

Improved outcomes and a patient-centred approach: clinical evaluation of continuous topical oxygen therapy

KEY WORDS

- ▶ Chronic wounds
- ▶ Oxygen therapy
- ▶ Clinical evaluation
- ▶ Case studies

The prevalence of chronic wounds has increased in recent years and has become a significant public health concern that consumes extensive resources and affects health and quality of life (Guest et al, 2015). Treating patients with wounds in our current healthcare system has been unsuccessful and has not helped reduce the burden of this chronic condition. Time, health and social care budgets have been, and continue to be under, increasing pressure, causing a demand and supply problem.

Living with a wound can lead to loss of independence or control; adopting patient-centred care that engages and educates patients about their condition and involves them in decisions about their health and care improves outcomes, strengthens individual well-being and contributes towards more cohesive and healthier communities by encouraging individuals to take responsibility for managing their health needs where they are able to do so (NHS, 2012; Wounds International, 2016).

A report by the Royal College of General Practitioners (2014) into patient-centred care in the 21st Century defines patient-centred care as:

- ▶ a holistic approach to care, considering the individual's needs as a whole rather than treating medical problems in isolation
- ▶ flexible care, tailoring support to an individual's personal priorities and individually defined outcomes
- ▶ a collaborative relationship between the patient and healthcare professional, through which patients are encouraged to be equal partners in their own care.

In relation to wound care, patients should expect that, where possible and appropriate, they and their family will be involved in their treatment and care, have the ability to participate in any discussions of available treatment options, choices and risks, and should expect to be kept informed during their treatment and the possible length of healing time, how often dressings will

be changed (this is particularly important for patients in the community) and what to expect on a clinic visit. This requires patients to have access to appropriate advice and for clinicians to be able to offer information, or direct patients to appropriate sources that are patient-friendly and can support decision-making.

Alongside patient-centred care, there are a number of other factors and requirements that need to be met. The literature, as expected, shows evidence of effective outcomes being achieved by treating wounds for the underlying aetiology and associated causes, effective management of health conditions and correct selection of dressings and wound care therapy. These aspects of wound management are focused on heavily; however, one of the major obstacles to the delivery of effective treatment is the reluctance of some patients to concord with appropriately prescribed therapy (Stanton et al, 2016). This would suggest that patient-centred care is not always considered. Consideration for patient preference is emerging as a key component in the redesign of healthcare processes, with significant benefits for improving outcome and safety (Fredericks et al, 2012).

Patient-centred care is now encompassed as an important approach in patient treatment pathways to improve the delivery of quality, safe and cost-effective services (Institute of Medicine, 2001; Epstein and Street, 2011). Historically, this has focused on quality of life (QOL), pain, adherence, and coping strategies. This approach emphasises the importance of communication, partnership, and

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health promotion, along with an appreciation for the patients' expectations, autonomy and beliefs.

There are a number of qualitative studies, although limited (Corbett and Ennis, 2014) that have reflected the patient lived experience, focusing on patient-centric symptoms and quality of life measurements of patients with leg ulcers (Moffat et al, 2006), diabetic ulcers (Jaksa and Mahoney, 2010), and pressure ulcers (Gorecki et al, 2009). These all show a consensus, with common themes including pain, a restricted lifestyle, loss of mobility, powerlessness, and coping challenges. Healthcare provider solutions in patients with pressure ulcers have focused on alleviating the negative impact of distressing symptoms including improved care delivery, symptom control, patient education, and social support (Spilsbury et al, 2007). Improving our understanding as healthcare professionals of the patient's perceived burden of illness is an important step toward patient-centred wound care, and Corbett and Ennis (2014) state that the evolution from empathy to shared wound care decision-making is what patients are asking for.

Vermeulen et al (2007) carried out a study looking at dressing preferences of patients, doctors, and nurses. While the desired attributes were similar in all groups (quickest wound healing, pain reduction, and shortest hospitalisation time), patients also indicated some willingness to pay out-of-pocket costs for a dressing that would result in quicker, less painful wound healing. Moffat et al (2008) in a study looking at four-layer compression versus two-layer, essentially found that patients prefer dressings that allow them to lead normal lives while healing faster.

