Test Result of Patient Products in Low-Pressure Oxygen-Enriched Atmospheres

The Beginning of a New Approach to Risk Assessments for Hyperbaric Clinical and Diving Operations

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Disclosure

I have no relevant financial relationship with a commercial interest.
Disclaimer

Richard C. Barry

- Chair of UHMS Material Testing Advisory Committee (MTAC)
- Chair of NFPA 53 Recommended Practice on Materials, Equipment, and Systems Used in Oxygen-Enriched Atmospheres
- NFPA 99 Health Care Facilities: Hyper/Hypobarics
- National Board of Diving and Hyperbaric Medical Technology
Introduction

- Material Testing Advisory Committee – MTAC
- Hyperbaric Oxygen Therapy – Low pressure (<200 psig (NFPA)) oxygen-enriched atmosphere for clinical treatments and commercial diving operations
- 1,500 U.S. based hospitals with hyperbaric chambers
- NFPA 99 – Health Care Facilities Code
  - Safety Director required
  - Safety and Medical Director *must determine approved and prohibited items*
Multiplace Hyperbaric Chamber (140)
Multiplace Hyperbaric Chamber
Multiplace Hyperbaric Chamber
Monoplace Hyperbaric Chamber (1,600)
Animal Hyperbaric Chamber
Diving Operations
Tunnel Boring Machine
The Problem

Traditional Risk Assessments for oxygen compatibility focus on “system” such as piping, gaskets, packing, and regulators.

The focus is on prevention and elimination of contamination.

Oxygen systems designed for humans and other biologicals are using an assessment approach designed for a different application.
The Problem

Lack of information for the Safety Director and Medical Director

- No published list of approved materials
- Oxygen risk assessments based on non-biological high pressure systems
- No standard for comprehensive testing of materials regarding low pressure systems

Use of the Precautionary Principle

*If an action has a suspected risk of causing harm, in the absence of scientific consensus that the actions is not harmful, the burden of proof that it is not harmful falls on those taking an action*

*Lack of scientific knowledge = conservative approach*

*Or*

*Lack of scientific knowledge = cavalier*
Why are we – MTAC – doing this?

• Few simple answers

• No recognized list of APPROVED products…but there is a PROHIBITED list

• To make informed decisions regarding items you will or will not allow in your chamber

• To protect patient, staff, equipment, and the industry of healthcare and hyperbarics

• NFPA 99 Code…Physician with concurrence of the Safety Director
What are your concerns?

• Heating
• Electrical
• Static
• Pressure
• Change in pressure
• Acrylic damage
• Spills
• Leakage
• Organisms…bugs, human, animal
• Radio waves…RFID and transmission (linen and pumps)
What are your concerns?

• Smoking
• Open flames
• Hot objects
• Personal warming devices
• Cell phones
• Sparking toys
• Entertainment devices (iPads)
• Active shooter

You must know what concerns you in order to determine if a product is allowable or not.
The physician in charge, with the concurrence of the safety director, shall be permitted to use one of the following prohibited items in the chamber:

(1) **Suture material**—Used for wound closure, suture materials: collagen, synthetic absorbable, and non-absorbable.  
The United States Pharmacopeia classification is as follows:  
• Silk or synthetic fibers of monofilament, twisted, or braided construction  
• Cotton or linen fibers or coated natural or synthetic fibers in which the coating contributes to suture thickness without adding strength  
• Metal wire of monofilament or multifilament construction

(2) **Alloplastic devices** – non-biologic material such as metal, ceramic, and plastic.

(3) **Bacterial Barriers** – Gloves, silver dressings…something that blocks bacteria.

(4) **Surgical dressings** – Dressing placed at time of surgery.

(5) **Biological interfaces** – Interface refers to the boundary between two parts. Grafts? Dressings?

(6) **Synthetic Textiles**—refers to any material made of interlacing fibers. Fabric refers to any material made through weaving, knitting, crocheting, or bonding. Cloth refers to a finished piece of fabric that can be used for a purpose such as covering a bed.

