

Case series:

Using NATROX[®] Oxygen
Wound Therapy in the
management of diabetic
foot ulcers

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Foreword

Diabetic foot ulcers (DFUs) are complex wounds with a complicated aetiology. Diabetic foot ulceration is a marker of serious complications and comorbidities of diabetes. DFUs have a major long-term health impact on patients' morbidity and mortality (Jupiter et al, 2016), and also represent a significant impact on patient quality of life. Many patients with DFUs report pain levels that affect daily activities and disrupt sleep (Bradbury and Price, 2011).

DFUs are often ischaemic in nature, and lack of oxygen (hypoxia) can delay healing and increase the risk of complications. Hypoxia may be corrected by early intervention with topical oxygen therapy. Topical oxygen has been proven to have positive effects on chronic, hard-to-heal wounds (Harding, 2016).

This document contains a series of case reports describing the use of NATROX® Oxygen Wound Therapy (Inotec AMD) in patients with DFUs, alongside local protocol and guidelines.

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INTRODUCTION

Economic burden of DFUs

It is estimated that 422 million (8.5%) of the world's adult population has diabetes (World Health Organisation [WHO], 2016), and these patients have a one-in-four risk of developing a DFU over their lifetime (Armstrong et al, 2017). In the UK, the Burden of Wounds study, estimated that there were 169 000 DFUs, equating to 5% of adults with diabetes having a foot ulcer (Guest et al, 2015).

It is estimated that the NHS cost of DFUs is £1 billion per year (Kerr, 2017; Guest et al, 2018), associated with the management of complications, such as infection, delayed healing and amputation. Additional social costs to the patient, such as reduced mobility and sickness absence are estimated at £13.9 billion per year. Around 50% of DFUs become infected, and in approximately 20% of these patients, infection will lead to amputation (Wu et al, 2007).

Challenges in assessment and management

DFUs are often ischaemic in nature, but many patients with DFUs are not good candidates for revascularisation surgery due to complications arising from comorbidities, late presentation, or chronic ischaemia associated with irreversible tissue injury (Yu et al, 2016). Emerging evidence suggests that topical oxygen therapy may provide innovative solutions to some of these wound healing challenges (Harding, 2016; Yu et al, 2016).

One challenge is the length of time for referrals into specialist services, which can have a particularly significant clinical impact and can also determine healing time. Greater pressure is, therefore, placed on foot protection and multidisciplinary foot care services, with a need for assessment and referrals to be made promptly, in order to treat DFUs before they become severe (National Diabetes Footcare Audit [NDFA], 2017).

DFU assessment tools

Patients with a DFU need to be assessed holistically; intrinsic and extrinsic factors need to be considered. A physical examination should determine wound characteristics, such as size, musculoskeletal deformities, level of ischaemia, and risk of infection and future complications. A classification system should encompass all the variables that contribute to wound severity and outcome.

Texas Foot Classification

In Scotland, the Texas Foot Classification System (Figure 1) is used to record diabetes foot ulceration in the Scottish Care Information Diabetes (SCI-Diabetes) ulcer management system. Wounds are given a grade and stage, which can help to direct care.

Figure 1. Texas Foot Classification System

TEXAS CLASSIFICATION SYSTEM				
Stage	Grade			
	0	1	2	3
A	Pre or postulcerative lesion completely epithelised	Superficial wound not involving tendon, capsule or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
B	With infection	With infection	With infection	With infection
C	With ischaemia	With ischaemia	With ischaemia	With ischaemia
D	Infection and ischaemia	Infection and ischaemia	Infection and ischaemia	Infection and ischaemia

SINBAD Classification

In the rest of the UK, advocated by NICE (2015) and used by the NDA, the SINBAD Classification system is a simple tool that grades ulcers according to Site, Ischaemia, Neuropathy, Bacterial Infection, Area and Depth. Each parameter is allocated a score of either '0' or '1' (Figure 2) and the total score for the DFU is calculated. Higher scores indicate greater severity.

