



case study programme interim results

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

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




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OXYZYME[®] CASE STUDY PROGRAMME

OXY-CS001-04/07: THE USE OF OXYZYME[®] ON CHRONIC WOUNDS



SUMMARY

- 72 year old female
- Venous leg ulcer
- Duration 6 years
- Patient withdrawn after 3 weeks due to discomfort
- Reduction in wound area
- **IMPROVED**

PATIENT INFORMATION

Patient JC is a 72 year old female who presented with a venous leg ulcer to the left lateral malleolus, that she had for 6 years.

Medical History: Parkinsons disease.

Current Medication: Sinemet Plus and paracetamol

Previous Dressings: Mepilex and Tegaderm. Honey.

WOUND CONDITIONS

The wound was initially described as being a shallow wound of indeterminate size due to an indistinct border (no photograph suitable for use with the LUTM measurement software was obtained.) An estimated area of 5cm² was calculated using the LUTM software.

The wound bed comprised 50% slough and 50% granulation. Exudate was clear but the periwound skin was inflamed. The wound was considered to have deteriorated since the previous dressing had been applied (Honey).

An emollient was applied to the periwound and a foam and PU film were applied as secondary dressings.

ASSESSMENTS

Week 1

At the first assessment, following a week of treatment with OXYZYME[™], a reduction in wound area was noted (11%). The condition of the wound remained 50% slough and 50% granulation. The wound exudate

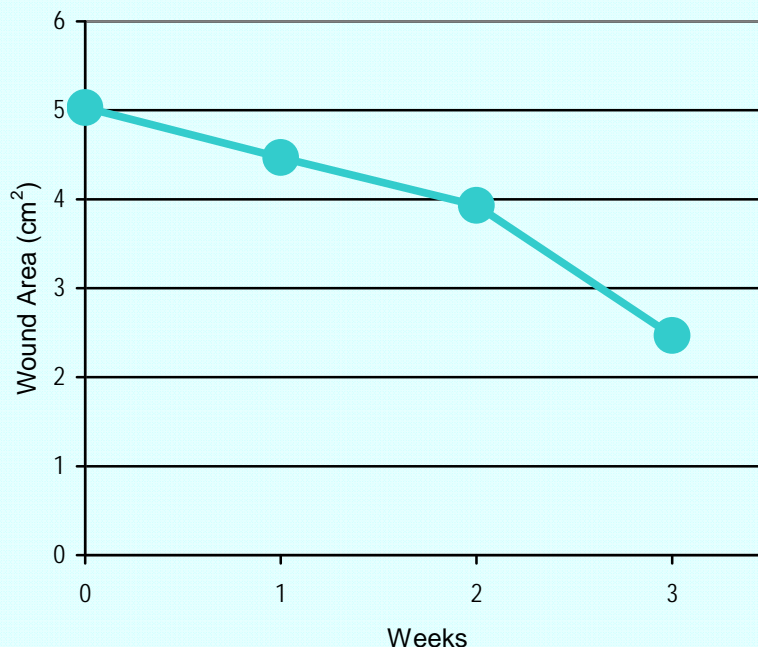


Fig. 1: Graph of change in wound area (measured by LUTM telemedicine software) with time.



Fig. 2: Wound on entry

was moderate in amount and blood stained. The surrounding skin was less inflamed.

Week 2

The wound was found to have decreased in size by a further 12% and was now 20% slough and 80% granulation. The level and type of wound exudate remained unchanged. The surrounding tissue was assessed as healthy.



Fig. 3: Final assessment showing removal of the OXYZYME[™] dressing prior to cleaning

Week 3

By week 3 the total wound area had decreased by 37%, but the case was stopped due to patient discomfort.

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COMMENTS

There had been an overall improvement in the condition of the wound. The patient was withdrawn after 3 weeks of treatment due to discomfort.

Further studies are required to identify the cause of pain that is experienced by some patients when using Oxyzyme[™].

SATISFACTION

The patient described the dressing as comfortable and was satisfied with the dressing up until week 3 where the patient complained of mild discomfort and was no longer satisfied.

OXYZYME[®] CASE STUDY PROGRAMME

OXY-CS001-14/01: THE USE OF OXYZYME[®] ON CHRONIC WOUNDS



SUMMARY

- **69 year old female**
- **Venous leg ulceration**
- **18 months duration**
- **Wound area reduced by 95%**
- **IMPROVED**

PATIENT INFORMATION

Patient BC is a 69 year old female who presented with a venous leg ulcer to the medial gaiter aspect of her left leg. Medical History: degenerative disc disease Medication: Bendroflumethiazide, Ferrous Sulphate, Omeprazole Previous dressing: Urgotulle SSD and 4 layer compression bandaging

WOUND CONDITIONS

Upon entry into the programme the wound was described by the investigator as having distinct margins which were of a healthy nature. The wound bed was assessed as 67% granulation tissue and 33% slough. Exudate was clear.

Oxyzyme was applied to the wound and a secondary dressing of gauze was used as the secondary dressing. 4L compression was then applied.



