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Research Article

Hyperbaric Pressure Chamber Structural Integrity Testing for Vascular Access Ports

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Abstract

A total of 25 commercially available vascular access ports were evaluated in this study. Included were 5 different port models and n=5 ports per model. Port types were placed into separate water baths with respect to each model. Each was pressurized to 3 ATA (atmosphere absolute) in a hyperbaric pressure chamber simultaneously. Ports were investigated for escape gases in the water bath as well as for surface tension changes at the distal catheter end while under hyperbaric pressure. No escape gases or catheter surface tension changes were observable. The study concludes successful results for all ports in a hyperbaric chamber, when no fluid injection flow rate is necessary during pressurization.

Introduction

Hyperbaric Oxygen Therapy (HBOT) is a medical treatment in which the patient is entirely enclosed in a pressure chamber breathing 100% pure Oxygen (O_2) at greater than one atmosphere (atm) of pressure. Air contains nearly 21% oxygen, and approximately 78% nitrogen. Of the total oxygen carried in the body 98% is carried in the blood bound to the hemoglobin, with the remaining 2% dissolved in the plasma. At sea level (1 ATA) the concentration of dissolved oxygen in the plasma is 0.3 mL/dL. The amount of an ideal gas dissolved into solution is directly proportional to its partial pressure (Henry's Law): In Hyperbaric Oxygen Therapy (HBO), the oxygen breathed by the patient is 100%. At 1 ATA that's almost five times more than in air (1.5 mL/dL), and 20 times more at 3 ATA (6 mL/dL) [1].

Aetna considers systemic hyperbaric oxygen therapy medically necessary for many different conditions. Examples include, but are not limited to, acute air or gas embolism, acute cerebral edema, unresponsiveness to surgical management, exceptional blood loss anemia, acoustic trauma, noise-induced hearing loss, non-healing infected deep ulcerations, chemotherapy-induced hemorrhagic cystitis, and radiation-induced proctitis or necrosis. However, continued treatment with HBOT is not considered medically necessary if measurable signs of healing have not been demonstrated within any 30-day period of treatment [2]. Hyperbaric oxygen therapy can be used as either a primary or adjunctive treatment by increasing the partial pressure of inspired oxygen and hydrostatic pressure. It can be used to prevent or treat the side effects of other treatments and to influence healing by enhancing oxygen partial pressure and thereby regeneration. Literature suggests HBOT is beneficial to patient who received external beam radiation therapy [3]. Radiation therapy given from particle accelerators cause tissue to become hypoxic. This is the case both for targeted tissue and for normal organs at risk within the path of the beam. Similar causes can be said for patients receiving chemotherapy. Researchers provided a study where in 14.8% of nearly 149 patients treated with intermittent continuous infusion of different chemotherapeutic agents, the vascular access port had to be explanted due to complications [4]. It is unknown whether those complications were due to the need to require hyperbaric pressure, with device testing not verifiable and therefore possibly avoided.

Infusion pumps and syringes have been investigated in the past for potential application during hyperbaric treatment. It was extracted from that research that in cases where there is a discovered decrease of infused volume during compression, followed by an increase after decompression, that a non-equilibrated gas space should be suspected within the system [5]. A different group of researchers fit vascular access ports to swine, with a compression to 180 ft of sea water (fsw), in order to examine blood platelet activation and counts [6]. That research ties in well with the applied research for our study, as we too have employed a unique design.

One of the most alarming complications of accessing the vascular system externally is the air embolism. Fatalities of air emboli depend on the position of the patient to a large extent. If the patient is in a Fowler's (sitting) position, neurologic complications occur because the embolus will

go into the cerebral system. If a patient is laying supine, symptoms such as shortness of breath and chest pain occur when the embolus goes into the lungs. Micro-bubbles are thought to cause pulmonary hypertension in the lungs and chronic changes in the brain in the long run, but usually do not result in acute symptoms in patients [7].

Intravascular air emboli are serious complications of endovascular procedures resulting in a pressure gradient that allows air to enter the blood stream. Although these situations are rare, and generally preventable, it can result in occluded blood flow [8]. The main causes of systemic and cerebral air embolism are shifting from the traditional malefactors of open surgery and trauma to endoscopy, angiography, tissue biopsy, and peripheral venous access [9,10]. One study concluded that air emboli occur at a rate of 0.13% in 11,000 clinical cases documented involving central venous catheter placements [11]. When bubbles enter the vascular system, i.e. through arteries or veins, blood flows at a reduced speed, thereby causing poor oxygenation to the body. A gas embolism can impact both morbidity and mortality. Possible consequences of irrevocable damage may include brain trauma, lung distress, paralysis and even death. Using hyperbaric pressure therapy, poorly oxygenated areas receive cellular oxygen enhancement, while reducing local swelling. This is induced when either the atmospheric pressure or fluid pressure are increased. The size of air bubbles confined to the vascular system then reduce inversely proportional to the pressure experienced. We know that pressure and volume are directly inversely proportional. The physics of the system is explained by the Ideal Gas Law; PV = nRT. In this form, n represents the number of moles of the gas, R is the Rydberg constant, T is the temperature, and P and V represent the pressure and volume respectively. As the pressure goes from 1 ATA (normal) to 3 ATA without a temperature change, the volume then changes to 1/3 directly inversely proportional. This physically means that any air molecules inside the patient would reduce in size to 1/3, thus enabling better blood blow.