The SINBAD Classification provides a standardised approach to DFU assessment and can identify improvement or deterioration of DFU in the planning and monitoring of treatment, and in predicting outcome (Ince, 2008). In an international multi-centre study, a SINBAD score of three or more was associated with a step-up in time to healing and in eventual failure to heal.

Figure 2. SINBAD Classification

SINBAD	
Ulcer feature and severity score at presentation	
▪ Site - ulcer penetration of the hind-foot	0/1
▪ Ischaemic - impaired circulation	0/1
▪ Neuropathy - loss of protective sensation	0/1
▪ Bacterial infection - clinical signs of infection	0/1
▪ Area - ulcer area greater than 1cm ²	0/1
▪ Depth - ulcer reaches tendon or bone	0/1
SINBAD Score	Time to Heal
0-2 (Moderate)	Up to 77 days
3-6 (Severe)	Range 126-577 days

Clinical objectives/goals of managing DFUs

The "Best practice recommendations for the implementation of a DFU pathway" shares five key objectives, agreed by an expert panel, as the pillars of DFU standard care (Wounds UK, 2018). These include offloading, metabolic control/holistic management, assessment of infection, assessment of perfusion, ischaemia and evidence-based local wound care.

NATROX® Oxygen Wound Therapy has been shown to compliment these five pillars through a growing evidence base and examples of its use in practice.

Following holistic assessment that includes assessment of infection, perfusion and ischaemia, NATROX® may be a suitable therapy choice to achieve ulcer healing.

NATROX® Oxygen Wound Therapy

The use of NATROX® should be considered when treating non-healing DFUs, particularly as multiple studies to date have shown both clinical and patient benefits. This device supports patients to remain mobile, and for frequent assessment, debridement, dressing changes and offloading to be carried out, based on the presentation of the DFU.

The purpose of this device is to achieve complete re-epithelialisation through continuous active therapy, which can be maintained 24 hours a day, 7 days a week.

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NATROX® is battery-operated, portable, discreet and silent, alleviating patients of the burden of living with a chronic wound, and allowing daily activities to continue (Figure 3). It also encourages patient involvement, allowing patients to change and charge the battery-operated device at home. This is an important factor in health care, as it offers patients the opportunity to feel empowered and to control decisions which directly affect their health and wellbeing. The burden on a patient's quality of life has already been well established in the literature (WHO, 2016).

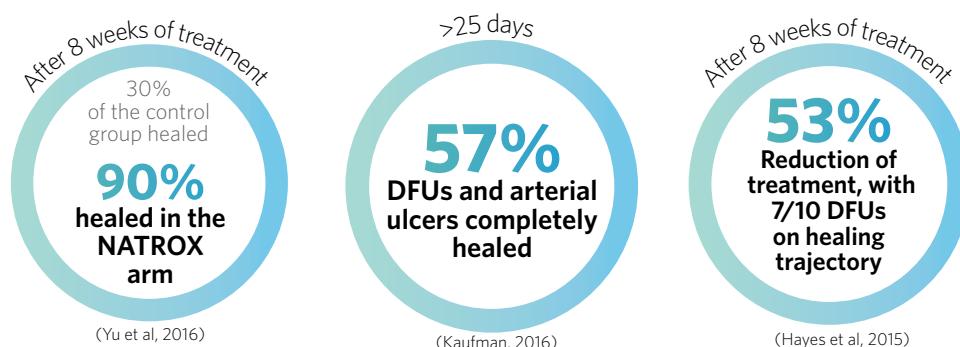


Figure 3. NATROX® Oxygen Wound Therapy

CASE STUDIES

CLINICAL SNAPSHOT

Duration of wound:
18 months

Frequency of dressing changes: Twice weekly

Duration of NATROX therapy:
15 weeks



Baseline



+35 days



+91 days



End of treatment

Case 1: Chronic neuroischaemic DFU

Debbie Wilson, Diabetes Specialist Podiatrist, University Hospital Hairmyres, NHS Lanarkshire

