



case study programme interim results

ARCHIMED CASE STUDY OXY CS001:
THE USE OF OXYZYME® ON CHRONIC
WOUNDS.

PART 6A: VENOUS AND OTHER
(UNSPECIFIED AETIOLOGY) LEG ULCERS




Archimed[™]
A division of Insense Ltd.
Colworth Science Park, Sharnbrook,
Bedford, MK44 1LQ, UK

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OXYZYME® CASE STUDY PROGRAMME

OXY-CS001-03/04: THE USE OF OXYZYME® ON CHRONIC WOUNDS



SUMMARY

- **71 year old female**
- **Venous leg ulcer**
- **7 years duration**
- **75% reduction in wound area**
- **IMPROVED**

PATIENT INFORMATION

Patient BD is a 71 year old female who presented with a venous leg ulcer of 7 years duration.

Medical History: eosinophilic fasciitis, hypertension, steroid induced type 2 diabetes

Current Medication:

methotrexale, folic acid, glicazide, lisinopril, omeprazole,

simvastatin, insulin, paracetamol
Previous Dressings: not recorded

WOUND CONDITIONS

The wound was described as a shallow venous ulcer with indistinct wound margins. The wound measured 13cm². There was a moderate amount of clear wound exudate. The wound bed was assessed as 70% slough and 30% granulation tissue. The surrounding tissue was macerated.

Oxyzyme was applied and covered with ActivHeal Foam as the secondary dressing.



Fig.2. Wound on entry

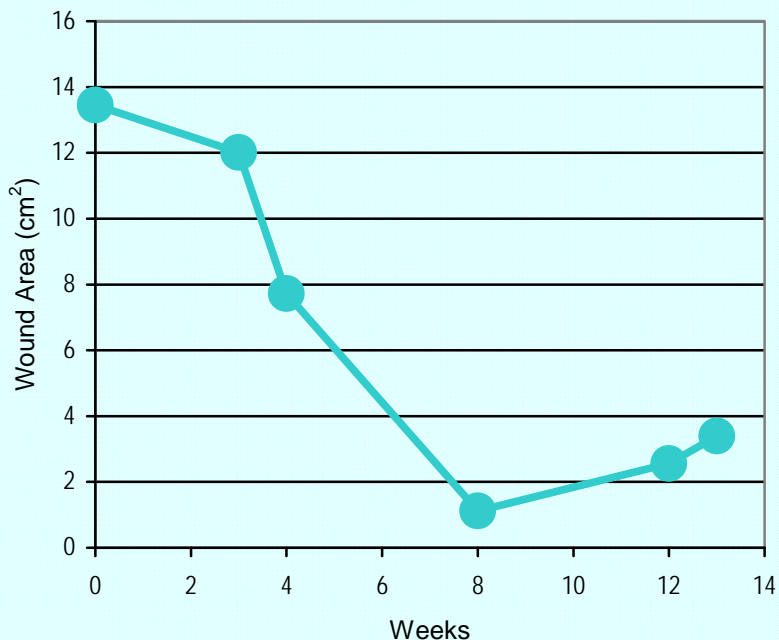


Figure 1. Wound area progress.

ASSESSMENTS

Week 1

No significant change in wound area was noted by clinician. The wound bed was described as 100% granulation tissue. The wound exudate remained moderate in amount and was now blood stained. The surrounding tissue continued to be macerated. The patient described the dressing to be painful after 24 hours of wear.

Week 4

There was a reduction in wound area of 41%. The wound bed was described as 90% granulation and 10% epithelial tissue. The wound exudate remained blood stained and the surrounding tissue macerated. Cavilon was applied for protection. The patient continued to complain of pain following 24 hours wearing the dressing.



Fig.3. Wound at week 4

Week 6

The wound continued to show improvement. The clinician chose to continue with Oxyzyme as the treatment for this patient.

Week 8

There was a further reduction in wound area of 85%. The wound was described as almost healed. The wound bed comprised of 99% epithelial tissue & 1% granulation. There was no exudate. The surrounding tissue

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was healthy. There were no complaints of pain.



Fig.4. Wound at week 8

Week 12

An increase in wound area was noted by the clinician. Exudate levels had increased to low levels of clear fluid. The surrounding tissue had become macerated. The wound bed was assessed as a combination of epithelial and granulation tissue. The patient complained that the dressing became painful after 3 days of wear.



