

# INTERIM RESULTS FROM THE OXYZYME® CASE STUDY PROGRAMME OXY-CS001 ON CHRONIC WOUNDS (MAR 2008)



## SUMMARY

- ◆ 67 wounds were included in this analysis
- ◆ 10% (7) of the wounds treated healed in under 6 weeks
- ◆ 6% (4) healed in 6-16 weeks
- ◆ A further 52% (35) improved or showed some improvement during the course of the case study
- Thus a total of 68% of wounds healed or improved
- ◆ 18% (12) wounds treated remained static
- ◆ 13% (9) wounds deteriorated

## PURPOSE

Archimed's mission is to deliver new, more effective approaches to wound healing, based upon a fresh look at the fundamental processes at work in the wound and on close co-operation with wound care professionals.

Archimed is committed to working with those involved in wound care at every level. Part of this involves running an extensive European case study programme designed to allow professionals to evaluate new technology products, such as Oxyzyme®, under normal working conditions. Further products and case study programmes will follow shortly. All of our case study programmes are designed to allow the various data sets from many different centres and countries to be combined to give greater statistical significance.

The primary objective of this ongoing programme is to evaluate the ability of the Oxyzyme® dressing to provide a healing environment in wounds. Secondary objectives are to examine the characteristics of the wound base, exudate, odour and the surrounding skin, and to gather patient and carer feedback on the comfort, use and performance of the dressing.

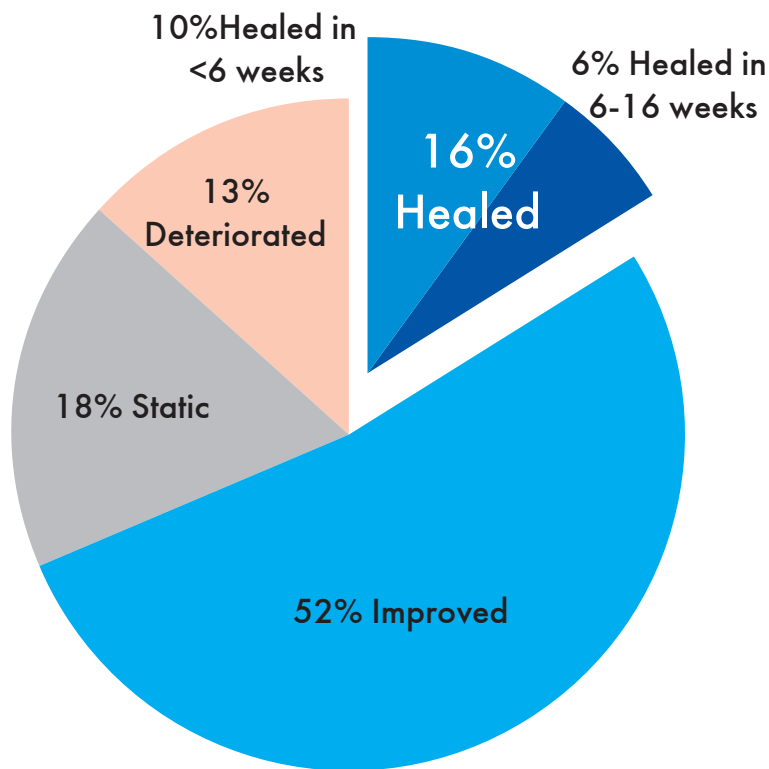


Figure 1: Summary of Outcomes

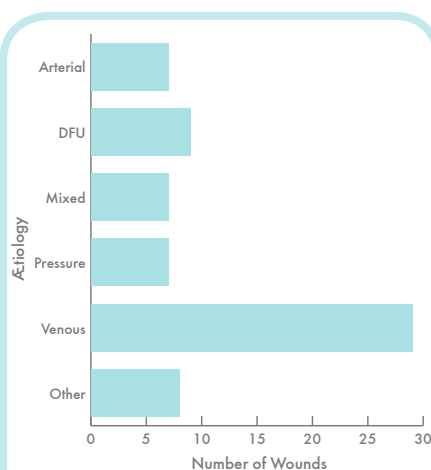


Figure 2: Cohort by Aetiology

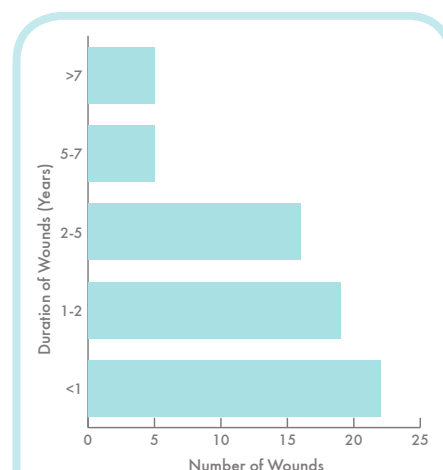


Figure 2: Cohort by Duration of Wound

## STUDY DESIGN

This case study programme is part of a two year, multi-centre and international programme, which will include up to 200 patients suffering from wounds, treatable using a 10cm x 10cm sheet hydrogel wound dressing. Patients are screened for eligibility and their informed consent is obtained prior to their entry into the study.

Patients with various wounds are included: diabetic foot ulcers, venous stasis ulcers, pressure ulcers and miscellaneous wounds.

The underlying cause of the wound is treated and corrected. The Oxyzyme® dressing is applied for a period of up to six weeks or until healing. The characteristics of the wound base and surrounding skin will be recorded at weekly intervals.