History: 58-year old male patient who presented with a chronic neuroischaemic ulcer over the plantar aspect of the right first metatarsal head, which had been present for 18 months. He had undergone a right popliteal angioplasty 3 months prior, which had failed to improve healing. He had also suffered multiple episodes of wound infection during this time. Diagnosed with type 1 diabetes 30 years ago, he had related co-morbidities including chronic ischaemic heart disease, peripheral arterial disease, chronic kidney disease (stage 3B) and neuropathy. In 2015, he had a right first toe amputation and consolidation of the right mid-foot Charcot neuroarthropathy. The wound measured 15mm (length) x 13mm (width), comprising of 100% granulation tissue with localised peripheral maceration. The ulcer was classified with a TEXAS Foot Score of C1.

Therapy: Following a surgical review by the orthopaedic team, it was deemed that there was not a viable surgical option available. Hence, it was imperative to heal the wound quickly and avoid further deterioration or infections. NATROX was introduced due to the chronicity of the ulcer and underlying blood flow issues in order to promote acute wound behaviour and healing. Initially, NATROX was covered with an antimicrobial absorbent secondary dressing and, as the wound progressed, this was changed to an absorbent secondary dressing. The wound was reviewed weekly in clinic where debridement was carried out. NATROX was changed at every dressing change which was twice weekly, however, due to the simplicity of the dressing regimen, the patient's partner was able to change the dressing between clinic visits.

Wound Lifecycle:

Commenced NATROX® 

Non-healing - 18 months

Healed in 15 weeks

Results: Complete wound closure was achieved with NATROX after 15 weeks of therapy. Due to peripheral neuropathy, engagement with a pressure relief device had been a continuous challenge. However, an increased level of engagement was noted while NATROX was in use, allowing the patient to be put in a total contact cast after 11 weeks of therapy. Overall, the patient was delighted to see the ulcer heal and had become more engaged with treatment as the wound progressed through the stages of healing. They found NATROX easy to use and their partner was happy to apply dressings.

CLINICAL SNAPSHOT

Duration of wound:
4 months

Frequency of dressing changes: Twice weekly reduced to once weekly

Duration of NATROX therapy:
15 weeks



Baseline



+21 days



+49 days



End of treatment

Case 2: Post-amputation dehiscence ulcer

Kaye McIntyre, Diabetes Team Leader, University Hospital Monklands, NHS Lanarkshire

History: 54-year-old female patient presented with a neuroischaemic ulcer, which had been present for a month following digit amputation. This patient had an extensive medical history, which included type 2 diabetes for 22 years, now managed with insulin, severe vascular disease, coronary heart disease, chronic kidney disease and anaemia. She had previously undergone a below-knee amputation (BKA) of her right leg in August 2017. In March 2018, she underwent further surgery where the second toe on her left foot was amputated, within a month of this surgery her wound had dehisced.

At this time, the patient developed sepsis and the clinical team decided there was little vascular intervention they could offer other than to perform a left BKA. Outpatient Parenteral Antibiotic Therapy (OPAT) and wound management using a range of advanced antimicrobial dressings were utilised to try and salvage the leg, without success. Following admission for her elective BKA the patient developed pneumonia and heart failure, hence she was transferred to critical care. Surgery was cancelled and palliative wound management was reinstated. The wound was deep, sloughy and malodorous with some peripheral maceration. It measured 40mm (length) x 20mm (width) and was classified as a TEXAS Foot Score of D2 (a wound penetrating to tendon or capsule with ischaemia).

Therapy: Due to the patient's prolonged stay and indefinite timeframe for surgery, NATROX therapy was initiated in an attempt to salvage the limb or delay amputation for as long as possible. The clinical team felt NATROX would reduce the likelihood of further deterioration or additional complications while the patient recovered enough for surgery. NATROX was positioned directly on the wound bed and covered with an absorbent dressing. Initially the dressing changes were carried out twice weekly due to the high levels of exudate. Within 3 weeks of therapy the wound had reduced in size and significant improvement was noted in the appearance of the wound bed. As the exudate levels decreased, dressing changes were reduced to weekly.