Fig. 2. Wound on entry to study

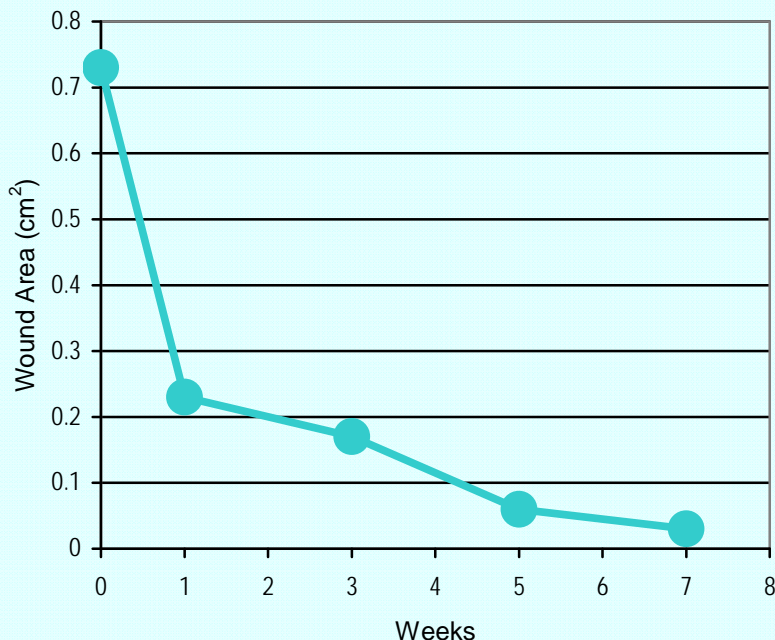


Figure 1: Wound area progress.

ASSESSMENTS

Week 1

The wound bed condition had improved to 95% granulation tissue and 5% slough. Exudate was noted to be clear and minimal with a healthy peri-wound area. The patient described the dressing as very comfortable and did not experience any pain during the first week of application.

Oxyzyme was reapplied to the wound bed and gauze and 4L bandage compression was applied.



Fig. 3. Wound at week 1

Week 2

Further improvement was noted although the investigator felt that the wound was not as clean as the assessment after the first week of use. The assessment of slough was noted to be 20% compared to 5% the previous week to and 80% granulation tissue compared to 95%.

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Week 3

The wound was smaller and granulation appears to be increasing compared to the previous assessment. No other changes noted within the dressing regime.



Fig. 4. Wound at week 3

Week 4

The wound size had reduced. The wound bed was now described as 90% epithelialising and 10% granulating tissue. The peri-wound was described as healthy.

Week 5

Further reduction was observed in wound size with 95% of pink epithelisation tissue and 5% granulation tissue.



Fig. 5. Wound at week 5

Week 6

The wound was described as 98% epithelialised with no other notable comments for the wound. It was noted that the patient forgot to have the dressing changed during this week and Atrauman dressing was used until the next change.

Week 7

The investigator describes the wound as difficult to assess due to its small size! It was measuring less than 2mm by 3mm.



Fig 5 wound at completion of study week 7

COMMENTS

The investigator rated the overall performance of Oxyzyme as better than other types of dressings used on similar wounds, and recommended that Oxyzyme be added to the local formulary.

SATISFACTION

Patient satisfaction throughout the study was extremely positive. There were no reports of pain whilst using Oxyzyme and the dressing was comfortable at all times when in place.

OXYZYME[®] CASE STUDY PROGRAMME

OXY-CS001-14/02: THE USE OF OXYZYME[®] ON CHRONIC WOUNDS



SUMMARY

- **74 year old male**
- **Venous ulceration**
- **Duration of 8 months**
- **IMPROVED**

PATIENT INFORMATION

Patient CW is a 74 year old gentleman who presented with a venous/pressure ulcer to the right lateral malleolus.

Medical History: type 2 diabetes, Ischaemic heart disease, left above knee amputation

Medication: Levothyroxine, Fucithalamic eye drops, Amiodarone, Lisinopril, Glicazide, Codeine Phosphate, Pravastatin Warfarin Nitrazepam and Tamsulosin.

Dressings: Aquacel AG, Allevyn adhesive, 10mmHg liner, Class 2 compression stocking

WOUND CONDITIONS

Upon entry into the programme the wound was described as having indistinct margins which were noted to be inflamed. The wound bed was assessed as 100% slough with clear exudate. The wound was described as static.

Oxyzyme was applied to the wound and covered with Allevyn and the compression stocking applied.



