Topical Wound Oxygen (TWO_2) Versus Conventional Compression Dressings in the Management of Refractory Non- healing Venous Ulcers; A Parallel Observational Pivotal Study

Wael Tawfick ', Sherif Sultan
Western Vascular Institute, Department of Vascular & Endovascular Surgery, University College Hospital, Galway, The Galway Clinic, Doughiska, Dublin Road Galway, Ireland

Royal Academy of Medicine in Ireland, Irish Journal of Medical Science, Volume 176, Number 1, 2007 Supplement 2, 5th Annual Vascular Institute Symposium, Galway

Venous ulceration is a common ailment with an incidence of 3 per 1000 population and 20 per 1000 population in Octogenarians. The cost of managing venous ulcers amasses to 1.6 Billion Euros per year. The aim of this study is to prove the safety and efficacy of topical wound oxygen (TWO2) in managing refractory venous ulcers.

Our primary end point is the proportion of ulcers healed, percentage reduction in the ulcer size, time taken for full healing or for the ulcer to be ready for skin grafting, degree of bacterial elimination at end of therapy and absence of scarring and reverse gradient phenomenon. Our secondary end points are quality of life, pain reduction and recurrence rates. Leg ulcers were digitally photographed and swabbed. The ulcer was measured using Visitrak to determine surface area, maximum width, length and depth of the ulcer. Punch biopsies were taken from all ulcers. Necrotic tissue was debrided after 7_2 hours of treatment. In the TWO_2 group the limb was placed in the chamber for 180 minutes twice daily under pressure of 50mbars, with oxygen supplied at 10 litreslminute. The compression group were managed using Profore compression dressings with underlying low-adherent dressings. Ulcers were digitally photographed & measured at 3 day intervals and swabbed weekly.

	TWO,	Compression Therapy	
Ulcers Showing Signs of Healing in 3 Weeks	90% (n=28/31)	69% (n=20/29)	X^2 =0.039
Ulcers Completely Healed by 2 Months	55% (n=17/31)	7% (n=2/29)	X^2 <0.0001
Mean Time to 70% Reduction in Surface Area	22 days	189 days	P<0.0001 95% CI: −176.774– −138.641
MRSA Elimination	8/14	0/15	X^2 =0.018

Size of Ulcer	Duration to 70% Reduction in Surface Area	Duration to 70% Reduction in Surface Area	
<5cm2	21 days	165 days	P=0.005 95% CI: −205.579 – −82.82078
5–10cm2	24 days	172 days	P=0.015 95% CI: −241.557 – −54.44342
11–20cm2	21 days	191 days	P=0.011 95% CI: −266.021 – −73.40779
21–40cm2	22 days	187 days	P=0.001 95% CI: −206.119 – −123.517
>40cm2	22 days	183 days	P=0.007 95% CI: −239.922 – −82.0779
Ulcer Duration	Duration to 70% Reduction in Surface Area	Duration to 70% Reduction in Surface Area	
2–3 yrs	21	126	P<0.0001 95% CI: −119.725 – −91.51312
3–4yrs	23	148	P<0.0001 95% CI: −138.098 – −111.902
4–5yrs	22	204	P<0.0001 95% CI: −228.923 – −136.038
5–10yrs	22	220	P<0.0001 95% CI: −222.383 – −172.717
10–20yrs	21	200	P<0.0001 95% CI: −178.3333 – −6.99.603

31 ulcers were managed using TWO_2, and 29 with compression dressings. Both groups were comparable regarding demographics and risk factors. 45 days post completion of therapy, none of the TWO_2, healed ulcers (n=17) showed signs of recurrence as well as the 2 fully healed compression dressing ulcers. However 7 of the 20 healing compression dressing ulcers showed signs of regression and deterioration. TWO_2 is a valuable tool in management of chronic non-healing venous ulcers. We believe that TWO_2 is safe and effective in refractory venous ulcer management.