

The Development of Standards for the Use of Topical Pressurized Oxygen Therapy (TPOT)

Introduction

TSS has been in the medical supply industry for over eight years, specializing in complex wound and ostomy care and recognizes the challenges encountered in chronic wound management. TSS strives to bring the very latest technology to the forefront of Canadian wound care, and to this end have introduced Topical Pressurized Oxygen Therapy (TPOT). TPOT is a method of delivering pressurized and humidified oxygen to support the healing of chronic and hypoxic wounds.

Though TPOT is approved by the Therapeutic Products Directorate as a Category 2 Medical Product it has been a challenge to integrate this technology into practice—despite the evidence showing the benefits to patients, clinicians, health-care administrators and cost-conscious policy-makers.

There are many questions to ask in order to maintain a high standard of care with this—and any—technology. In an effort to address these questions eQuadra Solutions Inc. was commissioned by TSS to design a process by which the evidence related to TPOT could be evaluated, enabling TSS to produce evidence-based educational and promotional material, as well as a rationale for decision-makers who must deliver cost-effective patient care.

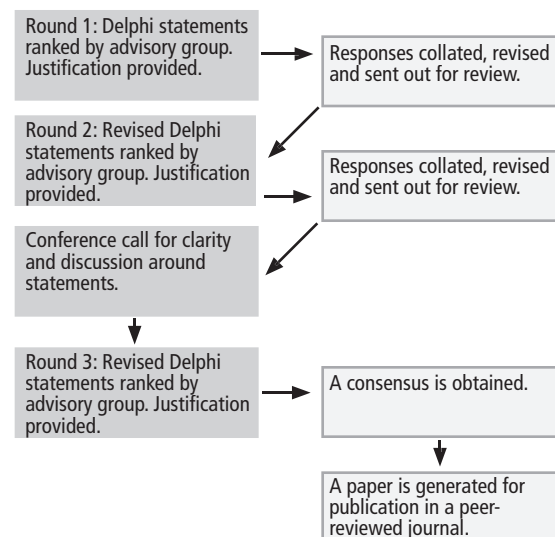
Goals

The goals of the process used by eQuadra to address the most common questions around the effective use of TPOT included:

1. Create an evidence-based peer-reviewed article with an independent group of expert health-care professionals that identifies standards that would support efficient and effective clinical decision-making relating to the use of topical pressurized oxygen therapy.
2. Use the peer-reviewed article for the development of educational and promotional material.
3. Use the process to identify gaps in evidence to support further research.

Methodology – The Delphi Method

The process chosen to develop the set of standards was the Delphi method. The Delphi method has been linked with the term “collective intelligence,” used to support the development of a knowledge base by structuring a *group communication* process to facilitate *group problem-solving*.



The Advisory Group

An interprofessional advisory group was selected to participate in the Dephi method. This group was chosen based on discipline and geographic location and met four expertise requirements: i) knowledge and experience with wound care and/or topical pressurized oxygen therapy; ii) capacity and willingness to participate; iii) sufficient time to participate in the process; and iv) effective communication skills. The 10 interprofessional clinicians chosen were:

1. Joseph Baum, MD, FRCS(C); Department of Surgery, Division of Plastic Surgery, Etobicoke General Hospital, Toronto, Ontario
2. Dawn Christensen, BScN, RN, MHSc(N), CETN(C); Clinical Nurse Specialist/Advanced Practice Nurse, KDS Professional Consulting, Ontario
3. Marc Despatis, BSc, MSc, RVT, MD FRCS; Vascular Surgery, Centre Hospitalier Universitaire de Sherbrooke, Quebec
4. Kyle Goettl, RN, BScN, MEd., IIWCC; Nurse clinician, Amputee Rehabilitation, Parkwood Hospital, London, Ontario
5. David Haligowski, BSc (physics), MD; General practitioner and medical director at two nursing homes, member of the board of the CAWC since 2006, lecturer in the Department of Family Medicine the University of Manitoba.
6. Chester Ho, MD; Physiatrist, associate professor and head, Division of Physical Medicine & Rehabilitation, Department of Clinical Neurosciences, University of Calgary, Alberta
7. Keith Louis, MD; Fellowship in general and vascular surgery, in practice since 1985 with a special interest in diabetic wounds, Ontario
8. Deirdre O’Sullivan-Drombolis, BSc PT, MCISc (Wound Healing); Physical therapist and wound care team lead, Riverside Health Care Facilities, Fort Frances, Ontario
9. Valerie Winberg, RN(EC), BScN, MN, NP-PHC, ENC(c), IIWCC; Emergency department of the Chatham-Kent Health Alliance, independent consultant, provides leadership to the implementation of the Twin Bridges NP-Led Clinic in Sarnia, Ontario
10. Kevin Woo, RN, MSc, PhD(c), ACNP, GNC(C); Assistant professor, School of Nursing, Queen’s University, Kingston, Ontario

The Resource Material

Forty articles relating to oxygen and wound healing were reviewed. Eight current articles with the best supporting evidence were selected; additionally the manufacturer's website was considered as a resource since it contained recommendations for product use. The articles and website are:

1. Blackman E, Moore C, Hyatt J, Railton R and Frye C. Topical wound oxygen therapy in the treatment of severe diabetic foot ulcers: A prospective controlled study. *Ostomy/Wound Management*. 2010;56(6):24-31.
2. Flanagan M. Improving accuracy of wound measurement in clinical practice. *Ostomy/Wound Management*. 2003;49(10):28-40.
3. Fries RB, Wallace WA and Roy S. Dermal excisional wound healing in pigs following treatment with topically applied pure oxygen. *Mutation Research*. 2005;579:172-81.
4. Frye C. Medical Director for AOTI. www.aotinc.net. Accessed June 13, 2011.
5. Gordillo GM and Sen CK. Evidence-based recommendations for the use of topical oxygen therapy in the treatment of lower extremity wounds. *The International Journal of Lower Extremity Wounds*. 2009;8(2):105-11.
6. Gordillo GM, Roy S, Khanna S, Schlanger R, Khandelwal S, Phillips G, Sen CK. Topical oxygen therapy induces vascular endothelial growth factor expression and improves closure of clinically presented chronic wounds. *Clinical and Experimental Pharmacology and Physiology*. 2008;35:957-964.
7. Scott GF. New Therapeutic Angiogenesis Biomarkers for Chronic Diabetic Foot Ulcers Treated with Transdermal Hyperoxia/Topical Wound Oxygen (TWO₂). 2005. Department of Cell Biology and Genetics, University of North Texas Health Science Center at Fort Worth.
8. Sibbald RG, Orsted HL, Coutts P, Keast D. Best practice recommendations for preparing the wound bed: Update 2006. *Adv Skin Wound Care*. 2007;20(7):390-405.
9. Tawfick W, Sultan S. Does topical wound oxygen (TWO₂) offer an improved outcome over conventional compression dressings (CCD) in the management of refractory venous ulcers (RVU)? A Parallel Observational Study. *European Society for Vascular Surgery*. 2009;38:125-132.

Standard Statements

Standard statements were developed from the resource material and put into categories that best describe the use and utility of topical pressurized oxygen therapy. The strength of the evidence of the statements was based on Registered Nurses Association of Ontario (RNAO) Interpretation of the Evidence. The standard statements and their strength of evidence are:

Category	Statement	
1. Product Description	1.1 Topical pressurized oxygen therapy is an adjunctive modality/device designed to support wound healing.	Level IIa
	1.2 Topical pressurized oxygen therapy delivers humidified oxygen to the wound bed at variable pressures above atmospheric pressure.	Level IIa
	1.3 Topical pressurized oxygen therapy delivers oxygen into the wound bed, penetrating into the tissue approximately 2 mm in depth.	Level IIb
2. Patient Selection	2.1 Topical pressurized oxygen therapy is indicated for the treatment of chronic wounds such as diabetic/neuropathic foot ulcers, venous stasis ulcers and pressure ulcers.	Level IIa
	2.2 Topical pressurized oxygen therapy is contraindicated if the patient has an untreated acute DVT or acute thrombophlebitis.	Level IV
3. Patient Preparation	3.1 The presence of necrotic tissue must be minimized in the wound bed prior to the initiation of therapy.	Level III
	3.2 The cause(s) of trauma and co-factors that may interfere with healing of the wound must be removed prior to the initiation of therapy.	Level IV
	3.3 Client and caregiver concerns must be addressed prior to the initiation of therapy.	Level IV
	3.4 Topical dressings post therapy must meet the needs of the wound in terms of debridement and bacterial and moisture balance.	Level IV
	3.5 Any dressings or preparations that create an oxygen impermeable barrier, such as any petrolatum-based product or occlusive dressing, cannot be used in conjunction with topical pressurized oxygen therapy.	Level IV
4. Application Principles	4.1 The frequency and duration of therapy is dependent on wound etiology, wound response and patient tolerance.	Level IV
5. Evaluating Therapy	5.1 Patients being treated with topical pressurized oxygen therapy require assessment using standardized instruments and documentation on a regular basis according to agency health-care-setting practice and policy.	Level III
	5.2 If the wound is not reduced by 20%–40% after 2–4 weeks of therapy, despite efforts to address the underlying causes and co-factors, therapy should be discontinued and alternate methods sought.	Level IV

6. Expected Outcomes	6.1 Increased wound oxygenation, through the application of topical pressurized oxygen, results in increased collagen deposition and tensile strength.	Level IIa
	6.2 Topically applied oxygen increases angiogenesis-related growth factor expression in wound fluids from chronic diabetic foot ulcers that may be consistent with revascularization and renewed healing.	Level IIa
	6.3 A lower recurrence rate may be expected in venous leg ulcers and diabetic foot ulcers following topical pressurized oxygen therapy.	Level III
	6.4 Topical pressurized oxygen therapy may reduce wound-related pain in venous leg ulcers.	Level III
7. Resources	7.1 Education needs to be provided to patients, caregivers and health-care providers regarding the purpose and process of using topical pressurized oxygen therapy.	Level IV
	7.2 Preliminary studies have shown that topical pressurized oxygen therapy has the potential for cost savings.	Level IV
8. Safety & Precautions	8.1 Protocols for oxygen safety must be followed when therapy is in use.	Level IV
	8.2 The Hyperbox system should only be used with medical grade oxygen from a cylinder, piping system, and liquid oxygen system or high-flow oxygen concentrator.	Level IV

Conclusion

Topical pressurized oxygen therapy has a place in the wound healing arena. In limited studies it has shown to decrease healing times, reduce recurrence rates, and have the potential to be a cost-effective method to heal wounds. Since patients do not have to travel to a central location because the therapy can be home-, hospital-, or clinic-based, use of the therapy could have a positive impact on adherence to treatment.

Studies are planned to focus on identifying endpoints such as the control of bacterial burden, edema and patient quality of life. RCTs would be beneficial to further increase the evidence around the use and effectiveness of topical pressurized oxygen therapy and to establish optimal parameters for use.