Fig.5. Wound at week 12

Week 13

An increase in wound area was documented by the clinician. The wound bed was assessed to comprise of 90% epithelial tissue 10% granulation. The wound exudate remained clear and low in amount. The surrounding tissue was described as healthy. However due to the increase in wound area, the application of Oxyzyme was stopped.



Fig.6. Wound at week 13

COMMENTS

There was an overall reduction in wound area of 75%. The wound was described as almost healed at week 8, However the wound then began to increase in size. The reason for this increase in wound area is unknown.

The patient initially complained of pain after 24 hours of wearing Oxyzyme. The cause of the pain is unclear. Further studies are required to understand why some patients experience pain when wearing Oxyzyme.

SATISFACTION

The patient described the dressing as comfortable on application but experienced pain following 24 hours of treatment. Despite pain the patient was satisfied with the dressing due to the improvements in the condition of the wound.

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SUMMARY

- **74 year old female**
- **Venous leg ulcer**
- **4 year duration**
- **59% reduction in wound area**
- **IMPROVED**

PATIENT INFORMATION

Patient SB is a 74 year old female who presented with a 4 year old venous leg ulcer. Medical History: diabetes, hypertension, anaemia, glaucoma, goitre. Current Medication: folic acid, vitamin C, ramipril, ferrous gluconate, atenolol. Previous Dressings: not recorded

WOUND CONDITIONS

On entry the wound was described as a shallow wound with distinct wound margins. The wound bed was 20% slough and 80% granulation tissue. The clinician noted that the granulation tissue was unhealthy in appearance. There were moderate levels of clear wound exudate. The surrounding tissue was documented as healthy. Cavilon was being applied to the surrounding skin for protection. The patient was suffering mild levels of pain (2 out of 10).

Oxyzyme was applied with ActivHeal Foam as the secondary dressing.



Fig 2. Wound on entry

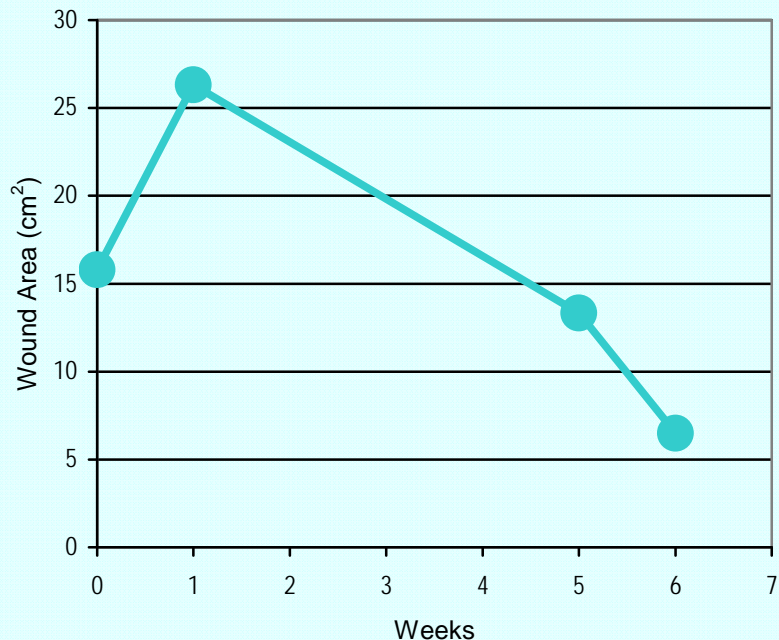


Figure 1. Wound area (measured by LUTM telemedicine software).

ASSESSMENTS

Week 1

The patient complained of severe pain (level 8-9) a few hours after dressing application which stopped when the dressing was removed. There was an increase in wound area following debridement of devitalised tissue. The wound bed was assessed as 100% healthy granulation tissue. The level of wound exudate had increased and was blood stained. The surrounding tissue had become macerated.

Week 2

No change in wound area was noted by the clinician. The wound bed comprised healthy granulation tissue. The exudate level had reduced slightly but remained blood stained. The surrounding tissue remained macerated. Cavilon was continued for protection. The level of pain had reduced slightly and was being managed with paracetamol.

