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# Topical oxygen therapy for chronic wounds: a report on the potential of Inotec® 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 the Inotec® topical oxygen used to treat a short series of patients with venous ulcers. The uncontrolled study permits the observations that the Inotec® 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 (TcPO<sub>2</sub>) levels of 20 mm Hg and less around venous ulcers though these tissues had pulsatile dermal blood supply.<sup>1</sup> How the tissues could survive in such low oxygen levels? It is now understood that the microcirculation in ulcerated tissue is impaired<sup>2</sup> and that peri capillary cuffs exist trapping molecules including growth factors<sup>3</sup> which cause venous ulceration. Better understanding of the TcPO<sub>2</sub> 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.<sup>4</sup> 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



Figure 1. Inotec device, shown here to be worn around the Waist. Pure (96.2%) humidified oxygen is produced at ~15ml/hr.

human? This paper describes a new TOT device Inotec's *Velox*™ 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 RHM 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-



Figure 2. The *Velox*™ system: Oxygen generator and the Island Oxygen Delivery Pad. Within 5 hours of fitting Oxygen concentration in the headspace above the Wound increases by 20%.

→ 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 Velox device was worn around the waist on most occasions. All patients had compressive bandage support over the dressing.



Figure 3. Patient wearing Velox™.

## Results

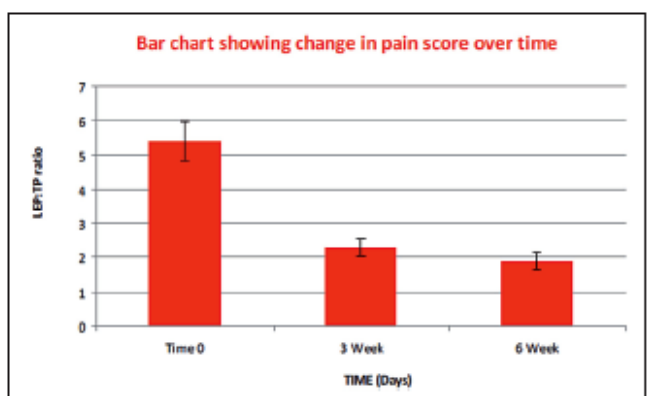
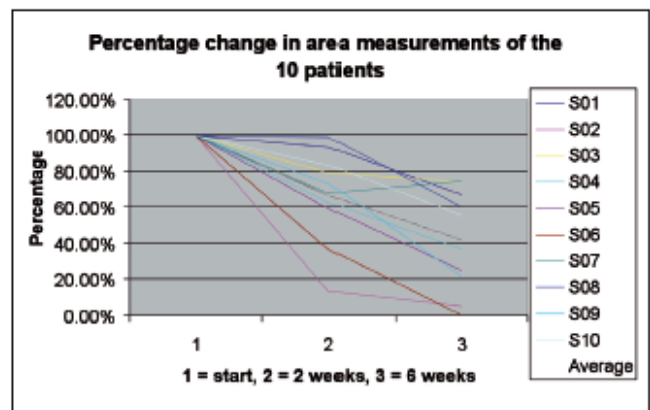
There were no adverse events during the study. No patients rejected the Inotec device. Overall, a mean reduction of 58.9 % in wound areas was observed see Figure 3. Pain scores also decreased in all patients during the study period.

## 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.



Pain scores at week 6 were significantly reduced compared to the scores at the start ( $p < 0.009$ , Student T test). (source: TVCS report)

Furthermore, the use of the TOT device was associated with a statistically significant reduction in pain perceived by patients in this study.

However, this was an uncontrolled non randomised study the results of which are very persuasive not only in terms of reducing wound area but also in pain reduction.

The results indicate further use of this TOT device following the advice of Gordillo to select patients randomly and at least, in a controlled fashion to establish its efficacy.

There is a global increase in the prevalence of chronic lower extremity wounds and every possible means of treating these should be welcomed. The Inotec TOT Velox™ device is safe and offers a chance of healing chronic venous ulcers. ■

CASE 1			
PATIENT'S DETAILS	S03 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 Velox 32.		
SWAB RESULTS	Start	2 Weeks	6 Weeks
	++ Staphylococcus aureus +++ Coliform spp.	+++ mixed skin and enteric flora	+++ mixed skin flora
SIZE OF THE WOUND	8.34	6.61	6.18
PATIENT'S SATISFACTION	Comfort	Convenience	Overall Assessment
	2	3	3
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 Velox 25 Low Flow oxygen Device.		
SWAB RESULTS	Start	2 Weeks	6 Weeks
	+++ mixed enteric flora ++ Staphylococcus aureus	+++ Coliform spp. +++ beta-haemolytic Streptococcus of Lancefield Group B isolated	+++ Coliform spp.
SIZE OF THE WOUND	16.24	10.18	5.94
PATIENT'S SATISFACTION	Comfort	Convenience	Overall Assessment
	5	3	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 the Inotec. 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 Velox 30		
SWAB RESULTS	Start	2 Weeks	6 Weeks
	+++ Staphylococcus aureus	+++ mixed skin flora	+++ mixed skin flora
SIZE OF THE WOUND	24.48	14.53	6.12
PATIENT'S SATISFACTION	Comfort	Convenience	Overall Assessment
	No answer given	No answer given	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 Velox 36.		
SWAB RESULTS	Start	2 Weeks	6 Weeks
	+++ Staphylococcus aureus +++ Coliform spp.	+++ Coliform spp.	Not Applicable (healed)
SIZE OF THE WOUND	36	13.22	0
PATIENT'S SATISFACTION	Comfort	Convenience	Overall Assessment
	4	3	5
CASE DESCRIPTION	When started using Inotec 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

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

## Velox™ Topical Oxygen Therapy Delivery System Inotec AMD Ltd

FDA CLEARANCE     CE MARKING

### DESCRIPTION / COMPOSITION

Assist the healing of wounds such as skin ulcerations including leg ulcers and trauma wounds. The device is initially intended for application to the leg, gaiter and ankle regions. The Velox™ Oxygen Generator is a small battery powered device producing pure (96.2%) humidified oxygen from atmosphere. This valuable oxygen is directed through a cannula to a specific wound dressing maintaining an oxygen enriched headspace. This dressing also absorbs and retains exudate.

Oxygen is delivered to the wound site through a Velox™ 'Island Oxygen Delivery Pad'. This occlusive dressing allows oxygen to diffuse across the wound with exudate retained in an absorbent layer. This dressing is designed for use as a primary and with compression bandaging.

### INDICATIONS

For wounds which have not responded to treatment having an area less than 10x10cm. The company is engaged in continuing a series of clinical studies further demonstrating the benefits of the Velox™ System over a broad range of wounds.

### CONTRAINDICATIONS

N/A

### COUNTRIES WHERE THE PRODUCT IS AVAILABLE

Throughout the EC

### UNDESIRABLE EFFECTS

None

### PRECAUTIONS

N/A

### COST + COST EFFICACY

The pricing of the Velox™ system components gives a cost effective solution for the healing of non-healing wounds.

### PRESENTATION / DIMENSIONS

Velox™ is designed to be worn around the waist. Dimensions L 14x10x35cm. Weight 285g. Occlusive, absorbent, translucent, adhesive, active area 10x10cm fitted with Oxygen delivery cannula.