Fig 1. Wound on admission to case study

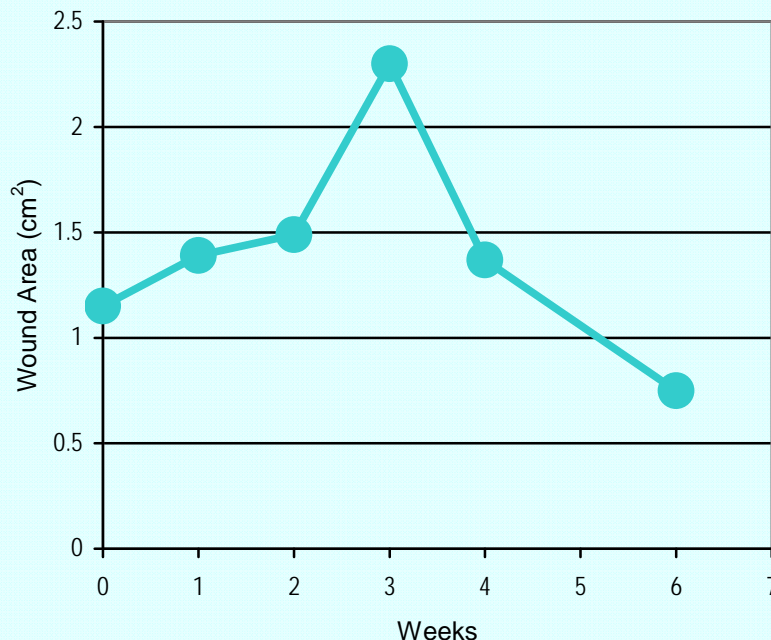


Figure 1: Wound area progress

ASSESSMENTS

Week 1

The wound was assessed to be larger in size and deeper. The slough (50%) was noted to be lifting and the wound bed granulating (50%). The exudate was noted to be bloody but the peri-wound was assessed to be more healthy. It was documented by the investigator that the wound was desloughing.

Although pain levels were not documented at entry into the study it was noted that the patient described the pain during the wear-time as severe although the dressing was comfortable to whilst in-situ.



Fig 2. Wound at week 1

Week 2

The wound was assessed to be reducing in size and an improvement in the wound bed was seen. Some maceration was visible to the wound edge. Pain remained severe for the patient whilst wearing the dressing. No other changes were noted to the protocol.

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OXY-CS001-14/02: THE USE OF OXYZYME® ON CHRONIC WOUNDS



Week 3

The wound was assessed to be improving with no change in any observations noted of the wound bed by the investigator. Pain was seen to be moderate this compared favourably to the previous week. Changes were recorded to the patient's medication; the patient was prescribed Mucodyne three times per day.



Fig 3.Wound at week 3

Week 4

The wound was assessed to be static; no improvement was visible. It was noted that Oxyzyme was only changed once during the week.



Fig 4.Wound at week 4

Week 5

The wound was documented to be improving again; an improvement was seen in the amount of granulation and epithelial tissue and a reduction in the amount of slough. The patient did however complain that on one day of this week that his pain levels changed to severe.

Week 6

The final assessment of the wound was documented as improving. No slough was present; the wound bed consisted of granulation and epithelial tissue. The peri-wound tissue was healthy and the wound exudate was clear.



Fig 5.Wound on completion of 6 week study

COMMENTS

During the initial week a period of autolytic debridement took place; thus explaining the increase in dimensions of the wound bed. During week 4 the patient did not have the dressing changed; thus did not benefit and maximise the oxygenation to the wound bed as per user recommendations.

SATISFACTION

Patient satisfaction throughout the 6 week study was extremely positive in terms of comfort; however, CW did experience severe pain most weeks. What is not clear is if this pain was due to the claudication?

OXYZYME[®] CASE STUDY PROGRAMME

OXY-CS001-18/08: THE USE OF OXYZYME[®] ON CHRONIC WOUNDS



SUMMARY

- **81 year old female**
- **Venous Leg Ulcer**
- **Duration 1 year**
- **41% reduction in wound area**
- **IMPROVED**

PATIENT INFORMATION

Patient MF is an 81 year old female who presented with a venous leg ulcer of 1 year duration.

Medical History: Varicose veins left leg.

Current Medication: Frusemide, Aspirin

Previous Dressings: Not known

WOUND CONDITIONS

On entry into the case study programme the wound measured 50cm² and was described as a shallow wound with distinct wound margins. There was a low level of haemoserous fluid. The wound bed was slightly dehydrated. The surrounding tissue was assessed as healthy. The wound bed was comprised of 70% dull granulation tissue 30% slough.

Oxyzyme was applied to the wound and covered with absorbent padding. The wound was to be redressed twice a week.



Fig.2. Wound on entry to study

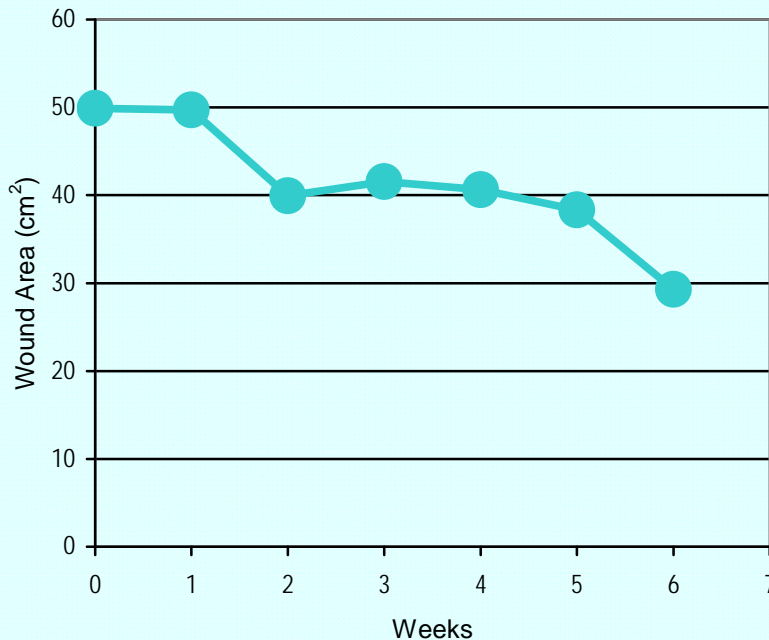


Figure 1: Wound area progress.