Physicians and HSD approval to use prohibited items shall be stated in writing for all prohibited materials.
Safety Data Sheet (FastCast by Hollister) 
SDS HB2520/HBRS4520-00

• Vapor Density: Not determined
• Vapor Pressure: Not determined
• Percent Volatile: Not determined
• Evaporation Rate: Not determined
• pH: Not determined
• Viscosity: Not determined
• Coefficient of Water/Oil Distribution: Not determined
• **Flash Point: Not determined**
• Flash Point Method: Not determined
• **Auto Ignition Temperature: Not determined**
• Flammability (solid, gas): Not determined
Again, why are we doing this?

• To make informed decisions regarding items you will or will not allow in your chamber

• To protect patient, staff, equipment, and the industry of healthcare and hyperbarics

• NFPA 99 Code…*Physician with concurrence of the Safety Director*

  • 2015 ed: 14.3.1.5.4.3 (and past additions)
How do you assess risk?

Risk Assessment Process
(NFPA Fig. A.14.3.1.5.4.3)
How do you assess risk?

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Very Likely</th>
<th>Medium</th>
<th>High</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Likely</td>
<td>Low 1</td>
<td>Medium 2</td>
<td>High 3</td>
<td></td>
</tr>
<tr>
<td>Unlikely</td>
<td>Low 1</td>
<td>Low 1</td>
<td>Medium 2</td>
<td></td>
</tr>
</tbody>
</table>

What is the chance it will happen?

- Minor
- Moderate
- Major

Impact
Process for Consideration

1. HSD gathers info
2. HSD and Physician confer
3. Approve or prohibit the item
4. Document in writing
5. Add to Approved or Prohibited List
Recommended resources for every Hyperbaric Safety Director

1. NFPA 99 Health Care Facilities Code *(NFPA)*
2. NFPA 53 Recommended Practice on Materials, Equipment, and Systems Used in OEA *(NFPA)*
6. Risk Assessment Guide *(International ATMO)*
Dear Tech Support,

I operate hyperbaric oxygen therapy chambers in (Hospital, City, and St.). I am very cautious about the materials allowed in these chambers, as the chambers are pressurized with 100% oxygen/air to a depth of 2.0 ata (equal to 33 fsw). We have a patient with your (implanted, product, device, widget) that has been prescribed hyperbaric therapy. I am gathering information to see if (product) is compatible with the oxygen enriched atmosphere, prior to starting this patient.

Do you have any information describing what the (product) is made of?
Examples: Testing data, SDS, make, manufacture, model, technical specification….

Has it been tested for use in:
- Hyperbarics
- SCUBA diving
- Flying
- Driving through the mountains
- Operating room

I will appreciate any information you provide and if you have any questions, please e-mail or call me at the information listed below.

Thank you in advance for your assistance.
<table>
<thead>
<tr>
<th>Center:</th>
<th>MRN:</th>
<th>Date:</th>
<th>Item:</th>
<th>Description:</th>
<th>Material(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Unknown:</td>
<td>Comments:</td>
<td></td>
</tr>
</tbody>
</table>

| Flammable Gas |                              |                              |                              | |
| Vapors       |                              |                              |                              | |
| Odor         |                              |                              |                              | |
| Liquid       |                              |                              |                              | |
| Gel          |                              |                              |                              | |
| Metal        |                              |                              |                              | |
| Rubber       |                              |                              |                              | |
| SDS          |                              |                              |                              | |
| FDA          |                              |                              |                              | |
| Approved     |                              |                              |                              | |

Signatures:  
HSD
Physician 1
Physician 2

Stipulations:
What has MTAC accomplished?
Why does hyperbarics need its own test?

- Contaminant – a foreign substance that can have harmful effects on system operation, life, or reliability.

