Topical oxygen therapy for chronic wounds: a report on the potential of NATROX™
a new device for delivering enriched oxygen to chronic wounds

Abstract

Topical oxygen therapy has excited wound healers for some considerable time. This paper presents the potential of NATROX™ topical oxygen used to treat a short series of patients with venous ulcers. The uncontrolled study permits the observations that the NATROX™ device is safe and has promise towards the treatment of chronic lower extremity wounds.

Keywords: topical oxygen therapy, chronic wounds

Introduction

Some 25 years back in pursuit of the pathogenesis of venous ulcers the author measured transcutaneous oxygen (TCPO₂) levels of 20 mm Hg and less around venous ulcers though these tissues had pulsatile dermal blood supply. How the tissues could survive in such low oxygen levels? It is now understood that the microcirculation in ulcerated tissue is impaired and that peri capillary cuffs exist trapping molecules including growth factors which cause venous ulceration. Better understanding of the TCPO₂ technique now exists and taken together, it seems reasonable to state that some indolent venous ulcers may have less than necessary oxygen available for healing, and topical oxygen therapy (TOT) may offer a solution.

In a recent review, Gordillo and Sen explained the mechanistic reasons behind TOT and proposed how to select patients for this treatment modality. In the same paper, the authors described an experiment that demonstrated that topically delivered oxygen could diffuse through superficial dermal tissues in wounds. Oxygen has critical roles in the production of collagen, in angiogenesis through the production of vascular endothelial growth factor and in the scavenging process that is essential before repair is initiated. All this knowledge has accrued from acute and chronic experimental wounds. Does this translate to chronic wounds in the human?

This paper describes a new TOT device Inotec’s NATROX™ and preliminary clinical experiments to demonstrate its safety and potential.

Safety and efficacy study

A first safety study was done by the authors group at Southampton University Hospital Trust with Ethics Approval from the local Ethics Committee NHS Trust No RHUM MED0818. This study on 4 patients with evidence of venous disease and chronic wounds lasted 6 weeks on each case. The study was discontinued on 2 patients. Patient 1 expressed a wish to discontinue; the other became ill for unrelated reasons. Overall the study showed the device to be safe.

A second study was done. This was an uncontrolled observational study on 10 patients over 6 weeks and carried out by a specialist group of Tissue Viability Nurses at Tissue Viability Consultancy Services Ltd (TVCS) in Eastbourne. The aims of this study were:

• To examine the safety of the device and;
• To record changes in wound area over the 6 weeks the device was used.

Patients [N = 10, 8F, 2M, age range 51–84 years, mean age 69.5 years] with venous ulcers but without any other significant comorbidity were included with prior informed written consent.

Swabs were done on all 3 visits for all patients and sent for semi quan-
titative assessments. Pain associated with having an ulcer was assessed using a visual analogue score. The ease of use and comfort of wearing the device were scored at patient interviews on 3 visits.

Wound area was traced using a Visitrak® device [Smith&Nephew] on all visits.

Wounds were cleaned, debrided and the Island Oxygen Delivery Pad positioned over the wound as the primary dressing. No activated or other dressings were used. The NATROX™ device was worn around the waist on most occasions. All patients had compressive bandage support over the dressing.

Results

There were no adverse events during the study. No patients rejected the NATROX™ device. Overall, a mean reduction of 58.9% in wound areas was observed see Figure 3. Pain scores also decreased in all patients during the study period.

Discussion

The aims of this study were to examine the safety of the Inotec TOT device and to study its efficacy to treat venous ulcers. There was no adverse event associated with the use of this device. Admittedly there was some increase in exudate on occasion. Whether this was due to the Inotec device or a change within the wound is impossible to say. It will however, inform further studies using the device.

All swabs taken during this study pointed to the presence of wound bacteria that were not affected during the study. From theoretical considerations alone, oxygen has anti microbial properties and should have reduced the bacteria present in these wounds. It is impossible to argue whether these findings militate against TOT or are inconclusive. However future controlled studies should serve to help conclude this argument.

Clearly, there was a reduction in wound size in all cases in this study. It is not argued that TOT helped with wound contraction in all cases though this finding is very persuasive.