Week 3

The clinician noted a reduction in wound area. The wound bed was assessed as 90% granulation and 10% epithelial tissue. The level of wound exudate remained moderate and blood stained. The patient stated that the dressing was comfortable for 2 days and then became painful.



Fig 3. Wound at week 1

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Week 5

The clinician noted an increase in epithelial tissue (20%). The wound exudate continued to be blood stained. The surrounding tissue was macerated. The patient stated that the dressing was comfortable this week with pain levels being 2-3.



Fig.4.Wound at week 5

Week 6

There was further reduction in wound area. The wound bed was assessed as 50% granulation tissue and 50% epithelialisation tissue. The wound exudate was clear. The surrounding tissue remained macerated.



Fig.5.Wound at week 6

COMMENTS

There was a total wound area reduction of 59%. The granulation tissue had become healthy in appearance. The epithelial tissue was very fragile in appearance. The clinician chose to continue using Oxyzyme following the completion of the 6 weeks of the study.

SATISFACTION

Initially the patient found the dressing comfortable on application but found it extremely painful after a few hours. This pain was relieved when the dressing was removed. The patient managed her pain with regular analgesia. As the condition of the wound improved the level of pain reduced.

Overall the patient was satisfied/ very satisfied with Oxyzyme.

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OXY-CS001-03/06: THE USE OF OXYZYME® ON CHRONIC WOUNDS



SUMMARY

- 56 year old female
- Venous leg ulcer
- 4.5 year duration
- 38% area reduction
- IMPROVED

PATIENT INFORMATION

Patient RP is a 56 year old female who presented with a venous leg ulcer which she had had for 4½ years.

Medical History: Stills Disease.

Current medications:

Prednisalone, Omeprazole,

Co-Dydramol & Alendronic Acid

Previous dressings: Aquacel & Actiform Cool.

WOUND CONDITIONS

On entry the wound was described as shallow with distinct wound margins. The wound bed was 95% granulation and 5% slough. The peri-wound tissue was healthy.



Fig.2. Wound on entry

ASSESSMENTS

Week 1

Following 1 week of treatment with Oxyzyme there was a wound area reduction of 28%. The wound bed was assessed to be 98% granulation and 2% epithelial tissue. The peri-wound tissue was slightly macerated.

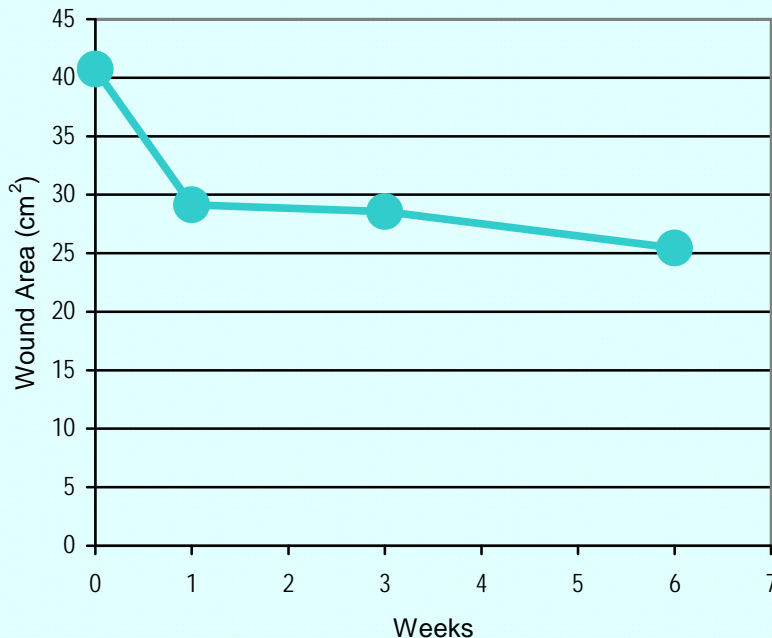


Figure 1: Graph of change in wound area (measured by LUTM telemedicine software) with time.

Week 2

The wound bed was 50% granulation and 50% epithelial tissue. There was blood-stained exudate and the peri-wound tissue remains macerated.