Despite the findings from earlier studies regarding patient preference, Stanton et al (2016) found that non-concordance rates in chronic wounds remain a major problem and are similar to those in other chronic illnesses, standing at around 50% of patients (van Hecke et al, 2009). Mandal (2006) stated that there were a number of factors that could increase concordance, which encompass the findings in studies relating to patient-centred care; among these are a therapeutic bond between the patient and clinician, where the patient believes the clinician has a sustained interest in understanding their problems, and treatment that can be fitted into the patient's everyday life with little disruption. If we

are able to truly encompass patient-centred care, we should achieve increased concordance, improving wound healing outcomes.

NATROX CLINICAL EVALUATION

The Leg Ulcer Clinic at the Great Western Hospitals NHS Foundation Trust sees patients referred to them with chronic complex non-healing wounds. Two patients were selected for case studies with a new therapy made available in the clinic, which had the potential to help maintain patient concordance through patient engagement with the aim to achieve wound healing. Both of these patients had expressed the importance of being able to self-manage their wound care as much as possible due to their busy lifestyles.

Natrox[®] oxygen wound therapy was made available for evaluation within the clinic; this therapy allows for the continuous administration of humidified oxygen to be delivered directly to the wound bed. Natrox is a small battery-powered electrochemical 'Oxygen Generator' (OG) and delivers approximately 13mls of humidified oxygen per hour. It is delivered through a fine soft tube to a disposable Oxygen Delivery System (ODS) that is placed directly over the wound; this is then held in place by a conventional dressing. The OG is small enough to be carried in the patient's pocket or secured close to the patient's wound, making it completely portable. It uses rechargeable and interchangeable batteries, which supply enough power to generate oxygen for a full 24 hours. Despite Natrox therapy being an advanced wound care therapy product, the simplicity of application means that it is possible for patients to be actively involved and to self-manage between specialist wound clinic appointments. Not only does this then impact on healing through patient compliance and concordance, wound healing is heavily reliant on the presence of oxygen and it is critical to almost all of the processes involved (see Box 1).

The leg ulcer clinic evaluated the product on the following two patients, both of whom had chronic diabetic foot ulceration. Diabetes affects small arterial vessels, causing distal disease, and this therefore contributes to low oxygen levels in the wound bed, and is often challenging to treat with open surgical or endovascular intervention; therefore, the decreased oxygenation at the wound bed continues to be a challenge.

Box 1. Oxygen and wound healing

The presence of oxygen increases the production of energy to fuel cell function and metabolism, angiogenesis, collagen synthesis and cross linking, epithelisation and resistance to infection (Castilla et al, 2012). Chronic wounds are known typically to be in a hypoxic state (Yip, 2015), and while temporary hypoxia is required after tissue injury to trigger wound healing, prolonged or chronic hypoxia delays the continuing wound healing process (Bishop, 2008; Rodriguez et al, 2008).

The presence of biofilm creates a chronic inflammatory environment where neutrophils and macrophages from the immune system consume oxygen leading to a wound with deficiency in oxygen supply to aid healing (James et al, 2016). By improving the wound environment with the presence of oxygen, wound healing is much improved, there is reduction of infection through the increased ability of white blood cells to kill and ingest bacteria (Gottrup, 2004) and acceleration of the healing process. Correcting wound hypoxia increases the healing response; if surgical or endovascular intervention is not possible, it is essential that we as nurses seek other modes for the delivery of oxygen to chronic ulcers to achieve healing.

