

Xelma[®] Evaluation in Seinäjoki Finland

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A Case Study Evaluation of Xelma® on a hard-to-heal venous leg ulcer

Background

Xelma is a new advanced treatment that has been developed and adapted from a successful periodontal disease management therapy. This treatment consists of an extracellular matrix (ECM) biocompatible protein amelogenin. When applied to the wound bed it provides a temporary extracellular matrix protein for cell attachment, thereby aiding in the restoration of cellular and biochemical balance and promoting granulation tissue formation and stimulating normal wound healing in hard to heal wounds such as venous leg ulcers.

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.

Results

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

The overall impression of the product was good, Xelma was easy to use and could be applied under standard dressing types (eg 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

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.

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.

in wounds that had failed to heal when treated with standard dressing therapies. At six months follow-up (17-08-06) the wounds were and still are fully healed.

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.

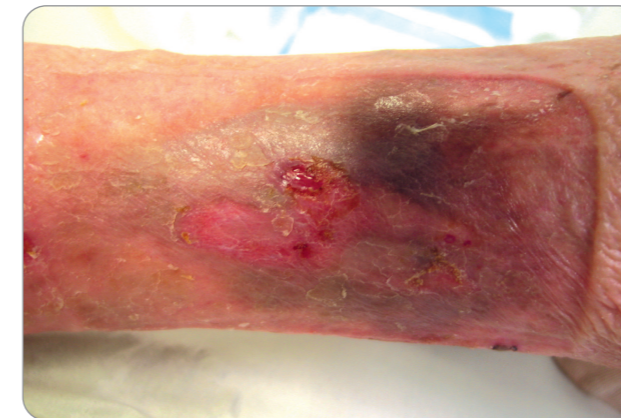


Figure 2. The patient's wounds at the 6 week time point are demonstrated, with one wound fully healed by week 4 and the two remaining wounds showing good progression of healing.



Figure 3. The patient's wounds at the 12 week time point are demonstrated, with a further wound fully healed by week 11 and the remaining wound almost completely healed. At six months of follow-up all of the wounds remained completely healed.

Xelma® Extracellular matrix protein

Time for a change in hard-to-heal wounds

Xelma is a novel treatment for hard-to-heal wounds, primarily venous leg ulcers. Xelma provides a temporary extracellular matrix protein for cell attachment. This biological treatment approach is novel because it is designed to restore the balance by replacing crucial components of the defective extracellular matrix. In clinical investigations Xelma has shown promising benefits in hard-to-heal wounds.

The product

Xelma is a sterile ready-to-use product for topical application. Xelma consists of 1 ml viscous solution of extracellular matrix proteins (amelogenins) in propylene glycol alginate and water.

Areas of use

Xelma is indicated for hard-to-heal ulcers, primarily venous leg ulcers. Xelma can be used under compression therapy.

Application

Xelma is intended for topical application and should be covered by a secondary dressing such as Mepitel®, Mepilex® or Mepilex® Border and applied to the wound surface once weekly. If no improvement is observed within 6 weeks the treatment is to be reassessed.

How Xelma works

When applied to the wound bed Xelma provides a temporary extracellular matrix protein for cell attachment. This creates favourable conditions for wound healing by restoring vital cell functions including proliferation, migration, and production of growth factors and essential extracellular matrix components. Restoration of the cellular and biochemical balance is facilitated in the hard-to-heal wound, which will promote wound healing.



Assortment

Art No	Size	Pcs/shelf cont	Pcs/transport cont
373737	1ml	1 syringe	6 syringes