NATROX™
Oxygen Wound Therapy

Cambridge University Hospitals NHS
NHS Foundation Trust

A Case Series of Patients with Diabetic Foot Ulcers treated with the NATROX™ Continuous Diffusion of Oxygen Therapy delivery system

INTRODUCTION

Diabetic foot ulceration currently costs around £600M per year in the NHS alone. Both in the UK, and globally, there is an epidemic of diabetes and these costs are set to spiral upwards rapidly in the coming years. This study examined the ability of the novel NATROX™ system to aid ulcer healing through increased oxygenation.[1]

Healing wounds require a lot of cellular activity, so that things such as cell division, new blood vessel growth, fighting infection and producing collagen can take place. Without a very significant increase in cells' activity, then wounds won't heal. All cellular activity needs oxygen to power the conversion of glucose into a form of energy that cells can make use of (ATP). With plenty of oxygen one glucose molecule can produce 36 molecules of ATP, but in hypoxia only 2 molecules will be produced. Supplying wounds with an increased level of oxygen should enable them to make much more efficient use of the available nutrients.

The concept of increasing the oxygen concentration in healing wounds developed originally with hyperbaric oxygen therapy. Poor tissue oxygenation, as is often seen in diabetic foot ulcers, is a significant impediment to cellular activity, and is therefore very likely to impair wound healing. Hyperbaric oxygen has shown only limited success in this field because it is only possible to use this for very short periods of the week (approx. 5%) limiting its efficacy in raising oxygen levels in wounds for a prolonged period. In addition, access to the treatment is not easy, patients are confined into a chamber by the treatment and it is also very costly.[2]

The NATROX™ Continuous Diffusion of Oxygen Therapy (CDOT) delivery system developed by Inotec AMD Limited employs a small battery-powered electrochemical 'Oxygen Generator' (OG) to concentrate atmospheric oxygen and feed the pure, moist, oxygen at a rate of around 13 mL/hour through a fine, soft, tube to a dressing-like 'oxygen distribution system' that is placed over the wound and is held in place by a conventional dressing. The Oxygen Generator is worn in a holster on the waist or above the calf or is placed in a trouser pocket, thus enabling the patient to enjoy normal mobility (hence 'ambulatory') while receiving continuous treatment.

Addenbrooke's Hospital in Cambridge and St George's in London jointly carried out a 6-month case study involving 10 patients with chronic diabetic foot ulcers who were studied using NATROX™ for a period of 8 weeks.

Fig. 5 The NATROX™ Device

1. State of the Nation 2012 England Diabetes UK.
2. Technical and clinical outcome of topical wound oxygen in comparison to conventional compression dressings in the management of refractory non-healing venous ulcers. Tawfick WA1, Sultan S. Vasc Endovascular Surg Jan 2013;47(1):30-7

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METHOD

Patients were selected from those currently being treated by the multi-disciplinary team (MDT) in Cambridge University hospital (CUH) and St George's hospital. They had previously all had a full diabetes/ arterial assessment.

Basic Criteria included:

- No significant wound reduction despite best practise care for a minimum of 4 weeks
- The patients also needed to be able to change/charge the battery in the NATROX™ device.

Follow up in clinic was for 8 weeks, this matched standard follow-up practice.

Secondary dressings were chosen from the hospital wound care formulary. The disposable NATROX™ ODS (Oxygen Delivery System) was placed on the wound bed, it was then dressed with a sliver alginate, a traditional absorbent pad and film.

Patients returned to clinic every week and in between were treated by community nurses. Wounds were photographed digitally and measured. All relevant consent and permissions gained.

RESULTS

The most significant results from this phase 1 trial highlighted the reduction in ulcer size, despite the difficult nature of the wounds chosen. The median duration of the ulcers prior to entering the study was 25 weeks (mean 43 weeks), indicating that these were wounds unlikely to ever heal. Half of the patients had documented peripheral vascular disease in addition to their diabetes.