Fig.3. Wound at week 1

Week 6

The wound bed was 100% granulation tissue. There was an increase in wound exudate and maceration of the peri-wound tissue. The clinician identified that the granulation tissue did not appear to be healthy.



Fig.4. Wound at end of study

COMMENT

There was an overall reduction in wound area of 38% over the 6 weeks treatment with Oxyzyme.

SATISFACTION

The clinician was satisfied with Oxyzyme and reported that it performed better than previous dressings on similar wounds. The patient found the dressing very comfortable and was very satisfied.

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OXY-CS001-04/01: THE USE OF OXYZYME[®] ON CHRONIC WOUNDS



SUMMARY

- 94 year old female
- Venous leg ulcer
- Duration 6 months
- **HEALED**

PATIENT INFORMATION

Patient VP is a female who presented with two venous leg ulcers on her right leg.

Medical History: Osteoarthritis, Mild cardiac failure, Bilateral leg oedema

Current Medication: Diuretics

Previous Dressings: Not documented

WOUND CONDITIONS

On entry into the case study the wound was described as being a shallow wound with an indistinct margin. The wound bed was assessed to be 80% sloughy 20% granulation tissue. There was a low level of serous wound exudate. The surrounding skin was dehydrated.

Tegaderm film was used as a secondary dressing throughout the case study.

ASSESSMENTS

Week 1

At the first assessment, following a week of treatment with OXYZYME[™], the wound area had decreased significantly (35%), the slough was reduced to 50% and the wound assessed by the clinician to have "healthier granulation tissue". The exudate remained clear and surrounding skin was "much improved".

Week 2

With the slough removed, healthy granulation tissue was apparent and the wound had again reduced in size (a further 10%). Exudate remained clear and the surrounding skin remained healthy.

Week 3

By week 3 the wound had significantly reduced in size (a

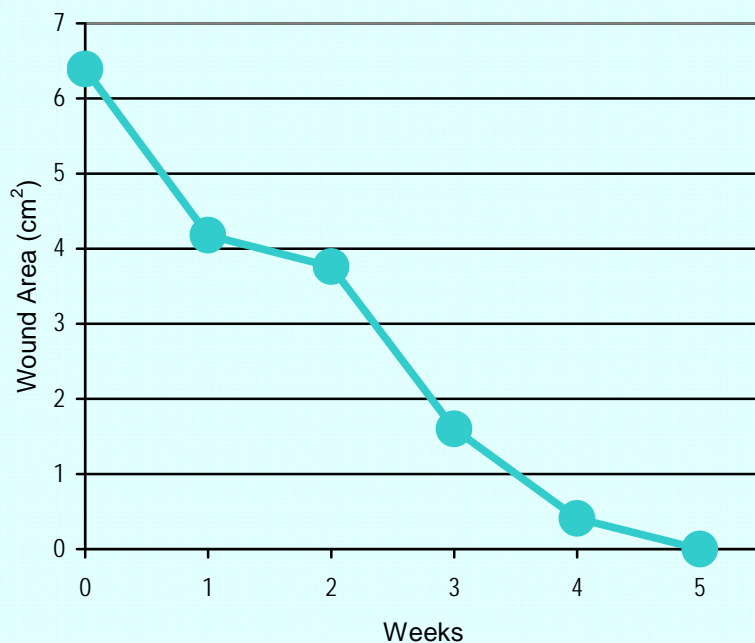


Fig. 1: Graph of change in wound area (measured by LUTM telemedicine software) with time.



Fig. 2: Wound on entry



Fig. 3: Healed at the 5 week assessment

further 57%). The exudate had become blood stained.

Week 4

The wound was now almost closed, following a further 74% reduction in size. A small (5%) amount of slough was observed. Exudate remained blood stained.

Week 5

On assessment at week 5 the wound had completely re-epithelialised. The clinician documented that the wound had healed.

COMMENTS

The wound bed and surrounding tissue was dehydrated on entry into the case study, however after only 1 week of treatment with Oxyzyme[™] the wound bed and surrounding skin had become re-hydrated and healthy. The wound healed within 5 weeks of treatment.

SATISFACTION

The patient was satisfied with the outcome and considered the dressing to be comfortable.

