A Case Series Of Patients With Diabetic Foot Ulcers Treated With The Natrox Topical Oxygen Therapy Device.

Introduction
Diabetic foot ulceration currently costs around £600M per year in the health service 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

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The most significant results from this phase 1 trial highlighted the reduction in ulcer size, despite the difficult nature of the wounds chosen. The duration of the median healing 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 4) healed completely (figure 5), 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, but by the end of the 8 week period his ulcer was down to 30% of its baseline. A summary of these results is displayed in graphical form (figure 1). 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 their wound care.

A significant proportion of patients experienced an improvement in their ulcer from a visual impression. Three staff independently reported that they felt the patients were to some extent empowered by their active involvement in their wound care.

Results

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 50% of patients with diabetes who have had ulcers survive for 3 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 the Natrox are that this is a completely ambulatory oxygen therapy which is worn 24 hours 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 straightforward with no complicated training needs required.

A further large multi-centre study is now planned.

References

1. State of the Nation 2012 England Diabetes UK