By week 8, the median ulcer size had decreased by 53% (mean 51%). Seven of the 10 chronic ulcers were on a healing trajectory, with a decrease in size. One heel ulcer that had been present for 56 weeks (figure 3) healed completely (figure 4), a further 2-year old ulcer was less than half of its original size, and a third that had been present for 88 weeks was down to 10% of its size at the start of the 8 weeks. The first patient into the trial was deemed to have such a poor outlook that he had already been offered an amputation (figure 1), but by the end of the 8 week period his ulcer was down to 30% of its baseline (figure 2). Summary of all the results can be seen in graphical form in figure 6. It is of note that by week 6 there appeared to be a clear separation between the ulcers that were doing well, and those that failed to respond to the therapy.

A further positive from the trial was a non-significant trend towards a reduction in overall pain scores. With such a small pilot study, and a number of the patients not feeling pain secondary to neuropathy it was not surprising this did not reach significance but it is an encouraging result.

Despite its complete novelty, both to staff and patients, the device was really well tolerated. No patient stopped using the device at any point out of choice. Our feedback from the patients was wholly positive, and a number of patients commented on enjoying being actively involved in the process of managing the device. Three staff independently reported that they felt the patients were to some extent empowered by their active involvement in their wound care.

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RESULTS (CONTINUED)

Examples of Wounds Patient A

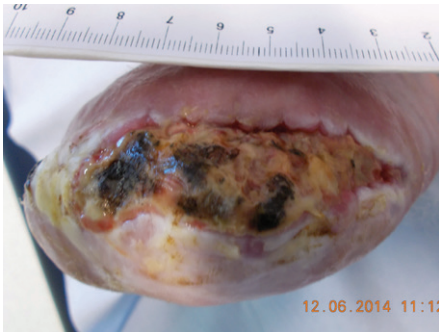


Fig. 1 Wound on 12.06.14

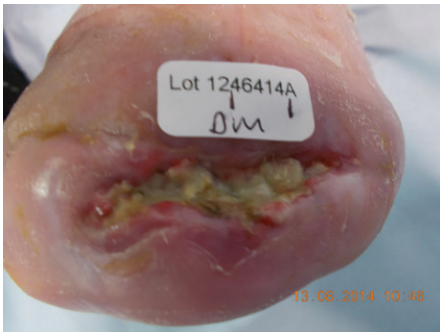


Fig. 2 Wound on 13.08.14

Examples of Wounds Patient B

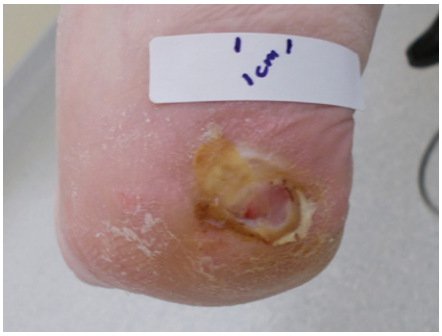


Fig. 3 Wound on 19.06.14

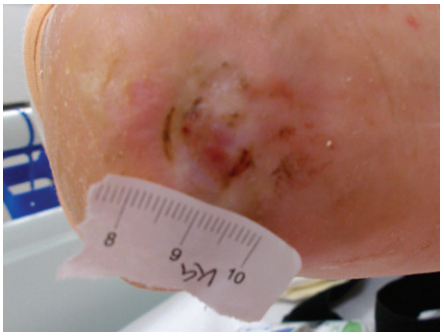
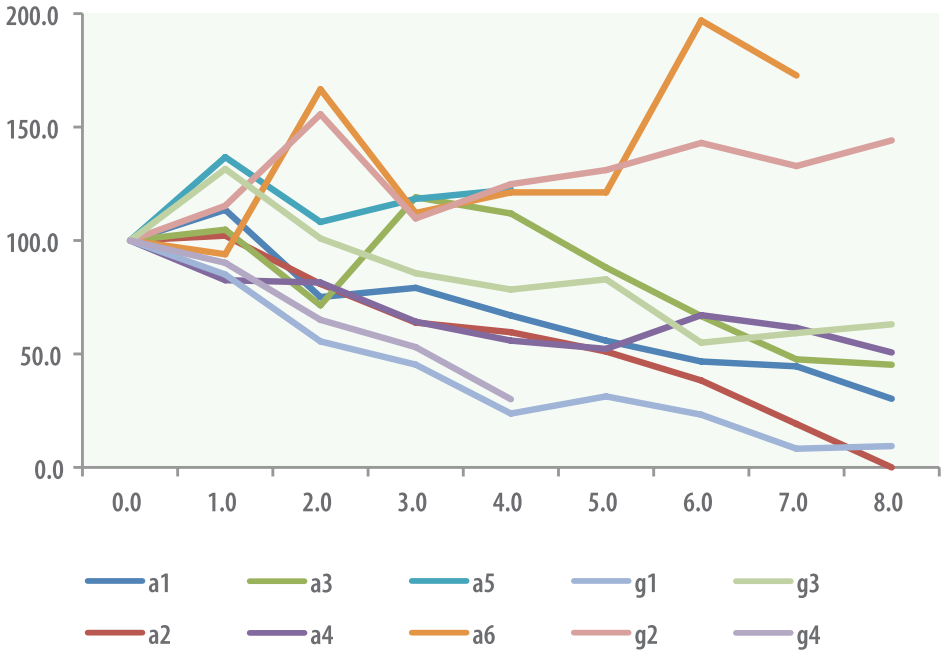


