

An Evaluation of a Matrix Replacement Treatment in Intractable Wounds

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INTRODUCTION

The cost of an unhealed leg ulcer was calculated in 1992 at £1,067 per year (Bosanquet, 1992) and that cost would have greatly increased over 15 years.

A healing wound will produce an extracellular matrix (ECM), which serves as a support for new cells and regulates cellular functions through cell adhesion. Decreased ECM production combined with excessive degradation of ECM can result in slow-healing wounds. A new treatment (Xelma[®], Mölnlycke Health Care) for hard-to-heal wounds has been developed to temporarily replace the required ECM protein within a wound, to restore cellular and biochemical balance and promote healing.

SUMMARY

This work was based on a series of case studies. The overall aim was to evaluate how Xelma is used in general practice for hard-to-heal leg ulcers. Case studies allow us to see how valuable any particular therapy is for treating wounds that are cared for daily by the nurses within the community, including wounds which may not always be included in formal research studies due to strict inclusion/exclusion criteria.

In this series of case studies, held over a period of 24 weeks, there was an overall healing rate of 50% full closure of wounds treated with Xelma. One of the case studies, an elderly gentleman with a wound of 65 years, healed completely in the 24-week period of the study.

AIM

To evaluate the healing potential in patients with hard-to-heal venous stasis wounds when treated with Xelma. To gain practical experience of using Xelma, to provide guidance to clinicians. To assess patient and clinician satisfaction with use and application of Xelma.

METHODS

Patients were consented prior to taking part in the evaluation and consent was also provided for photographs to be taken. Each patient was given a full written and verbal explanation of the evaluation. This was a non-intentional post-marketing surveillance study of a product CE marked to the Medical Devices Directive, where the product was used within its intended purpose. In such incidences, ethical approval is not considered a requirement (NHS National Patient Safety Agency 2006).

Xelma was applied weekly to wounds and covered with a dressing (Mepilex[®] or Mepitel[®], Mölnlycke Health Care). All patients received either high compression bandaging or compression hosiery during the evaluation. Wounds were assessed and photographed weekly. Treatment duration with Xelma was 12 weeks and patients were followed up for a period of 24 weeks. (No Xelma was applied between weeks 13 and 24.)

RESULTS

A total of 8 patients took part in the evaluation. One patient had 3 separate ulcers, giving a total of 10 wounds. The average duration of the wounds evaluated was 9.3 years: (one wound was 65 years duration, following a war injury); one was 10 years; one was 5 years; two were 3 years; three were 2 years; and two were 6 months.

Patient 1



Figure 1: 90-year old gentleman sustained an ankle wound in the 2nd World War. The wound never fully healed in the 65-year duration and measured 3cm² at baseline.



Figure 2: The wound achieved full closure.

Patient 2



Figure 7: 69-year old lady, foot wound of 3 years duration, measuring 26cm² at baseline.



Figure 8: Wound has almost achieved full closure at week 9.

Patient 3



Figure 9: A 71-year old lady with Parkinson's Disease. Wound was of 5 years' duration, measuring 40cm² at baseline.



Figure 10: Wound has almost achieved full closure at week 24.

Patient 4



Figure 9: A 51-year old lady with a wound of 6 months' duration. Measures 14cm² at baseline.



Figure 10: Wound is fully closed by week 8.

Patient 5

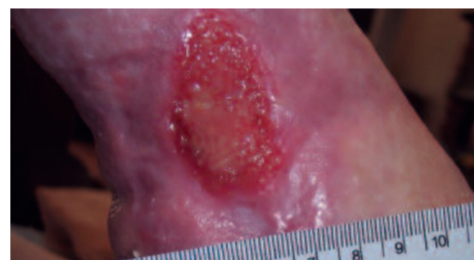


Figure 13: 94-year old gentleman with a recurring leg ulcer of two years' duration, measuring 7cm² at baseline.



Figure 14: Wound has achieved full closure by 24 weeks.

Patient 6



Figure 15: A very active 42-year old lady with a wound that was growing in size over last 6 months.

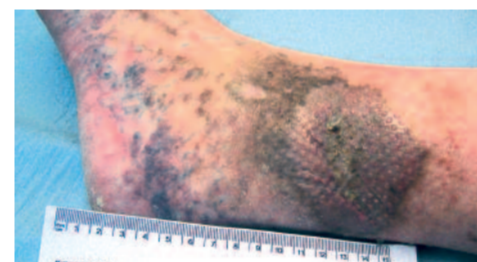


Figure 16: Wound has achieved full closure by week 3.