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OXY-CS001-04/02: THE USE OF OXYZYME[®] ON CHRONIC WOUNDS



SUMMARY

- 94 year old female
- Venous leg ulcer
- Duration 6 months
- **HEALED**

PATIENT INFORMATION

Patient VP is a female who presented with two venous leg ulcers on her right leg.
Medical History: Mild cardiac failure, Osteoarthritis, Bilateral leg oedema
Current Medication: diuretics.

WOUND CONDITIONS

On entry into the case study the wound was described as a shallow wound with an indistinct margin. The wound bed was assessed as 50% sloughy 50% granulation tissue which was documented as “not very active”. There was a low level of serous wound exudate. The surrounding skin was healthy but slightly dehydrated.
Tegaderm film was used as a secondary dressing throughout the case study.

ASSESSMENTS

Week 1

At the first assessment, following a week of treatment with OXYZYME[™], the wound area had decreased significantly (55%), the slough was gone and the wound presented with “healthier granulation tissue”. The wound exudate was blood stained. The surrounding skin was healthy and dry.

Week 2

Healthy granulation tissue was apparent and the wound had again significantly reduced in size (a further 32%). Exudate was still blood stained and the surrounding skin was noted to be “hydrated”.

Week 3

By week 3 the wound showed “very active granulation” and was

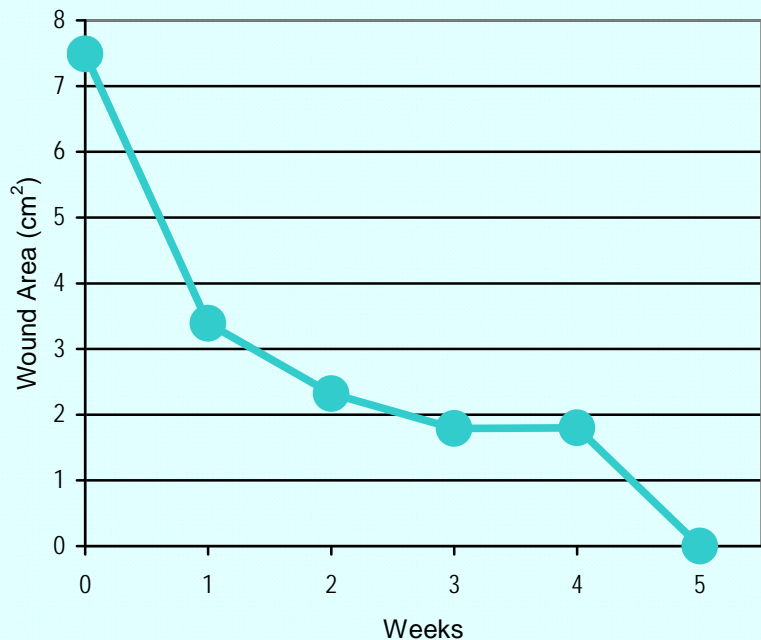


Fig. 1: Graph of change in wound area (measured by LUTM telemedicine software) with time.



Fig. 1: Wound on entry

again significantly reduced in size (a further 23%).

Week 4

Although the wound remained the same size as the previous week, the wound bed continued to improve with further evidence of epithelialisation.



Fig. 2: Wound healed at 5 weeks

Week 5

By the fifth week assessment the wound had healed.

COMMENTS

The wound healed within 5 weeks of treatment with Oxyzyme.

SATISFACTION

The patient was satisfied with the outcome and considered the dressing to be comfortable.

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OXY-CS001-04/03: THE USE OF OXYZYME[®] ON CHRONIC WOUNDS



SUMMARY

- 87 year old female
- Leg ulcer
- Duration 1 year
- **HEALED**

PATIENT INFORMATION

Patient IB is an 87 year old female who presented with a left lateral leg ulcer proximal to the malleolus.

Medical History: Rheumatoid arthritis, non-insulin dependent diabetes (NIDDM)

Current Medication: methotrexate, folic acid, oxycodone, iron sulphate, amperozide, glicazide and zopiclone.

Previous Dressings: Actiform Cool

WOUND CONDITIONS

Initially, the wound was described as being a shallow wound with a distinct margin. The wound bed was assessed as 90% slough 10% granulation, and it was considered by the clinician to be "static". There were low levels of clear serous fluid. The surrounding skin was inflamed with slight erythema. Duoderm was initially used as a secondary dressing, although at weeks 2 and 3, Mepilex Border was applied.

