

Evaluation of Negative Pressure Wound Therapy (NPWT) Dressings in a Hyperbaric Oxygen (HBO) Environment

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Background

- Negative Pressure Wound Therapy (NPWT) is a treatment modality in which suction is applied to a wound bed in conjunction with specialized dressings to promote healing.
- NPWT when used in parallel with Hyperbaric Oxygen Therapy (HBOT) may further promote wound healing.⁵
- The liberation of potentially toxic materials and autoignition are concerns when placing non-cotton materials in Hyperbaric Oxygen Environments.
- Current standards (NFPA-99) prohibit the admittance of non-cotton based dressings into hyperbaric chambers unless the attending physician and Hyperbaric Safety officer assume the risk for any malady that may occur.

Purpose

- Develop methods for testing common NPWT dressing materials in Hyperbaric Oxygen Environments to ensure that the materials are acceptable for use with regards to cytotoxicity and auto-ignition.

Materials

- Polyurethane foam³ dressing samples.
- Polyester/silicone⁴ dressing samples.
- Pressure vessel/chamber analog capable of 7ATA w/100% O₂.
- Recirculating air oven capable of 80C.

Clinical Relevance

- NPWT requires compliant therapy for at least 22 of every 24 hours. Dressing changes are indicated for every 48 – 72 hours. NPWT treatment is typically in place for 1-4 months. Depending on the complexity of the wound site, NPWT dressings may require 10-30 minutes to properly apply and seal.
- Removing NPWT dressings so that a patient may receive HBOT is time consuming and costly.

Methods - Cytotoxicity

Samples were treated as described below and sent to North American Science Associates (NAMSA) for testing. The test agency was blinded to the treatment modality.

- Controls
 - Handled aseptically.
 - Placed into polyethylene sample bags for shipping.
- HBO Treatment
 - Handled aseptically.
 - Exposed to 100% oxygen at 2.4 ATA for 110 minutes.
 - Placed into polyethylene sample bags for shipping.
- HBO and Negative Pressure Treatment
 - Handled Aseptically.
 - Exposed to 100% oxygen at 2.4 ATA for 110 minutes.
 - Exposed to manufacturer recommended negative pressure (75 and 125 mmHg) for 24 hours.
 - Placed into polyethylene sample bags for shipping.

Methods - Auto-Ignition

- Samples were placed into a sealed stainless steel pressure vessel.
- The vessel was evacuated to -550mmHg.
- The vessel was charged with 100% oxygen to 7 ATA.
- The vessel was then placed into an oven at 80C for 110 minutes.
- Sample weights were recorded before and after testing and samples were observed for any indications of combustion and /or material degradation.

Results - Cytotoxicity

- All cytotoxicity test criteria were negative with respect to vacuolization, swelling, crenation, and percent lysis.

Results - Autoignition

- No indications of auto-ignition or degradation were observed for either dressing.
- No significant weight changes were recorded for either dressing due to exposure to an elevated HBO environment.

	Initial Weight (g)	Final Weight (g)	Percent Change in Mass	Indications of Combustion/Degradation
Polyester/ Silicone Sample	0.3442	0.3448	0.17%	None
Polyurethane Foam Sample	0.6471	0.6483	0.18%	None



Conclusions

- Both polyurethane foam and polyester/silicone NPWT dressings were demonstrated to be safe with regard to cytotoxicity and autoignition when placed into typical therapeutic hyperbaric oxygen environments.
- Further refinement of testing procedures and protocols are necessary to develop an industry standard by which advanced therapeutic dressings, such as NPWT materials, can be approved for use within hyperbaric oxygen environments.

1. Currently Employed by Boshinger Wound Systems, LLC
2. Drexel University BS BMES '10

4. Bio-Dome™ P/N 6571, Boshinger Wound Systems, LLC, Norristown, Pennsylvania
5. Fabian, Tharideus S., Henry J. Kaufman, E.D. Lett, Jeffrey B. Thomas, and Et Al. "The Evaluation of Subatmospheric Pressure and Hyperbaric Oxygen in Ischemic Full-Thickness Wound Healing." The American Surgeon 66 (2000): 1136-1142.