Patient 7



Figure 17: A 70-year old lady with a wound of 2 years' duration and measured 3.5cm² at baseline.



Figure 18: Wound has achieved full closure by week 6.

Patient 8 wound 1 (left leg)



Figure 3: An 82-year old gentleman with a wound of 2 years' duration, measuring 18cm² at baseline.



Figure 4: At 19 weeks, wound measured 3cm².

Patient 8 wound 2 (right leg)

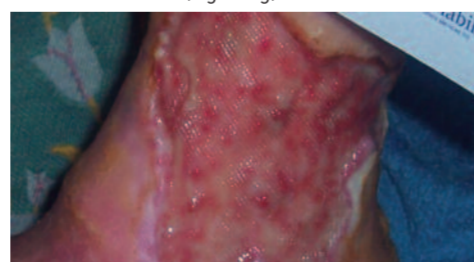


Figure 5: Measuring 67cm² with 'cliff' like edges approximately 1cm in depth at baseline.

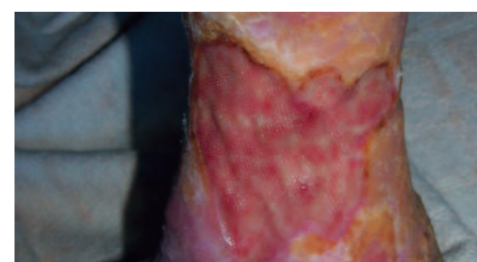


Figure 6: The wound is now shallow with a total surface 36cm² by week 24.

Patient 8 wound 3 (left leg medial malleolus)

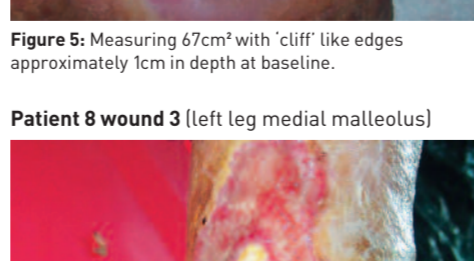


Figure 19: Wound on left medial malleolus treatment with Xelma, started 2 months after wounds 1 and 2. Wound measuring 32cm² at baseline.



Figure 20: Wound is fully granulating, with some epithelial tissue present by week 12.