ASSESSMENTS

Week 1

At the first assessment, following a week of treatment with OXYZYME[™], the wound area had decreased by 9%, and the slough had decreased to 65%. The wound exudate was blood stained and the surrounding skin was healthy with less erythema.

Week 2

The clinician noted deterioration in the condition of the wound. There was an increase in slough

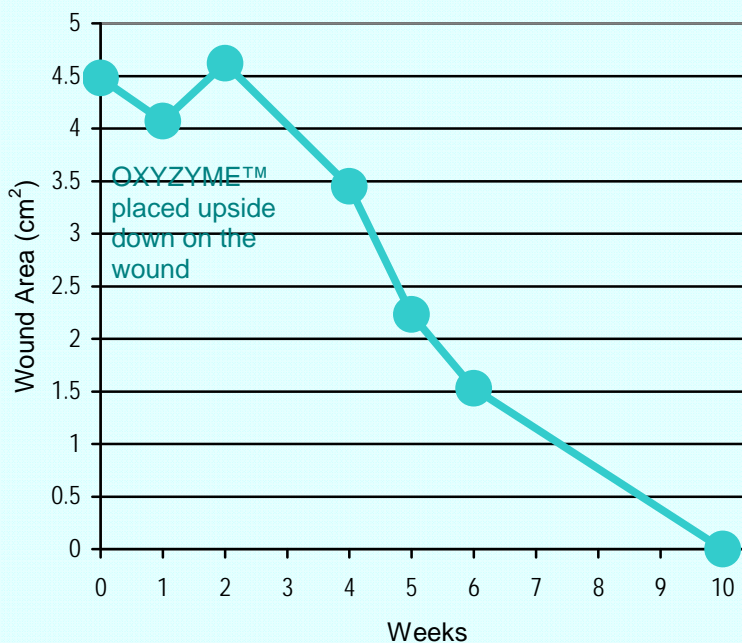


Fig. 1: Graph of change in wound area (measured by LUTM telemedicine software) with time.

comparable to that at the start of the trial. The exudate remained blood stained.



Fig. 2: Wound on entry

Week 3

It was discovered that the OXYZYME[™] dressing had been incorrectly applied (primary on top of secondary). No records were taken at this assessment, but the Oxyzyme was now correctly applied.

Week 4

There was a 52% reduction in wound area from the size measured at the Week 2 assessment.

The slough was gone and 90% of the wound was covered in epithelial tissue with only 10% remaining granulation tissue.



Fig. 3: Wound almost closed at the 6 week assessment

Whilst the exudate continued to be blood stained, the surrounding skin remained healthy.

Week 5

The clinician noted a small amount of slough present within the wound bed however the wound had decreased in size by 31%, and the exudate was now free from blood.

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Week 6

There was a further 57% decrease in wound area, and although the exudate was again blood stained, it was anticipated that closure was imminent.

Week 10

At a final follow up assessment, the wound remained closed.

SATISFACTION

The patient was satisfied with the outcome and considered the dressing to be comfortable.

COMMENTS

The wound began on a healing trajectory however when the Oxyzyme[™] dressing was incorrectly applied the wound size increased. When the Oxyzyme[™] dressing was correctly applied the wound healing trajectory resumed.

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OXY-CS001-04/05: THE USE OF OXYZYME[®] ON CHRONIC WOUNDS



SUMMARY

- 90 year old female
- Venous leg ulcer
- Duration 1 year
- **HEALED**

PATIENT INFORMATION

Patient JA is a 90 year old female who presented with a left lateral leg ulcer.

Medical History: PMH heart murmur, arthritis

Current Medication: Sleeping tablets

Previous Dressings: Not recorded

WOUND CONDITIONS

Initially, the wound was described as being a "static" shallow wound, with a distinct margin, and entirely covered in slough. Exudate was green, and the surrounding skin was inflamed and macerated. No measurement of the wound size was made at the initial assessment, (An estimated area of 23.5cm² was calculated using the LUTM software).

A PU film was used as a secondary dressing and Flamazine was applied to the surrounding skin.