ASSESSMENTS

Week 1

There was no change in wound area. The wound bed was significantly improved. The wound bed was 90% granulation tissue 10% slough. The granulation tissue was red and shiny demonstrating increased vascular response. The surrounding tissue remained healthy.



Fig.3. Wound at week 1

Week 4

There was no change in wound area. The wound bed continued to improve (100% healthy granulation tissue). The surrounding tissue was healthy. A moderate level of clear wound exudate was reported.



Fig.4. Wound at week 4

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OXY-CS001-18/08: THE USE OF OXYZYME[®] ON CHRONIC WOUNDS



Week 6

A reduction in wound area was recorded (25%). The wound bed remained 100% healthy granulation tissue. The surrounding tissue remained healthy. A moderate level of haemoserous wound exudate was noted.



Fig.5. Wound at week 6

COMMENTS

There was an overall reduction in wound area of 41% over the 6 week period of the case study.

Note. From week 2, Urgotul was applied beneath the Oxyzyme dressing, for unknown reasons. The presence of this barrier between the wound and Oxyzyme may have limited its effectiveness.

SATISFACTION

The clinician reported that Oxyzyme performed similarly to previous dressings used on similar wounds.

The patient described the dressing as “comfortable” throughout the study and was “satisfied” with the outcome.

OXYZYME® CASE STUDY PROGRAMME

OXY-CS001-18/11: THE USE OF OXYZYME® ON CHRONIC WOUNDS



SUMMARY

- **74 year old female**
- **Venous ulcer**
- **30 year duration**
- **IMPROVED**

PATIENT INFORMATION

Patient RS is a 74 year old female who presented with several venous ulcers on both ankles. The ulcer in this study is located on the outer aspect of the left ankle.

Medical History: n/a
Current Medication: None
Previous Dressings: Urgotul

WOUND CONDITIONS

On entry into the case study programme the wound was described as a shallow cavity wound with distinct wound margins. The surrounding tissue was slightly macerated but described as healthy. There was a moderate level of wound exudate. The wound bed was 70% slough and 30% granulation tissue. The wound measured 6cm².

The wound was dressed with Oxyzyme and covered with gauze padding. The wound was to be redressed twice a week.



Fig. 2. Wound on entry to study

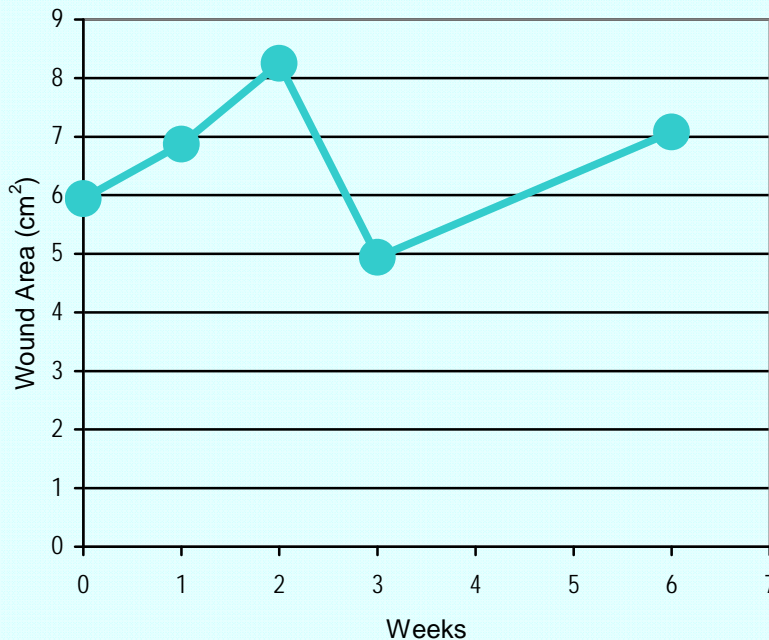


Figure 1: Wound area progress.

ASSESSMENTS

Week 1

An increase in wound area was noted (16%). There was a general improvement in the condition of the wound bed and surrounding tissue. Maceration was reduced and granulation tissue within the wound increased. Exudate levels remained unchanged.



Fig. 3. Wound at week 1

Week 3

There was a reduction in wound area (28%). The wound bed was 100% healthy granulation tissue. The surrounding tissue was macerated and slightly inflamed. A build up of dry skin was noted on the wound margins. Exudate levels remained moderate.



Fig. 4. Wound at week 3

OXYZYME[®] CASE STUDY PROGRAMME

OXY-CS001-18/11: THE USE OF OXYZYME[®] ON CHRONIC WOUNDS



Week 4-5

No photographs or records available.