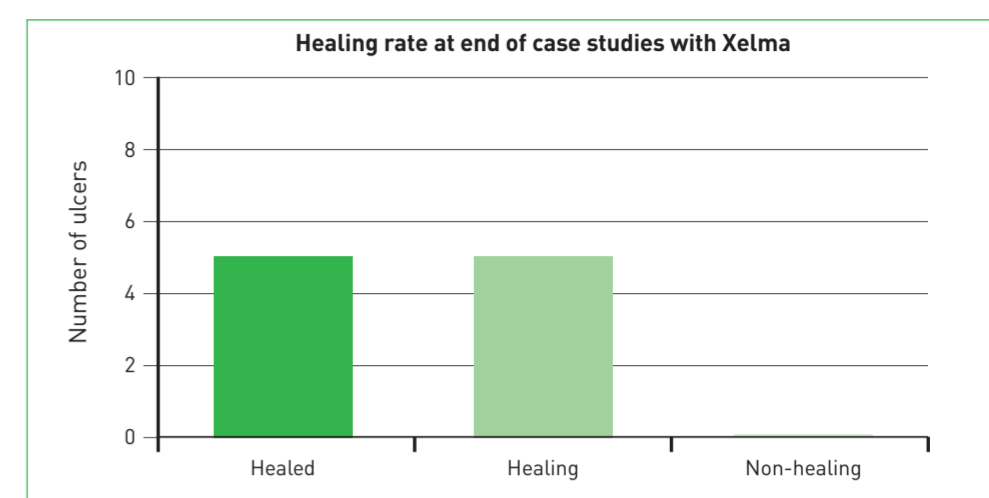


Figure A

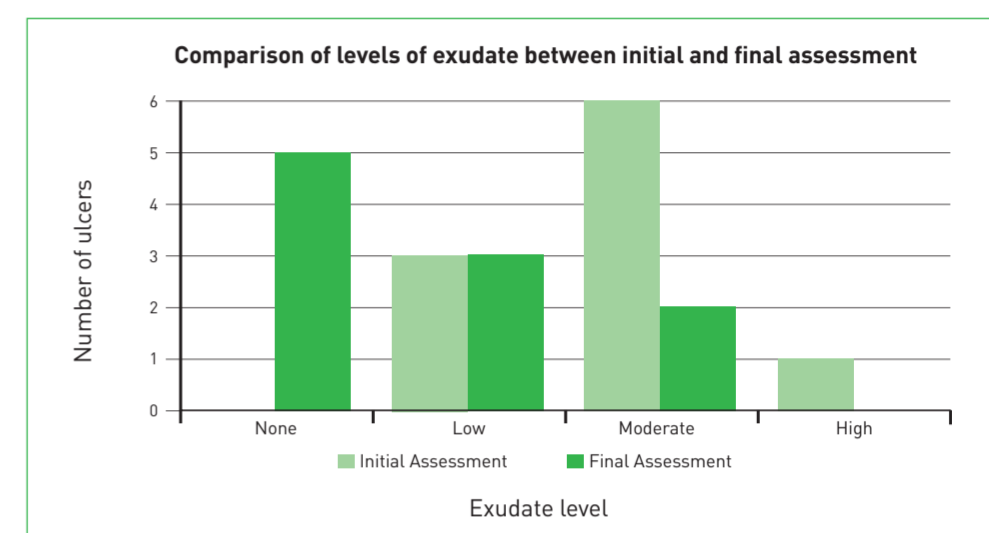


Figure B

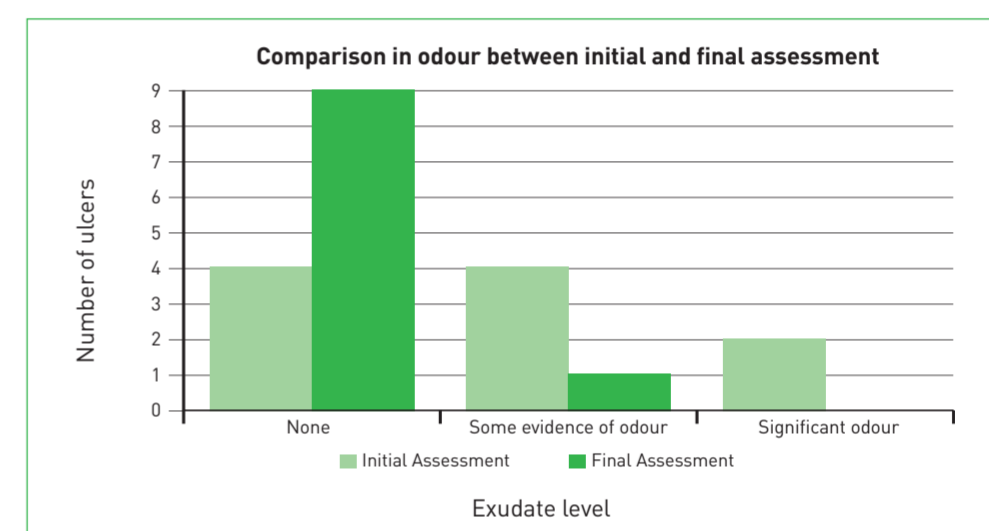


Figure C

Five wounds (50%) healed during the evaluation; three wounds during the 12-week treatment period (one after 3, one after 6, and one after 8 weeks of treatment with Xelma); and a further two wounds had healed by the 24-week follow-up visit (Figure A). The remaining five wounds were in a healing state at 24 weeks, with a mean reduction in size of 60% compared to baseline values. The patient in the case study of the 65-year old wound fully healed, as did those of 2 years and of 6 months duration. Exudate levels reduced over the period of the evaluation, as did wound odour (Figures B and C). The case studies are summarised in figures 1-20.

The most significant of these case studies, was a 90-year old gentleman who had been shot in the ankle in World War 2 (Figures 1 & 2). The wound had never healed, and his surgical consultant had advised amputation. Once Xelma was applied, the wound went on to full closure. This has revolutionised this gentleman's life, as he can now swim and go on holiday without fear. On two occasions, once the Xelma was discontinued, healing slowed. Xelma was reapplied at the end of the evaluation period and healing was reactivated.

CONCLUSION

These are 'real life' hard-to-heal wounds, of long duration, and are of the type commonly found by the nurse in the community. Xelma appears to 'kick start' the wound healing potential, with a 50% healing rate at 24 weeks.