provides a temporary matrix for cell attachment. In hard-to-heal wounds, restoration of the cellular and biochemical balance is facilitated and aids in the promotion of granulation tissue, initiating a healing response. As such, *Xelma* has been demonstrated to be successful in the treatment of both acute and chronic wounds. (See Table 1.)

MATERIALS AND METHODS

A case study is presented that shows the treatment (using *Xelma*) and progression of healing of a patient with three adjacent venous leg ulcers that had previously failed to heal despite standard treatment.

Patient History – A female presented with vascular insufficiency that had resulted in a series of three adjacent venous leg ulcers on the lower leg in place for more than 10 years. The patient had cardiac insufficiency and ASO (Arterio Sclerosis Obliterans). The wound had failed to heal despite treatment with Zip Zoc compression, Ventipres (1 hour weekly) and a succession of different dressings such as Acticoat Silver, and Aquacel Ag. Surgical techniques such as skin grafting and vein surgery had also been unsuccessful. The three ulcers were located on the right lower leg of the patient and, prior to treatment with *Xelma*, were 6.0 x 2.0 cm, 1.5 x 4.5 cm and 1.0 x 1.0 cm in size. Two of the closely adjacent ulcers were in danger of combining. Generally, the surrounding skin of the ulcer was healthy, with no signs of maceration.

The following parameters were used at baseline (prior to treatment) as a means of evaluating healing in these wounds:

1. Wound size (length x width).
2. Granulation tissue as a percentage of wound area.
3. Pain, measured using a Visual Analogue Scale (VAS).
4. Wound exudate level.
5. Wound Status.

The patient was treated with *Xelma*, applied topically to the wound weekly, for a maximum period of 12 weeks. Mepilex was used as a secondary dressing under compression therapy. The wounds were evaluated at weeks 6 and 12.

RESULTS

Table 2. Assessment of healing in VLU treated with *Xelma*

	Baseline	6 weeks	12 weeks
Wound Areas	Wound 1 = 12 cm ² Wound 2 = 6.5 cm ² Wound 3 = 1 cm ²	Wound 1 = not measured Wound 2 = not measured Wound 3 = healed week 4	Wound 1 = 1.5 cm ² Wound 2 = healed week 11
% Granulation Tissue	80	100	100
Wound Exudate	Moderate	Low	Low
VAS	1–2	1–2	1–2
Wound Status	Static, not healing	Improving	2 out of 3 healed
	See Figure 1	See Figure 2	See Figure 3

CONCLUSION

The overall clinical impression of the product was good: *Xelma* was easy to use and could be applied under standard dressing types (e.g. Mepilex) and compression therapy, on a weekly basis. It was not painful for the patient and, most importantly, was successful in initiating an excellent healing response in wounds that had failed to heal when treated with standard dressing therapies. These findings on a single patient with refractory VLU are consistent with those reported in a recent RCT (Vowden et al, 2006).

References

- Mustoe TA, O'Shaughnessy K, Kloeters O. Chronic wound pathogenesis and current treatment strategies: a unifying hypothesis. *Plast Reconstr Surg.* 2006 Jun;117(7 Suppl):355-415
- Barwell JR, Davies CE, Deacon J, Harvey K, Minor J, Sassano A, Taylor M, Usher J, Wakely C, Earnshaw JJ, Heather BP, Mitchell DC, Whyman MR, Poskitt KR. Comparison of surgery and compression with compression alone in chronic venous ulceration (ESCHAR study): randomised controlled trial. *Lancet.* 2004 Jun 5;363(9424):1854-9
- Vowden KR, Barker A, Vowden P. Leg ulcer management in a nurse-led, hospital-based clinic. *J Wound Care.* 1997 May;6(5):233-6
- Bouza C, Munoz A, Amate JM (2005). Efficacy of modern dressings in the treatment of leg ulcers: a systematic review. *Wound Repair and Regeneration* 13: 218-29
- Vowden P, Romanelli M, Peter R, Bostrom A, Josefsson A, Stege H. The effect of amelogenins (*Xelma*) on hard-to-heal venous leg ulcers. *Wound Repair Regen.* 2006 May-Jun;14(3):240-6

Photographs of venous leg ulcer wounds treated with *Xelma* at 0, 6 and 12 weeks



Figure 1. Baseline, prior to treatment with *Xelma*. Three large, clean wounds of more than 10 years ulcer duration are present.



Figure 2. At 6 weeks, the wounds have had 6 weekly treatments with *Xelma*. Good progress in wound healing is demonstrated.



Figure 3. At 12 weeks, the wounds have had 12 weekly treatments with *Xelma*. Complete healing is demonstrated. At six months of follow up, all the wounds were still fully healed.

Table 1. Summary Clinical Evidence

The effect of amelogenins (*Xelma*) on hard-to-heal venous leg ulcers.
Vowden P, Romanelli M, Peter R, Bostrom A, Josefsson A, Stege H. *Wound Repair Regen.* 2006 May-Jun;14(3):240-6.

Matrix Proteins – The innovative therapy changing the future for hard-to-heal wounds, WUWHS Meeting, Paris, July 2004.

Keith Harding, Christina Moffat, Gregory S Schultz, Stina Gestrelus, Magnus S Agren, Hilde Heyman, Jan Apelqvist and Tonny Karlsmark.

Case Studies from a Pan European Randomised Clinical Trial.

Peter Vowden, Jenny Wnorowski and Anna Josefsson.

Amelogenins (*Xelma*) in hard-to-heal venous leg ulcers, an open regime investigation.

M Romanelli MD PhD, T Ellervee MD, H Järve MD, E Kaha MD.