Wound Lifecycle:



Commenced NATROX®



Results: After just 15 weeks of NATROX therapy, the wound had completely healed and BKA was no longer necessary. The clinical outcome far exceeded all expectations of the multidisciplinary team. NATROX helped to resolve sepsis, it stimulated this non-healing ischaemic wound to completely heal and was an extremely cost-effective option compared to the financial complications of an amputation. The quality of healing was exceptional with little scarring evident, which would likely reduce the risk of recurrence. The patient was delighted with the outcome, she felt she had been given her life back and could not believe the wound had healed. This positive outcome would have an ongoing impact on the patient's quality of life.

CASE STUDIES

CLINICAL SNAPSHOT

Duration of wound:
4 months

Frequency of dressing changes: Weekly

Duration of NATROX therapy: 8 weeks



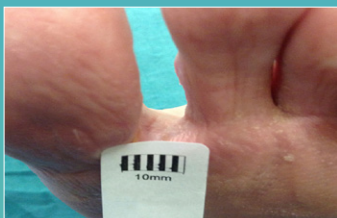
Baseline



+13 days



+35 days



End of treatment

Case 3: Inter-digit neurovascular ulcer

Kaye McIntyre, Diabetes Team Leader, University Hospital Monklands, NHS Lanarkshire

History: 71-year-old male presented with a neuroischaemic ulcer between his first and second toe, measuring approximately 3mm (length) x 4mm (width), which had been present for 4 months. The ulcer was classified with a TEXAS Foot Score of C1 (superficial wound with ischaemia). He had had type 2 diabetes for 27 years and multiple diabetes-related co-morbidities. The patient was initially referred to hospital from community podiatry as he was limping. He had an infection of his left first digital wound, which had been present for over a year – there was a 4°C temperature difference at the infection site. Osteomyelitis was confirmed, and the patient was admitted for IV antibiotics. Amputation of the left first digit was discussed with a vascular surgeon, and the risks of a below-knee amputation (BKA) if the amputation site did not heal were highlighted. The patient opted to continue with conservative treatment, which meant a further 4 weeks of outpatient antibiotic therapy. He was very concerned with the wound, which was impacting on his life – his family were waiting until it healed so they could book a holiday.

Ahead of using NATROX, the left first digit and second digit were separated using an absorbent silver foam dressing.

Therapy: NATROX therapy was initiated with the aim of healing the wound, as no other vascular interventions were available, and the patient did not want a left first digit amputation. A secondary foam dressing was used alongside therapy to manage moderate levels of exudate, and light wound debridement was performed until the wound became more superficial. Dressing changes were carried out twice weekly, and then reduced to once weekly as exudate levels decreased. Frequency of podiatry appointments also reduced to once weekly during treatment. For additional offloading and pressure relief, the patient was issued with a trauma shoe. During treatment, there was a short period of time when the use of NATROX was paused while the patient attended a family function.

Wound Lifecycle:



Results: After 7 weeks of treatment with NATROX, the wound had healed. The patient had been compliant and vigilant and found the therapy easy to use. NATROX was continued for a further week to improve wound closure. The patient had prepared himself for a non-healing wound, as there had been no wound progression for over a year. However, one year after therapy, the patient's feet had remained intact with no further issues. He was able to get back to his daily life and book a family holiday.

CLINICAL SNAPSHOT

Duration of wound:
16 months

Frequency of dressing changes: Twice weekly reduced to once weekly

Duration of NATROX therapy: 10 weeks



Baseline



+15 days



+104 days

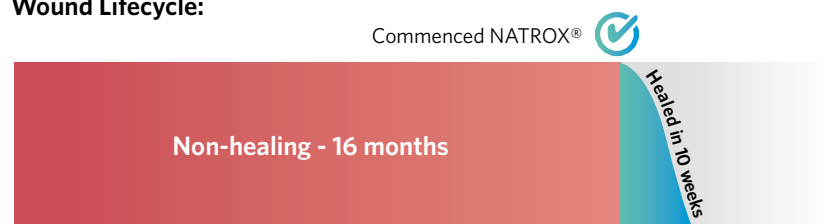
Case 4: Long-standing non-healing malleoli ulcer