To use vascular access ports during a hyperbaric treatment, the user is left with the option of either taking the entire piece of medical equipment into the hyperbaric chamber or revising the surgery with a device explant. The Hyperbaric Medical Society has indicated that if the port remains intact and therefore inside the chamber, there are concerns about its pressure integrity. It is thus necessary to have a methodical and practical means to assess the safety of the medical equipment [12]. Testing has already been conducted on related intravenous pumps, but with success limited to only a few models identified by the Navy Experimental Diving Unit as being appropriate for use. Still, in order to improve the level of patient care in the future, we also address the implications of pressurizing vascular access ports without power injection devices connected, during unmanned testing [13,14].

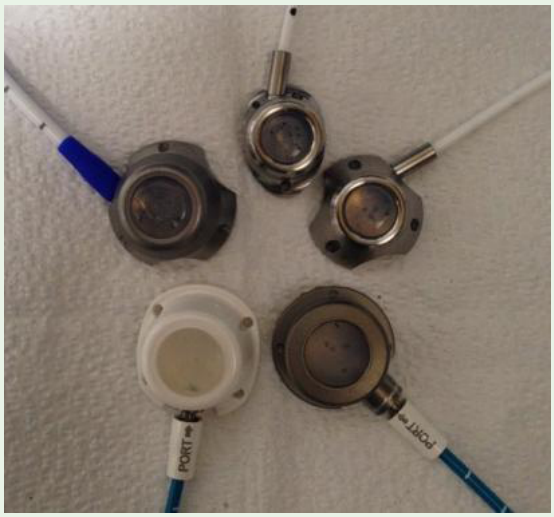

Figure 1: Starting at clockwise at 12 o'clock is the AngioDynamics™ Smart Port™ CT Mini, Smart Port™ CT Low Profile, BioFlo™ Port (Ti), BioFlo™ Port (Pl), Smart Port™ CT.

Materials and Methods

Ports used in this study include models currently marketed by AngioDynamics™ (Latham, NY). Various styles were chosen for the study including those with small, medium and large bodies. Both plastic and titanium ports were included. The specific models incorporated into the study were the Smart Port™ CT Mini, Smart Port™ CT Low Profile, BioFlo™ Port (Ti), BioFlo™ Port (Pl), and Smart Port™ CT. These are depicted in Figure 1.

The hyperbaric pressure chamber chosen for testing was a Sechrist Industries, Inc. (Anaheim, CA) Model 3200. The pressure chamber is manufactured in accordance with Section VIII, Division 1 of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, and the ASMR PVHO-1 Safety Standard for Pressure Vessels for Human Occupancy [1].

The set-up consisted of a plastic basin, 14x14 cm^2 in area and 4.5 cm deep. It was filled with distilled water to a level of 3.5 cm, fully submerging each port in the center of the basin. A total of 25 commercially available vascular access ports were evaluated in this study. Included were 5 different port models and n=5 ports per model. Port types were placed into separate water baths with respect to each model. The catheter ends were taped to the side of the basin so that the end was observable out of the water. Each port was injected with a needle and primed with 70 mL distilled water. The injection rate was kept high at nearly 5 mL/sec to rid all air bubbles. After priming, each port and catheter system were filled with water, leaving a meniscus of water in the form of surface tension at the end of the catheter. During hydrostatic pressurization, the success of port tolerance would depend on any formation of bubbles exiting the port or catheter. Volume changes would also impact the shape of the meniscus at the catheter tip. An emergency blow, returning pressure inside the chamber to 1 atm quickly, was also investigated for a more acute change similarly.

The hyperbaric pressure chamber flow rate was set to 5.0 psi/min (0.34 atm/min). The pressure within the chamber saturated once arriving at a level of 3 atm. Temperature was held constant within the entire chamber for simplicity. Pressurization to the programmed level was achieved in just over 8 minutes. The position of the ports within the basin as well as within the whole chamber is illustrated in Figures 2-4.

According to Pascal's Law, established by French mathematician Blaise Pascal from 1646-1647, the absolute pressure (ΣP_{ATA}), corresponding to the number of atmospheres (ATA), to be calculated at a point near the bottom of the port in the water, is defined as the

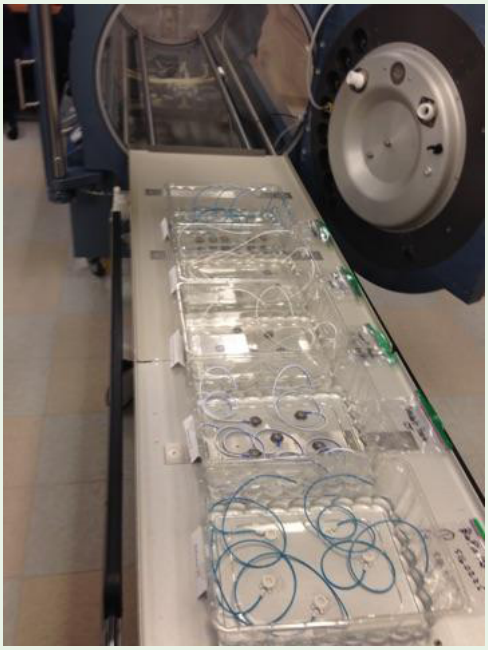

Figure 2: Ports prepared in bins according to model and primed.