CASE STUDY 1

A 46-year-old gentleman with type I diabetes diagnosed at age 4 years following illness with meningitis. His diabetes has caused complications, which have resulted in a renal transplant in 2001; this transplant is now failing and he is potentially looking at a second transplant to overcome this. He has also had a pancreatic transplant due to other complications of his diabetes. He has hypertension but this is well controlled on medication and he is an occasional smoker. This patient suffers with high levels of stress as the primary carer for his two sons; he is also the owner of a company, which requires many hours of his time. The combination of this has resulted in a lack of compliance and concordance with dressing and clinic regimens in the past due to placing very little time on his own health.

In February 2018, the patient awoke with pain in his left hallux; at this point there was no ulcer evident and after being seen by a rheumatologist he was treated for gout with allopurinol. Sometime between April and August 2018, he developed ulceration of his hallux following trauma, which then failed to heal. He was seen by podiatric surgeons, trauma/orthopaedics and rheumatology, and received different interventions from each of these teams, including surgical debridement. Despite the ulcer bed appearing healthy with little slough following the debridement, there continued to be no improvement in healing. The compliance issues were evident at this time as the patient was unable to attend regular appointments as a result of his social situation and he was therefore spending much of the time self-managing the ulcer.

In April 2019, he was referred to and seen in the leg ulcer clinic. They commenced larval therapy to deslough the ulcer, followed by a dressing regimen of Promogran Prisma to maintain the improved wound bed, aiding granulation and healing. Despite these therapies, the ulcer remained static, with well-defined edges. The ulcer bed became pale and later a recurrence of slough was observed (Figure 1).

The patient commenced Natrox oxygen wound therapy with the aim of healing the ulcer, by providing the vital oxygen required at the ulcer bed and also enabling the patient to self-manage his dressing regimen. The Natrox was applied directly onto the ulcer surface with Urgotul SSD applied as a secondary dressing. The Urgotul was



Figure 1. pre Natrox®



Figure 2. Six weeks of Natrox®

chosen for further anti-bacterial protection and for reassurance to the patient, as he was at this point at high risk of further surgical intervention including minor amputation. Kerramax care was applied as a superabsorbent layer to manage exudate. Use of Natrox elsewhere had previously noted an initial increase in exudate and a deterioration in terms of ulcer size, which has been attributed to the improvement in cellular activity and the ability for autolytic debridement to occur; once the level of exudate settles the ulcers are seen to improve and go on to heal.

Unfortunately, in the initial period there was little or no improvement in the ulcer due to the ODS being applied upside down; the ulcer bed appeared paler with potentially what appeared to be an increase in biofilm. However, once the error was noted and rectified with the device being applied

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Figure 3. Completion of therapy

the correct way the patient himself commented on the dramatic regression of the ulcer during the following 8–10 days. Within 6 weeks of Natrox therapy, the ulcer had progressed significantly, having reduced in size by more than 50%. The wound bed was covered with what appeared to be some macerated tissue that was at this point left undisturbed to continue to heal (Figure 2).

By week 16, the ulcer had all but healed: there was a small area of scab present that was left to lift alone (Figure 3).

Despite Natrox therapy being an advanced wound care product, the simplicity of application meant this patient was able to be actively involved in the therapy. He was able to manage his wound care needs between specialist appointments, making him actively involved in his treatment and this resulted in improved compliance. The patient stated that the experience and outcome of therapy exceeded his expectation even within the initial improvement period during the first 6 weeks. He had not experienced such a change in his wound during all previous therapies, and to then go on and achieve closure of this wound was the best possible outcome he could have hoped for. Natrox provided the healthcare professionals involved the ability to choose a therapy that encouraged independence and autonomy for the patient; this gave them confidence for patient compliance and allowed a holistic approach to achieve wound healing. The device is accompanied with an easy-to-follow patient information leaflet, which contains information regarding application of the device and the benefits of oxygen in wound healing.