ASSESSMENTS

Week 1

At the first assessment, following a week of treatment with OXYZYME[™], the amount of slough had decreased to 50%. The exudate was described as blood stained. The surrounding skin was not macerated but remained inflamed, and with less erythema. The use of Flamazine on the surrounding skin was continued.

Week 2

The level of slough had decreased to 10%, the rest of the wound bed showing healthy granulation tissue. The exudate remained blood stained, but the

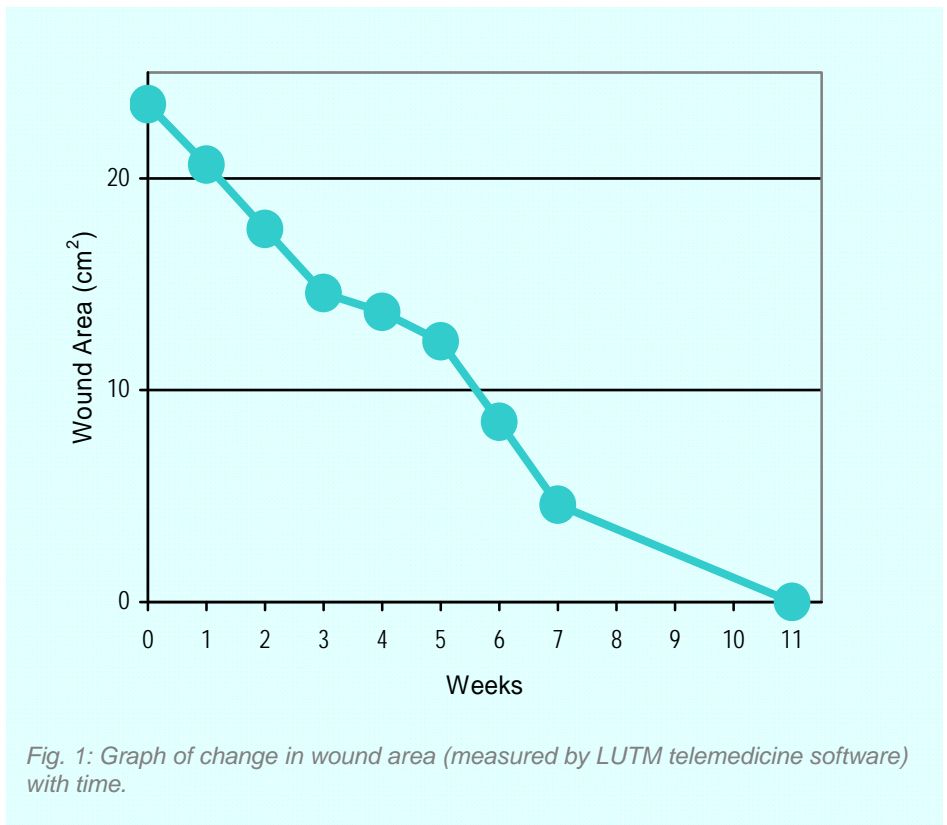


Fig. 1: Graph of change in wound area (measured by LUTM telemedicine software) with time.



Fig. 2: Wound on entry



Fig. 3: Almost closed at the 9 week assessment

surrounding skin was found to be healthy with only very slight erythema. The application of Flamazine was discontinued.

Week 3

The clinician assessed the wound bed to contain 100% healthy granulation tissue and had reduced in size by 29% since the week 1 assessment. The wound exudate remained blood stained and the surrounding skin remained healthy.

Week 4

By week 4, the wound bed remained covered by 100% healthy granulation tissue and

had reduced in size by a further 10%.

Whilst the exudate continued to be blood stained, the surrounding skin remained healthy.

Week 5

The wound continued on a healing trajectory, reducing in size by 7%. The surrounding skin was showing signs of "some over hydration". The exudate continued to be blood stained. Although the formal case study had completed the 6 week assessment, it was decided to continue this patient with OXYZYME[™] to healing.

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Re-examination, week 11

The wound was re-assessed and documented as healed by the clinician.

COMMENT

The chronic venous leg ulcer showed significant improvement over the 6 week period of the case study. Oxyzyme[™] was continued for a further 5 weeks at which point the wound was healed.

SATISFACTION

The patient described the dressing as comfortable and was satisfied with the outcome.