- **1,600,000 µm = 63” contaminant**
  - Patient
  - Staff
  - Animal
UHMS-Material Testing Advisory Committee
MTAC Timeline

• 2009 – Committee established
• 2009-2014 – Fundraising
• 2014 – Testing underway (approved products)
  • Develop standard test and petition ASTM to recognize a new standard and a new guideline (10/08/2014)
  • Feb. 2016 published
• 2017 – Testing of prohibited products (Feb. 2017)
• 2016 – Engage NFPA to cite (2018 ed. Of NFPA 99)
• 2018 – UHMS MTAC Committee Report
• 2018 – Industry standard…?
Why ASTM G04?

Committee G04 on Compatibility and Sensitivity of Materials in Oxygen Enriched Atmospheres

Committee Scope
The development and promulgation of test methods, definitions, recommended practices, and classifications for determining the compatibility and sensitivity of materials and configurations and applications intended for use in systems subjected to enriched oxygen atmospheres, taking into consideration but not limited to, ignition, combustion, off gassing and reaction products and decomposition tendencies. [...]
Why NFPA 99?

Technical Committee on Hyperbaric and Hypobaric Facilities

Committee Scope
1.1.12* Hyperbaric Facilities. Chapter 14 covers the recognition of, and protection against, hazards of an electrical, explosive, or implosive nature, as well as fire hazards associated with hyperbaric chambers and associated facilities that are used, or intended to be used, for medical applications and experimental procedures at gauge pressures from 0 kPa to 690 kPa (0 psi to 100 psi).
Why WHA testing facility?
Test Method

• Test Standard: ASTM G72/G72M – 15

• Oxygen Concentration: ≥ 99.5% O2 per Section 6.4

• Test Pressure: 3 atmospheres (44 psia) per Section 8.2.3 Special Case 2

• Temperature Ramp Rate: 100 oC/min per Section 8.2.3 Special Case 2

• Sample Mass: 20 and 200 mg per Section 8.2.3 Note 4
Approved Items – commonly found in HBO₂

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lowest AIT (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrofera Blue®READY</td>
<td>259</td>
</tr>
<tr>
<td>Tcom Fixation Ring</td>
<td>187</td>
</tr>
<tr>
<td>Micropore™ Surgical Tape</td>
<td>167</td>
</tr>
<tr>
<td>50/50% Cotton/Poly Blend</td>
<td>236</td>
</tr>
<tr>
<td>100% Cotton</td>
<td>241</td>
</tr>
<tr>
<td>Gauze Sponges (4”x4”)</td>
<td>183</td>
</tr>
<tr>
<td>Matrix Elastic Bandage</td>
<td>160</td>
</tr>
<tr>
<td>Vaseline™ Petrolatum Gauze</td>
<td>156</td>
</tr>
<tr>
<td>Xeroform Petrolatum Gauze</td>
<td>145</td>
</tr>
<tr>
<td>Plastic Mesh</td>
<td>228</td>
</tr>
<tr>
<td>Mattress Cover (Vinyl)</td>
<td>202</td>
</tr>
</tbody>
</table>
## Prohibited (?) Items

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lowest AIT (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinal (compressed paper)</td>
<td>252</td>
</tr>
<tr>
<td>Oil Emulsion Dressing (Medline)</td>
<td>243</td>
</tr>
<tr>
<td>Oil Emulsion Dressing (Curity)</td>
<td>247</td>
</tr>
<tr>
<td>Surgical Bootie (blue)</td>
<td>180</td>
</tr>
<tr>
<td>Tritec Silver Dressing</td>
<td>300</td>
</tr>
<tr>
<td>Tritec Non-Silver Dressing</td>
<td>209</td>
</tr>
<tr>
<td>65/30% Poly/Cotton</td>
<td>254</td>
</tr>
<tr>
<td>3M Transpore Tape</td>
<td>224</td>
</tr>
<tr>
<td>Foam Pad (EKG)</td>
<td>230</td>
</tr>
<tr>
<td>Adaptic Touch™</td>
<td>232</td>
</tr>
<tr>
<td>All Tested Items</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------</td>
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<tr>
<td>Urinal compressed paper</td>
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<td>145</td>
</tr>
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Material Selection:
Putting new information into practice
New Standard - ASTM

New Guideline to use the Standard

NFPA Annex A to Cite ASTM (2018)
What are our risk?
What are our risk?