Kaye McIntyre, Diabetes Team Leader, University Hospital Monklands, NHS Lanarkshire and *Paul Goodfellow*, Diabetes Specialist Podiatrist, University Hospital Monklands, NHS Lanarkshire

History: 73-year-old male presented with a long-standing non-healing wound on his left medial malleoli, which had been present for 16 months. The patient had recently been diagnosed with type 2 diabetes (HbA_{1c} ~54mmol/mol). Previous history included an angioplasty, right above-knee amputation and bypass surgery. The wound measured 20mm (length) x 16mm (width) and was extremely painful. The peri-wound skin was excoriated and friable, this was reportedly due to reactions to different dressings and creams that had been applied recently. The patient had been particularly intolerant to foams and had reacted badly to 1% hydrocortisone. Previous treatment included a wound gel containing soluble beta-glucan (SBG) and soft sterile gauze dressings, covered by a sock, which had been changed daily by the patient's partner.

Therapy: NATROX was implemented as there was no vascular intervention available to the patient and the goal was to achieve wound closure. It was also hoped that NATROX would not cause any reactions and help reduce the pain reported by the patient. Weekly visits to a clinic for review were in place and these were maintained during the therapy period.

Wound Lifecycle:



Results: NATROX helped to reduce the size of the wound each week until it measured just 6mm (length) x 4mm (width) and was documented as superficial. The peri-wound skin was no longer excoriated or friable and the patient reported that the wound was no longer painful. This outcome exceeded all expectations of the patient; his quality of life had greatly improved, and he no longer needed to attend weekly appointments. Prior to the use of NATROX, the wound had showed no signs of progressing to healing for at least 2 years.

CASE STUDIES

CLINICAL SNAPSHOT

Duration of wound:
7.5 months

Frequency of dressing changes: Weekly

Duration of NATROX therapy: 20 weeks



Baseline



+15 days



+18 days



+72 days


Case 5: Neuroischaemic DFU

Diane Knowles, Diabetes Specialist Podiatrist, Sunderland Royal Hospital and *Elaine Ricci*, Clinical Specialist Podiatrist, Sunderland Royal Hospital

History: 79-year-old male presented at the diabetic foot clinic with a neuroischaemic wound on his left first dorsal metatarsophalangeal joint. The wound had been present for over 7 months, caused by progression of peripheral arterial disease. The wound measured 60mm (length) x 40mm (width) and was quite shallow, with a sloughy base and sloped wound edges. The patient had been diagnosed with type 2 diabetes 24 years ago. Co-morbidities included Chronic Obstructive Pulmonary Disease (COPD) and ischaemic heart disease, the patient had previously suffered a heart attack and had undergone coronary artery bypass graft surgery three times, along with multiple angioplasty procedures. Treatment had previously included vascular interventions and conventional wound management with dressings however, the wound had become static and showed no signs of healing.

Therapy: The clinical rationale for using NATROX was to improve oxygen saturation at the base of the wound, thus increasing the likelihood of wound healing, while protecting the wound from developing any associated complications. A superabsorbent dressing with a soft, non-woven outer contact layer was applied as a secondary dressing during therapy, as it was anticipated exudate levels would increase during treatment with topical oxygen therapy. Due to the combination of a superabsorbent with NATROX, dressing changes could be maintained on a weekly basis.

Wound Lifecycle:

 Commenced NATROX®

Non-healing - 7.5 months

Healed in 20 weeks

Results: Complete wound closure was achieved in 20 weeks, with no complications during therapy. NATROX had been used as a primary wound healing device and had successfully healed this chronic wound, despite it being deemed as unsalvageable prior to treatment.