### CASE 1

<table>
<thead>
<tr>
<th>PATIENT’S DETAILS</th>
<th>503</th>
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<tbody>
<tr>
<td>JG 73 year old female with a venous leg ulcer on left anterior mid-gaiter area for 7 months. The wound had been non-responsive to various treatment modules. ABPI 1.21. Treatment used NATROX™32.</td>
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<table>
<thead>
<tr>
<th>SWAB RESULTS</th>
<th>Start</th>
<th>2 Weeks</th>
<th>6 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>+++ Staphylococcus aureus</td>
<td>+++ mixed skin and enteric flora</td>
<td>+++ mixed skin flora</td>
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| SIZE OF THE WOUND | 8.34 | 6.61 | 6.18 |

<table>
<thead>
<tr>
<th>PATIENT’S SATISFACTION</th>
<th>Comfort</th>
<th>Convenience</th>
<th>Overall Assessment</th>
</tr>
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<tbody>
<tr>
<td>2</td>
<td>3</td>
<td>3</td>
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| CASE DESCRIPTION | Wound area and size reduced. The patient described this product as being very comfortable, lowering the level of pain from 5 to 2. However there some bleeding observed at dressing changes. The wound had not healed completely during the course of the study. This wound now continues to heal. |
CASE 2

PATIENT'S DETAILS
S04: MG 74 years, female with a venous ulcer on a left medial malleolus. Wound duration was 2.5 years with the current episode of care 9 months. Ulcer failed to respond to various treatments. ABPI 0.97. Treatment used was NATROX™ 25 Low Flow oxygen Device.

SWAB RESULTS
- Start
  - +++ mixed enteric flora
  - ++ Staphylococcaureus
- 2 Weeks
  - +++ Coliform spp.
  - +++ beta-haemolytic Streptococcus of Lancefield Group B isolated
- 6 Weeks
  - +++ Coliform spp.

SIZE OF THE WOUND
16.24
10.18
5.94

PATIENT'S SATISFACTION
- Comfort: 5
- Convenience: 3
- Overall Assessment: 5

CASE DESCRIPTION
This patient was selected to use the low-flow oxygen device on account of a known hypersensitivity and tendency to get skin maceration. High levels of fluid produced during treatment with NATROX™. Patient was advised to switch this device off at night to lower amount of exudates which was helpful. Wound area decreased during the study.

CASE 3

PATIENT'S DETAILS
S05: RK 51 y.o. male with recurring venous leg ulcer on R) lateral gaiter skin. ABPI 1.15, treatment used was NATROX™ 30

SWAB RESULTS
- Start
  - +++ mixed skin flora
  - ++ Staphylococcaureus
- 2 Weeks
  - +++ mixed skin flora
- 6 Weeks

SIZE OF THE WOUND
24.48
14.53
6.12

PATIENT'S SATISFACTION
- Comfort: No answer given
- Convenience: No answer given
- Overall Assessment: No answer given

CASE DESCRIPTION
This patient was a chef. His work required him to stand for long periods in a stressful environment and he was a smoker. Ulcer pain significantly decreased from 8 to 2 during the study. However it was difficult for the patient to wear the device while continuing to work.

CASE 4

PATIENT'S DETAILS
S06: EL 82 year old lady with a non-healing venous leg ulcer on the right medial mid-gaiter region. Patient had a history of varicose veins and silver allergy, ABPI 0.97 and treatment used was NATROX™ 36.

SWAB RESULTS
- Start
  - +++ Staphylococcaureus
  - +++ Coliform spp.
- 2 Weeks
  - +++ Coliform spp.
- 6 Weeks
  - Not Applicable (healed)

SIZE OF THE WOUND
36
13.22
0

PATIENT'S SATISFACTION
- Comfort: 4
- Convenience: 3
- Overall Assessment: 5

CASE DESCRIPTION
When started using NATROX™ at first her surrounding skin became excoriated and macerated with characteristic red demarcation matching the TOT dressing. A zinc impregnated bandage was used to lower the risk of further skin damage with satisfactory results.

References


Conflict of interest: Raj Mani has received industry support towards clinical trials, honoraria for presenting lectures as well as unrestricted educational grants.

Disclaimer - The photos in this report have been updated to reflect the NATROX™ Oxygen Generator and Delivery System.