CASE STUDY 2

A 61-year-old gentleman with a history of type II diabetes and a history of cellulitis. His work is based in the USA and therefore he travels on a regular basis. He presented to the clinic with a non-healing diabetic foot ulcer on his left medial malleolus; this had been present for approximately 6 months prior to commencing Natrox wound therapy. He developed a swollen leg during a long-haul flight to China, which caused a blister that deteriorated and went on to develop into an ulcer. The patient was initially treated for the cellulitis and later referred to dermatology, who then prescribed Dermol for his skin alongside his dressing regimen. However, the ulcer remained and was static. Due to the gentleman's history of diabetes, he was referred to the specialist 'hot clinic' where he underwent a venous and arterial duplex scan. The arterial scan was normal; however, the venous scan showed insufficiency. He underwent laser therapy to treat this and was placed in thigh-length compression hosiery. The ulcer was dressed with honey for a period of time but still there was no further progression with healing (Figure 4).



Figure 4. prior to Natrox

The patient was commenced on Natrox therapy with the aim of achieving ulcer healing, with oxygen delivered directly to the wound bed, and this provided the added benefit of facilitating patient compliance. The ulcer was approximately 4.5cm x 2.5cm, with some small buds of granulation, but the ulcer was predominantly covered with a layer of slough and no obvious signs of healing from the wound edges. The peri-ulcer tissue appeared healthy but dry.

The ODS was placed directly over the ulcer

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Figure 5

and Kerramax Care used as a secondary dressing to manage the increase in exudate as per the previous patient. He continued with the previously prescribed compression hosiery, and the simplicity of this advanced therapy allowed the patient to be self-caring with his dressings, which was important due to his regular travelling.

Within a month of commencing the therapy, the ulcer decreased to approximately 4cm x 2cm, there was less slough present in the wound and the ulcer bed appeared healthy with evidence of granulation tissue (*Figure 5*). The ulcer continued to improve and decrease in size (*Figure 6*) and achieved full closure after 20 weeks of therapy (*Figure 7*).

Using Natrox wound therapy for this patient again allowed the gentleman to maintain his independence and continue with his travel and work commitments without detriment to the overall outcome. This also meant that the patient maintained his identity and his quality of life. Natrox provided consistency for the patient and the visible improvement and decrease in the ulcer size gave the patient the positive encouragement he needed to continue and remain compliant with therapy.

Using Natrox oxygen therapy on both of these patients highlighted how easy it is to incorporate the therapy into clinical practice and patients' lives. Often when patients are receiving advanced therapies, there are restrictions on their ability to carry out their everyday living activities, due to appointments for dressing changes, which can also disrupt work and other commitments. The ease of application for Natrox makes it easy to adopt a patient self-care strategy and engage these patients



Figure 6

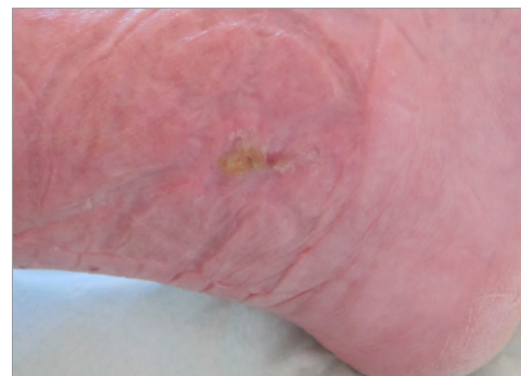


Figure 7. Twenty weeks

to participate in their treatment, despite being an advanced therapy.

Removing the need for other healthcare professionals to be involved between specialist clinic appointments, meant that both these patients could take responsibility for their treatment and monitor its effectiveness, helping to promote acceptance and concordance. The treatment increases the oxygen at the wound base, encouraging wound healing, and this enables patients to maintain their independence and identity while receiving their therapy. The device is lightweight and discreet and is easy to apply, with no requirement for training.

The therapy has the potential to reduce the overall cost burden of an ulcer, at the same time as achieving complete closure and therefore enabling discharge of patients from a leg ulcer service. It is recognised that this therapy and engagement in self-care may not be suitable for all patients between specialist clinic appointments; however, the overall impact on wound healing reduces the burden on an already overstretched service.

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