Week 6

There was an increase in wound area of 41%. The wound bed was less deep and comprised of 80% granulation and 20% sloughy tissue. The wound margins were less macerated. Exudate levels remained unchanged.



Fig. 5. Wound at week 6

COMMENTS

The wound area increased. This was believed to be due to debridement of unhealthy tissue surrounding the wound.

Following conclusion of the 6 week case study programme the clinician continued to treat the wound with Oxyzyme, and has reported that the wound has reduced in size and is “doing well”.

SATISFACTION

Despite the wound size increasing the clinician was happy with the performance of Oxyzyme and chose to continue to treat the wound with it.

The patient found the dressing to be “comfortable” throughout the study and was generally “satisfied” with the outcome.

OXYZYME[®] CASE STUDY PROGRAMME

OXY-CS001-18/12: THE USE OF OXYZYME[®] ON CHRONIC WOUNDS



SUMMARY

- **74 year old female**
- **Venous leg ulcer**
- **30 years duration**
- **70% wound area reduction**
- **IMPROVED**

PATIENT INFORMATION

Patient RS is a 74 year old female who presented with several wounds on both ankles. The wound in this case study was located on the inner aspect of the left ankle.

Medical History: deep vein thrombosis

Current Medication: N/A

Previous Dressings: Urgotul

WOUND CONDITIONS

On entry into the case study programme the wound measured 9cm² and was described as a shallow ulcer with indistinct wound margins. The wound bed was assessed as 80% slough and 20% granulation tissue. There was a low level of clear wound exudate.

The wound was dressed with Oxyzyme and covered with gauze padding. The dressing was to be changed twice a week.



Fig. 2. Wound on entry.

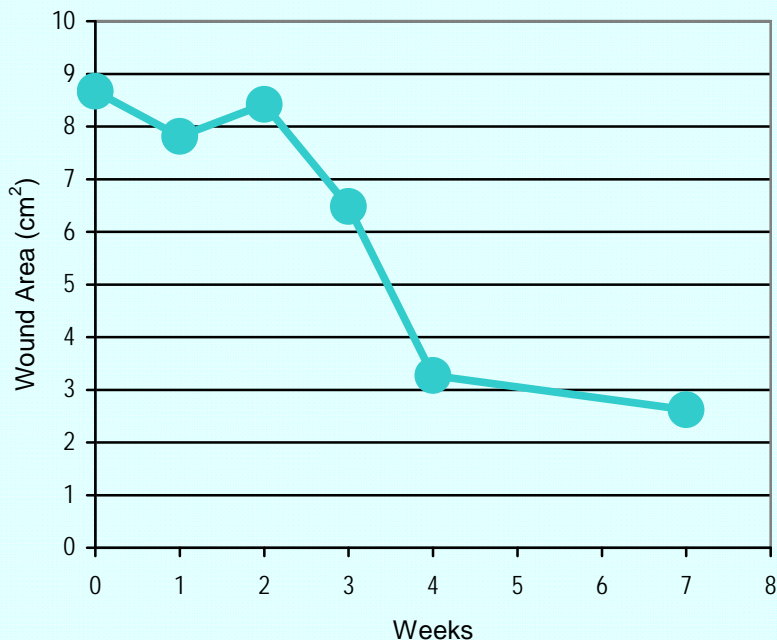


Figure 1: Wound area progress.

ASSESSMENTS

Week 1

There was a slight reduction in wound area (10%). There was a slight increase in wound exudate. The wound bed was described as 100% granulating. The wound margins were more distinct. The surrounding tissue was healthy.



Fig. 3. Wound at week 1.

Week 3

There was a further reduction in wound area (17%). The wound bed had deteriorated, and was described as 90% slough and 10% granulation tissue. The wound margins appeared slightly macerated.



Fig.4. Wound at week 3.

OXYZYME® CASE STUDY PROGRAMME

OXY-CS001-18/12: THE USE OF OXYZYME® ON CHRONIC WOUNDS



Week 4

A further reduction in wound area was noted (50%). The wound bed remained sloughy and the wound margins macerated. A build up of dry skin was also noted around the wound edges. Exudate levels were moderate. Extra padding was applied to reduce maceration from excess exudate.



Fig.5. Wound at week 4

Week 7

A significant improvement in the condition of the wound bed was noted. The wound bed was described as 100% healthy granulation tissue. The surrounding tissue remained slightly macerated but healthy. Exudate levels were reducing.



Fig.6. Wound at week 7.

COMMENTS

There was an overall reduction in wound area of 70% over the 7 weeks of this case study, and the condition of the wound bed had much improved.

The cause of the deterioration in the condition of the wound bed at weeks 3-4 was not identified.

SATISFACTION

The clinician documented that Oxyzyme outperformed previous dressings used on similar wounds.

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

OXYZYME[®] CASE STUDY PROGRAMME

OXY-CS001-18/13: THE USE OF OXYZYME[®] ON CHRONIC WOUNDS



SUMMARY

- 74 year old female
- Venous leg ulcer
- 20 years duration
- HEALED

PATIENT INFORMATION

Patient RS presented with several ulcers on both ankles. The ulcer in this study was located on the lateral aspect of the right ankle and had been present for 20 years. Medical History: deep vein thrombosis
Current Medication: None
Previous Dressings: Urgotul

WOUND CONDITIONS

On entry into the case study programme the wound was described as a shallow wound with indistinct wound margins. The wound measured 0.4cm² and had a wound bed which was assessed as 100% sloughy. The surrounding tissue was described as healthy.