CLINICAL SNAPSHOT

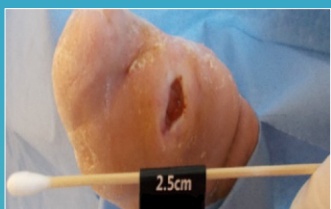
Duration of wound:
5 months

Frequency of dressing changes: Twice weekly (weekly community nurse and weekly podiatry clinic changes)

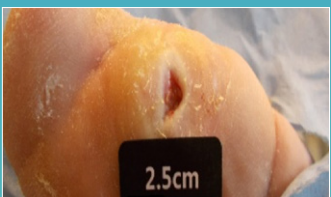
Duration of NATROX therapy: 18 weeks



Baseline



+28 days



+56 days



End of treatment


Case 6: Surgical amputation wound

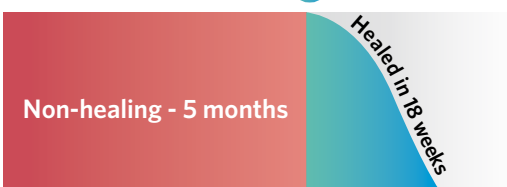
Prof. Keith Harding, Medical Director, Welsh Wound Innovation Centre

History: 72-year-old retired female presented with a surgical amputation wound of 5 months' duration, measuring 1.84cm² using a KLONK system. She had type 2 diabetes for 30 years. Past history included contralateral below-knee amputation and breast cancer, treated using oral hormone therapy. On assessment the wound was found to be colonised. Previous treatments had included the application of an iodine-based dressing which was changed twice weekly.

Therapy: NATROX was initiated with the aim of healing the wound as it had already been present for 5 months. A secondary foam dressing was selected for use during therapy, due to its high levels of absorbency, as NATROX can often stimulate increase in wound exudate. NATROX therapy was discontinued after 12 weeks of total therapy, as the wound was so superficial it could be managed with a simple adhesive dressing. This was applied weekly in a podiatry clinic after sharp debridement.

Wound Lifecycle:

 Commenced NATROX®



Results: An increase in neuropathic pain was noted after 4 weeks of therapy, however, re-assessment a month later showed that the pain had completely settled. Prior to this no pain had been experienced. After 16 weeks of total treatment, which included 12 weeks of NATROX therapy, wound closure was achieved, however edges of the wound remained fragile following sharp debridement. Complete closure was, therefore, documented after 18 weeks of therapy, and robust closure was attained.

Overall, the patient was wholly satisfied with the device and had been compliant throughout treatment. No complications were noted with changing the battery and the patient did not find that it affected everyday activities. Despite this, the patient was still concerned with her long-term quality of life and relied on others for help with some aspects of daily living. From a clinical perspective the wound had achieved closure following initial amputation, therefore, reducing the risk of further surgical intervention and infection. Continued treatment using iodine-based dressings would have been more cost-effective, however, as no signs of wound progression could be identified, this would have potentially led to additional clinical/social costs if further intervention had been required.

CASE STUDIES

CLINICAL SNAPSHOT

Duration of wound:
48 months

Frequency of dressing changes: Twice weekly

Duration of NATROX therapy: 14 weeks



Baseline



+26 days



+77 days



End of treatment

Case 7: Complex DFU

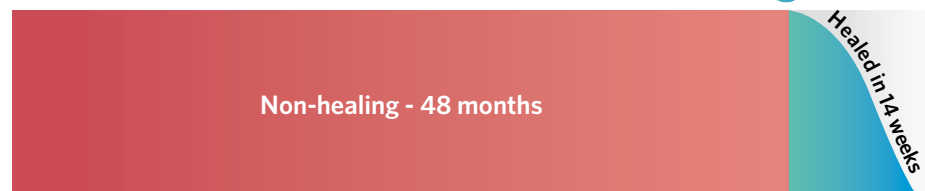
Keri Hutchinson, Clinical Lead Podiatrist (Acute Services) Cwm Taf Morgannwg University Health Board and *Leah Litchfield*, Specialist Podiatrist, Cwm Taf Morgannwg University Health Board

History: 59-year-old female with a second to fifth digit amputation on right foot in 2014, due to complications associated with diabetes. She was referred to podiatry in 2015 where limited wound improvement occurred, even with best practice of regular debridement, advanced dressings and specialist footwear. Her complex medical history of diabetic neuropathy, peripheral arterial and vascular disease, rheumatoid arthritis, hypertension, lymphoedema and chronic anaemia significantly compromised wound progression.