• Heat
• Static
• Low AIT
• Quantity
• Humidity levels (low vs. high)
• Treat or do not treat
• Pressure changes
• Enclosed space
• Oxygen
• Electrical current
TECHNOLOGY ADVANCES

Hyperbaric Oxygen Therapy and Oxygen Compatibility of Skin and Wound Care Products

Stéphanie F. Bernatchez,1,* Joseph Tucker,2 and Gwenael Chiffoleau2
13M Health Care Business Group, St. Paul, Minnesota.
2WHA International, Inc. (WHA), Las Cruces, New Mexico.

Objective: Use test methods to assess the oxygen compatibility of various wound care products.
Approach: There are currently no standard test methods specifically for evaluating the oxygen compatibility and safety of materials under hyperbaric oxygen (HBO) conditions. However, tests such as the oxygen index (OI), oxygen exposure (OE), and autogenous ignition temperature (AIT) can provide useful information.
Results: The OI test measures the minimum oxygen concentration that will support candle-like burning, and it was used to test 44 materials. All but two exhibited an OI equal to or greater (safer) than a control material commonly used in HBO. The OE test exposes each material to an oxygen-enriched atmosphere (>99.5% oxygen) to monitor temperature and pressure for an extended duration. The results of the OE testing indicated that none of the 44 articles tested with this method self-ignited within the 60°C, 3 atm pressurized oxygen atmosphere. The AIT test exposes materials to a rapid ramp up in temperature in HBO conditions at 3 atm until ignition occurs. Ten wound care materials and seven materials usually avoided in HBO chambers were tested. The AIT ranged from 138°C to 384°C for wound care products and from 146°C to 420°C for the other materials.
Innovation: This work provides useful data and recommendations to help develop a new standard approach for evaluating the HBO compatibility of wound care products to ensure safety for patients and clinicians.
Conclusion: The development of an additional test to measure the risk of electrostatic discharge of materials in HBO conditions is needed.
Keywords: hyperbaric oxygen therapy, wound care products, safety, test methods

INTRODUCTION

Hyperbaric oxygen (HBO) therapy is used as an adjunct treatment to help heal selected chronic wounds, among other conditions. The Undersea and Hyperbaric Medical Society (uhma.org) is a well-recognized source of scientific information for hyperbaric medicine and produces a list of medical conditions that are appropriate for the use of this therapy, which is approved by the Food and
**Figure IV.** Acceptability Indices are used to rank the oxygen compatibility of various materials. The index is based on the following equation\textsuperscript{16,17,18}: \[ [(OI)^2 \times (AIT)] / (HoC) \]

<table>
<thead>
<tr>
<th>Material</th>
<th>Acceptability Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALOE VESTA</td>
<td>99</td>
</tr>
<tr>
<td>AQUAFOR</td>
<td>48</td>
</tr>
<tr>
<td>CALAZIME</td>
<td>84</td>
</tr>
<tr>
<td>CRITIC-AID</td>
<td>42</td>
</tr>
<tr>
<td>NUTRASHIELD</td>
<td>1282</td>
</tr>
<tr>
<td>SECURA</td>
<td>71</td>
</tr>
<tr>
<td>SKIN REPAIR</td>
<td>1023</td>
</tr>
</tbody>
</table>
What do you (HSD and Provider) do next?

• Evaluation process – consider a Safety Management System Approach or a Risk Assessment Approach

• Dispute resolution

• List – approved items (Go)

• List – prohibited items (No-Go)

• Inform staff

• Holding – Archiving – Keep – Store
What do we (MTAC) do next?

• Dispel myths

• Committee Report
What is next for testing?

• Static potential
• Static generation…accumulation
• Static discharge
Thank you for your time.