The wound was dressed with Oxyzyme and covered with gauze padding.



Fig. 2. Wound on entry to study

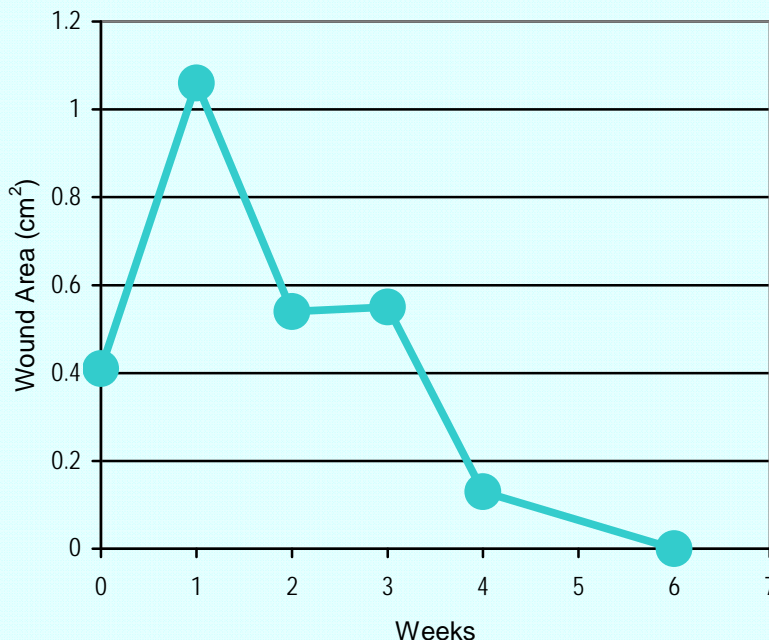


Figure 1: Wound area progress.

ASSESSMENTS

Week 1

Following treatment with Oxyzyme for 1 week an increase in wound area was noted by the clinician. The surrounding tissue had become inflamed and slightly macerated. The wound bed was now described as 100% healthy granulation.



Fig. 3. Wound at week 1

Week 2

The wound area reduced. The wound bed was described as 100% healthy granulation tissue. The wound margins were healthy and no longer macerated or inflamed.



Fig. 4. Wound at week 2

OXYZYME® CASE STUDY PROGRAMME

OXY-CS001-18/13: THE USE OF OXYZYME® ON CHRONIC WOUNDS



Week 4

There was a significant reduction in wound area. The wound was assessed to be almost healed and a dressing no longer required by the clinician.



Fig. 5. Wound at week 4.

COMMENTS

The wound was left uncovered following the 4 week review as the wound was almost healed.

The wound was re-assessed 2 weeks later and confirmed as healed by the clinician.

SATISFACTION

The clinician stated that Oxyzyme performed better than previous dressings used to treat similar wounds.

Throughout the study the patient found the dressing to be comfortable and was satisfied with the performance of the Oxyzyme dressing.

OXYZYME® CASE STUDY PROGRAMME

OXY-CS001-24/02: THE USE OF OXYZYME® ON CHRONIC WOUNDS



SUMMARY

- **79 year old female**
- **Venous leg ulcer**
- **Duration 2 years**
- **59% reduction in wound area**
- **IMPROVED**

PATIENT INFORMATION

Patient HC is a 79 year old female who presented with a 2 year old venous leg ulcer.

Medical History: Hypertension

Current Medication: Omeprazole, Frusemide, Calcichew, Captopril
Previous Dressings: Flamazine, Aquacel

WOUND CONDITIONS

On entry into the case study programme the wound was described as a shallow ulcer with distinct wound margins. The wound measured 16cm². There was a moderate level of haemoserous wound exudate.

The wound bed was assessed as 70% slough and 30% granulation tissue. The surrounding skin was inflamed.

Oxyzyme was applied and covered with a film dressing. The wound was to be redressed twice a week.