Therapy: Due to her medical history and non-healing wound, topical oxygen therapy was selected as a last non-surgical option. NATROX was commenced with the goal of stimulating wound healing and reducing the risk of further amputation. On commencement of NATROX the wound bed was free of any slough or necrosis, however, there were no signs of active granulation tissue. Dressing changes were scheduled for twice weekly.

Wound Lifecycle:

Commenced NATROX® 



Results: After just 25 days of therapy, with twice weekly dressing changes, the wound had reduced in size and the wound bed was much healthier in appearance, with signs of active granulation tissue. NATROX therapy continued for a further 7 weeks, by which time the wound had significantly reduced in size. The patient was discharged from the specialist clinic back into the community after receiving a total of 14 weeks of NATROX therapy, and achieving a 77% reduction in wound area. Therapy was continued after discharge and the wound successfully healed.

CLINICAL SNAPSHOT

Duration of wound:
8 months

Frequency of dressing changes: Weekly

Duration of NATROX therapy:
17 weeks



Baseline



+10 weeks

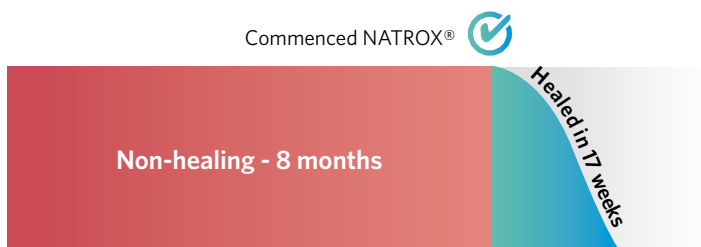
Case 8: Chronic neuropathic ulcer

Debbie Wilson, Diabetes Specialist Podiatrist, University Hospital Hairmyres, NHS Lanarkshire

History: 57-year-old male presented with a chronic neuropathic ulcer at the apex of his left second toe, which had been present for 8 months. The patient had been diagnosed with type 2 diabetes 18 years ago, and suffered from multiple diabetes-related co-morbidities, such as peripheral neuropathy. He also had structural abnormalities of his feet (claw toes, which was likely the cause of the ulceration) and worked at a clothes factory where he stood for up to 8 hours at a time. The wound measured 5mm (length) x 5mm (width) with a peripheral macerated callus. The wound bed comprised of granulation tissue and the ulcer was classified with a TEXAS Foot Score of A1.

Therapy: NATROX was initiated primarily to stimulate wound healing in this non-healing wound; the secondary goal was to improve patient self-management of his diabetes and overall health. Due to the position of the wound it was important to protect the area as much as possible from further damage, thus a foam dressing was utilised over NATROX for both protection and absorbency. In order to achieve concordance and facilitate the patient's continuation of work, pressure relief was achieved by using a forefoot pressure relief device with his walking boots, along with semi-compressed felt toe props. Due to the simplicity of NATROX, reviews were carried out weekly.

Wound Lifecycle:



Results: Complete wound healing was achieved in 17 weeks; this included a couple of weeks therapy after wound closure in order to promote strengthening of the wound tissue. The patient adapted quickly to the introduction of NATROX and expressed ease of wearing and managing the device. However, he did initially experience a couple of incidents of snapping the tube from the device end of the NATROX therapy when mobilising. Balancing reduced mobility with life is always a challenge, however, with some additional education, further breakages were prevented. Not only did the treatment regimen aid wound healing it also significantly enhanced patient engagement. As the patient could see the improvement in his wound it also motivated him to make positive behaviour changes on his own accord, which had previously been a challenge.



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