## INCLUSION CRITERIA

The inclusion criteria for patients entering the evaluation are: age between 10 and 85 years, and possession of a superficial (not cavity) wound suitable for treatment with a 10cm x 10cm sheet hydrogel dressing.

## EXCLUSION CRITERIA

- Obvious indications of infection in the wound.
- A known or suspected sensitivity or allergy to iodide or iodine.
- Thyroid disorder (e.g. Hashimoto's thyroiditis or non-toxic nodular goitre).
- Pregnancy or mothers who are breast-feeding.
- Severe liver, kidney or cardiac disease that is uncontrolled and that could impair healing.
- Medication with lithium.

## SPONSOR

This Case Study Programme is sponsored by Archimed, the Wound Healing Division of Insense Ltd.

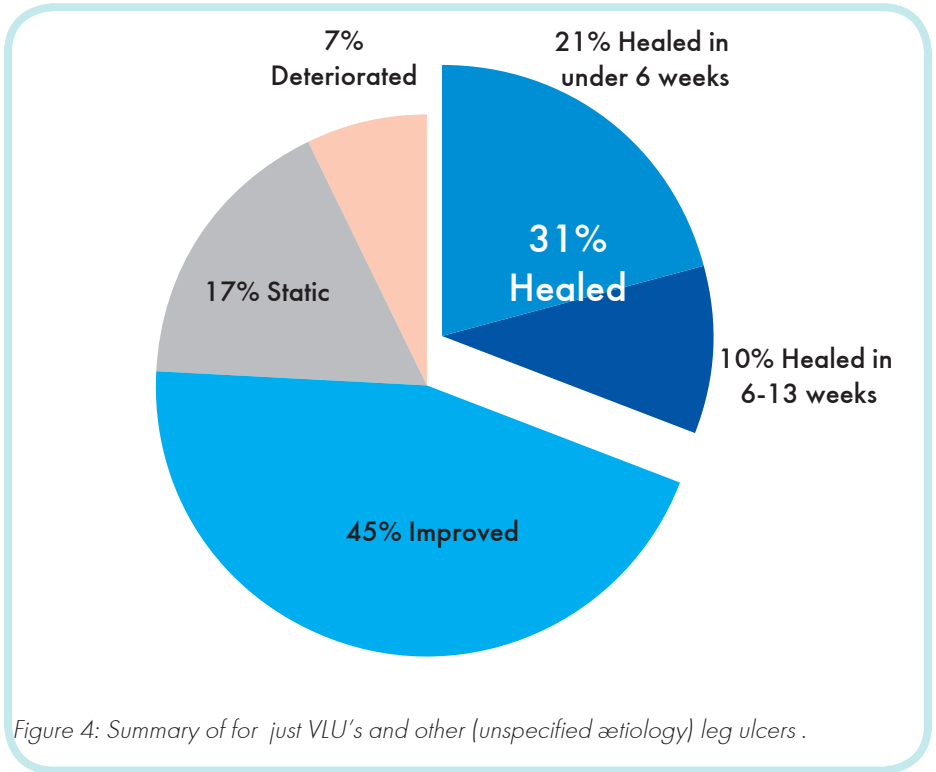


Figure 4: Summary of for just VLU's and other (unspecified aetiology) leg ulcers .

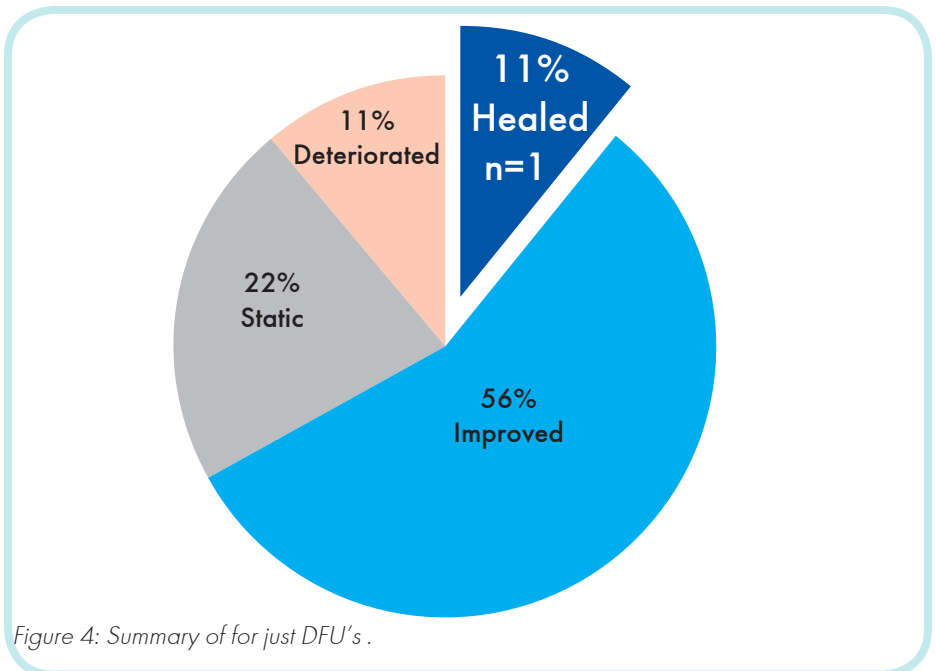


Figure 4: Summary of for just DFU's .