Fig. 2. Wound on entry to study

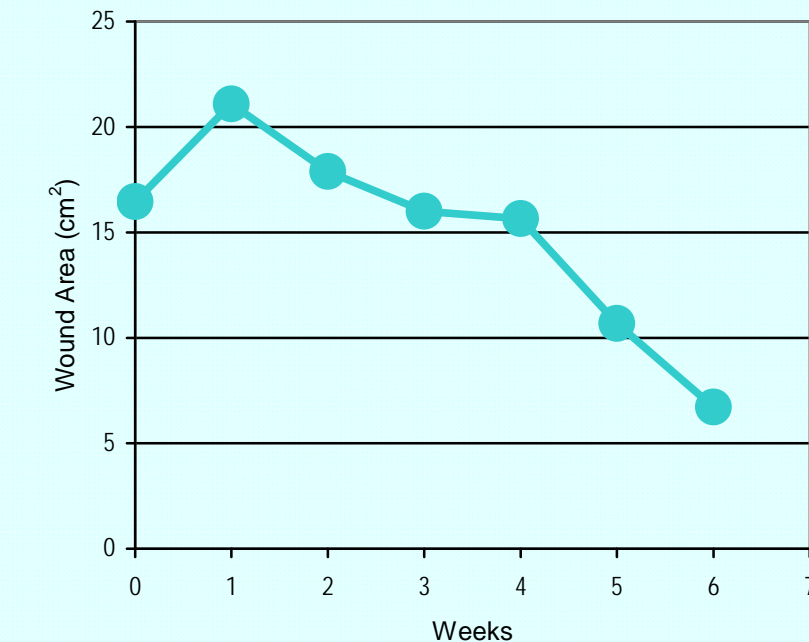


Figure 1: Wound area progress.

ASSESSMENTS

Week 1

An increase in wound area was noted (28%). The wound bed had become completely clear of slough and was described as 100% healthy granulation tissue. Moderate levels of haemoserous wound exudate continued. The wound was redressed with Oxyzyme and covered with a surgipad.



Fig. 3. Wound at week 1

Week 2

A reduction in wound area was noted (15%). A high level of haemoserous fluid was reported by the clinician. The wound bed remained 100% healthy granulation tissue. The surrounding tissue was still described as healthy.



Fig. 4. Wound at week 2

OXYZYME® CASE STUDY PROGRAMME

OXY-CS001-24/02: THE USE OF OXYZYME® ON CHRONIC WOUNDS



Week 5

A 40% reduction in wound area was reported. The wound bed remained 100% healthy granulation tissue. Moderate levels of haemoserous exudate remained. The wound was actively bleeding prior to removal of dressing and heavy haemoserous staining was documented on the surrounding tissue. This was easily removed by cleansing. The surrounding tissue was healthy. The ulcer had epithelialised in the centre creating 2 wounds.



Fig.5. Wound at week 5

Week 6

The wound was described as 2 small ulcers. The wound beds were 100% healthy granulation tissue. Active bleeding was still reported at dressing changes and haemoserous exudate continued. The surrounding tissue was healthy.



Fig. 6. Wound at week 6 with Oxyzyme in place

COMMENTS

The patient was treated with Oxyzyme for 6 weeks. There was a total reduction in wound area of 59%. There was an increase in wound area at week 1 due to Oxyzyme's ability to debride devitalised tissue. There were moderate to high levels of haemoserous fluid and staining.

There were reports of the wound actively bleeding at dressing change (not caused by trauma). When the wound bed was cleaned however there was obvious improvement in the general condition of the wound bed.

SATISFACTION

The patient found the dressing comfortable on application. Throughout the study the patient described moderate pain during the wearing of the dressing. Overall the patient was satisfied with the outcome of the treatment.

The clinician reported that Oxyzyme performed much better than previous dressings used on similar wounds.

OXYZYME[®] CASE STUDY PROGRAMME

OXY-CS001-55/01: THE USE OF OXYZYME[®] ON CHRONIC WOUNDS



SUMMARY

- **86 year old female**
- **Venous ulcer on right medial malleolus**
- **10 months duration**
- **HEALED**

PATIENT INFORMATION

Patient LH is an 86 year old female with a 10 month history of lower leg ulceration of diagnosed venous aetiology.

Medical history: paranoid schizophrenia, leg ulceration

Medication: Anadin

Previous dressings: Inadine and non-adherent dressings.

WOUND CONDITIONS

On admission to the study the ulcer was described as static and showing little sign of complete healing. Despite its small size (less than 1cm²) the wound bed was a cavity that was unable to epithelialise. There was a probable biofilm in place and due to the nature of the size of the wound a collection of debris had built up within the wound cavity.

There was 100% slough present. Clear exudate of minimal quantity. Oxyzyme[™] was applied to the wound and a secondary dressing of non adherent and short stretch bandage was applied. The surrounding skin was healthy with no signs of maceration or inflammation.



Fig 1. Wound on entry to study.

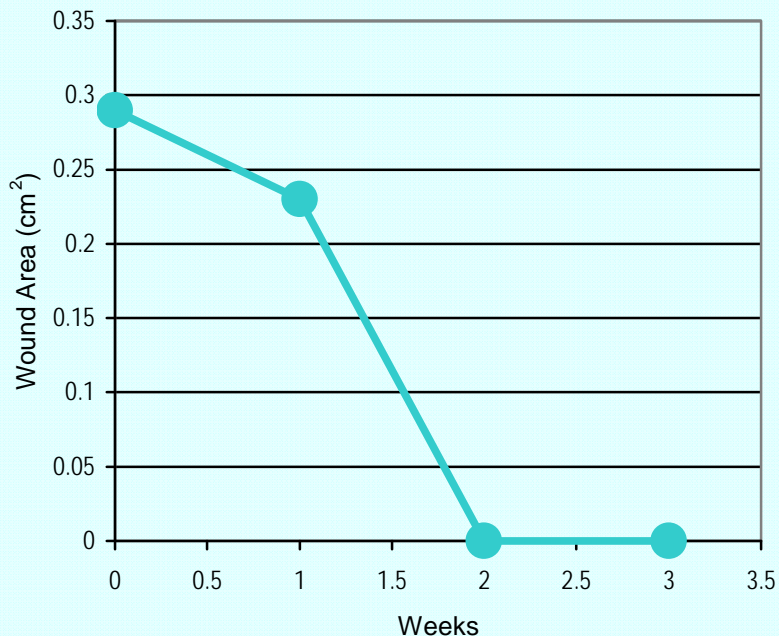


Figure 1: Wound area progress.