Fig. 4 Wound on 31.07.14

Fig. 6 NATROX™ Ulcer Database Results Chart



DISCUSSION / CONCLUSION

Around 6,000 people with diabetes have amputations each year in England. This substantially reduces quality of life, and is associated with high mortality. Studies suggest that only 50% of patients with diabetes who have had an amputation survive for a further 2 years. Around 56% of patients with diabetes who have had ulcers survive for 5 years.

Almost half of foot care expenditure is for primary and outpatient care. An inpatient with a diabetic foot ulcer spends on average 13 days longer in hospital (NHS Diabetes, 2012).

Interventions that can potentially heal or greatly reduce the size of these foot ulcers in patients with diabetes could have a massive impact, reduce infection rates, amputations, improve overall quality of life and reduce costs to the NHS. A device that can be safely and easily utilised by nursing staff and patients within the community environment is ideal and could prove cost effective.

The benefits of NATROX™ are that this is a completely ambulatory oxygen therapy which is worn 24hrs a day 7 days a week. It is a compact device that can be worn on the patient with ease and discretion, its application is straight forward with no complicated training needs required.

A further large multi-centre study is now planned.

Lead Author – Gail Curran
Lead Vascular Nurse
Cambridge University Hospitals, NHS Foundation Trust, Addenbrooke's Hospital Cambridge Vascular Unit, Box 201, Addenbrooke's Hospital, Hills Road, Cambridge, CB2 0QQ.
T: +44 (0)1223 596382 *Bleep 154-226*
M: +44 (0)7882 189844
E: gail.curran@addenbrookes.nhs.uk

Co-Author – Catherine Fisher
Vascular Research Nurse
Cambridge University Hospitals, NHS Foundation Trust, Addenbrooke's Hospital Cambridge Vascular Unit, Box 201, Addenbrooke's Hospital, Hills Road, Cambridge, CB2 0QQ.
T: +44 (0)1223 596382
E: catherine.fisher@addenbrookes.nhs.uk

Co-Author – Paul Hayes
Consultant Vascular Surgeon
Cambridge University Hospitals, NHS Foundation Trust, Addenbrooke's Hospital Cambridge Vascular Unit, Box 201, Addenbrooke's Hospital, Hills Road, Cambridge, CB2 0QQ.
T: +44 (0)1223 596382
E: paul.hayes@addenbrookes.nhs.co.uk

Ian Loftus – Consultant Vascular Surgeon
Leanne Sequeira – Vascular Research Nurse
St George's Healthcare NHS Trust, Blackshaw Road, Tooting, London, SW17 0QT.
T: +44 (0)20 8725 3205
E: ian.loftus@stgeorges.nhs.uk

Cambridge University Hospitals NHS
NHS Foundation Trust

Inotec AMD LTD
Butts Business Centre | Fowlmere | Cambridgeshire | SG8 7SL | UK
T: +44 (0)1763 209007 F: +44 (0)1763 208333 E: info@inotecamd.com
www.inotecamd.com

Inotec AMD LTD