ASSESSMENTS

Week 1

The wound bed was completely free of slough. Minimal, clear exudate was seen upon dressing removal. The wound was shallower. An area of excoriation noted on the surrounding skin (not in contact with Oxyzyme), was thought to be due to latex allergy reaction to the compression bandage system used.



Fig 2. Wound at week 1.

Week 2

At week 2 the wound was assessed as healed. It had completely epithelialised and cleaned up. The area of epidermal loss was also covered with OXYZYME[™] and this too had completely re-epithelialised.



Fig 3. Healed wound at week 2.

OXYZYME[®] CASE STUDY PROGRAMME

OXY-CS001-55/01: THE USE OF OXYZYME[®] ON CHRONIC WOUNDS



Week 3

A further review visit was undertaken to ensure complete healing.



Fig 4. Wound healed at week 3.

The wound was confirmed as completely healed, as was the area of epidermal loss to the surrounding skin.

COMMENTS

The wound bed was rapidly debrided by the dressing, permitting full healing to take place.

SATISFACTION

The patient was extremely satisfied with the outcome.

She experienced no pain apart from a drawing feeling after the first application. This disappeared overnight and was not experienced again.

OXYZYME® CASE STUDY PROGRAMME

OXY-CS001-62/01: THE USE OF OXYZYME® ON CHRONIC WOUNDS



SUMMARY

- **63 year old female**
- **Venous Leg Ulcer**
- **2 months Duration**
- **HEALED**

PATIENT INFORMATION

Patient AA is a 63 year old female who presented with a venous leg ulcer of 2 months duration.

Medical History: Diabetes, hypertension, hernia.

Current Medication: Not known

Previous Dressings: Mepilex, Flamazine, Mepitel.

WOUND CONDITIONS

On entry into the case study the patient was being treated with Flamazine and Mepilex Lite. The wound was a shallow superficial ulcer with distinct wound margins which covered approximately 24cm². The wound bed was 100% healthy granulation tissue. The surrounding tissue was dry and fragile. There was a low level of wound exudate.

The wound was dressed with Oxyzyme and secured with Mepilex Lite. The dressing was to be changed twice weekly.



Fig. 2. Wound on entry to study

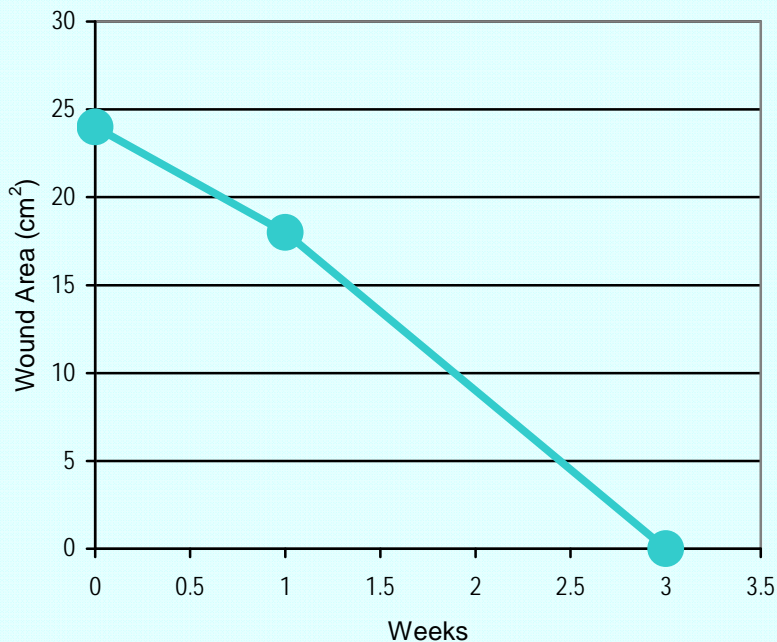


Figure 1: Wound area progress.

ASSESSMENTS

Week 1

Some of the small broken areas were epithelialised. The surrounding tissue was less dry and healthier in appearance. Exudate levels remained low.

Week 3

The clinician recorded that the wound had fully epithelialised. The surrounding tissue was healthy. The wound was documented as healed.



Fig. 3. Wound healed at week 3

COMMENTS

The wound was closed within 3 weeks of treatment with Oxyzyme.

The wound was not treated under compression bandages.

SATISFACTION

The clinician considered that the dressing performed better than previous dressings used on similar wounds.

The patient found the dressing comfortable and was satisfied with the outcome.

OXYZYME[®] CASE STUDY PROGRAMME

OXY-CS001-62/01: THE USE OF OXYZYME[®] ON
CHRONIC WOUNDS