sum of the Fluid Pressure (PF) and the atmospheric pressure (P_A) [15,16]. Hydrostatic fluid pressure is defined as the product of the density of the liquid (ρ), the acceleration of gravity, and the depth below water (h_w), given as $P_{Fw} = \rho_w gh$. Within the normal atmosphere, the standard pressure in air is 1 atm. However, the atmospheric conditions are altered when the user pressurizes the chamber to 3 atm for treatment. Beginning with normal conditions, the absolute pressure under 3.5 cm of water is thus found as:

Figure 3: Transport couch aligned to chamber for entry.

Figure 4: All ports sealed in chamber and prepared for pressurization.

$$\Sigma P_{ATA,w} = P_{F,w} + P_A = \rho_w gh + P_A$$

$P_{F,w} = (1.00x10^3\ kg/m^3)(9.8\ m/s^2)(0.035\ m)(1\ atm/101{,}325\ N/m^2) = 3.4x10\text{-}3\ atm$

$P_A = 1\ atm$

$\Sigma P_{ATA,w} = (3.4x10^{-3}\ atm) + (1\ atm) = 1.003\ atm\ (ATA)$

As one can see, the atmospheric pressure dominates the force exerted on the port comparatively. The experience is increased 3-fold when the chamber pressure increases such that $P_A = 3$ atm. Under these conditions, the absolute pressure is found as:

$\Sigma P_{ATA,w} = (3.4x10^{-3}\ atm) + (3\ atm) = 3.003\ atm\ (ATA)$

Results and Discussion

Ports were investigated for escape gases in the water bath during pressurization. Simultaneously, catheters were observed for surface tension changes at the distal end. No escape gases or catheter surface tension changes were observable for any of the 25 ports investigated.

One may take consideration of the depth of water as compared to sea water. For sea water, the density is then 3% greater at $\rho_{sw} = 1.03x10^3\ kg/m^3$. As observed above, this is negligible in the scheme of this study at such a shallow depth. However, we can consider an equivalent scenario where the absolute pressure is nearly the same as inside the hyperbaric chamber, in order to determine the equivalent depth. The port will experience $P_A = 1$ atm of atmospheric pressure in addition to this where the combined fluid pressure and atmospheric pressure yield the net pressure on the port. If we assume an absolute pressure of $\Sigma P_{ATA,sw} = 3$ atm (ATA) experienced by the port when submerged under water in an ocean, the equivalent sea water depth (h_{sw}) this study directly compares to under standard conditions is calculated as:

$h_{sw} = (\Sigma P_{ATA,sw} - PA)/ \rho_{sw}g$

$h_{sw} = (3 \text{ atm} - 1 \text{ atm}) / \rho_{sw}g = (2 \text{ atm}) / (1.03x10^3 \text{ kg/m}^3)(9.8 \text{ m/s}^2)$ {1 atm/101,325 N/m^2}

$h_{sw} = 20.1 \text{ m} = 65.9 \text{ fsw}$

It is then found that the pressure experienced by the port under standard conditions would be roughly the same if the port were intact in a patient being treated with HBOT at a pressure of $P_A = 3$ ATA, as compared to the same patient diving in the ocean at 65.9 ft. As a general approximation, the hydrostatic fluid pressure (in units ATA) of a vascular access port under water is roughly equivalent to the depth of the port (in feet units) divided by 22.

Conclusion

In this study, a total of 25 commercially available vascular access ports were investigated, including 5 different ports per model. Ports were placed into separate water baths with respect to each model. Each was pressurized to 3 ATA in a hyperbaric pressure chamber simultaneously. Ports were monitored for escape gases in the water bath as well as for surface tension changes at the distal catheter end while under hyperbaric pressure. No escape gases or catheter surface tension changes were observable. Further, no changes were found during an emergency blow, returning the air pressure to 1 atm. The study concludes successful results for all ports in a hyperbaric chamber, when no fluid injection flow rate necessary during pressurization.

We offer no information on whether or not external forces acting on the port during pressurization may affect outcomes. In relation to that, future research should be considered for pressure testing with applications of power injection pumps. Further, that research is recommended to consider the ability of the port to provide fluid at a fixed rate.

AngioDynamicsTM plastic ports are made of implant-grade Polysulfone. Since Polysulfone has very high dimensional stability, including high compaction resistance, it is generally recommended for use over non-thermoplastic polymers when in higher pressure environments. For these plastic ports studied, pressure testing success was hypothesized. However, we warn that testing with ports having non-thermoplastic polymers for composition may not fare as well.

The decision to place a patient in a hyperbaric pressure chamber with an intact port should be at the sole discretion of the supervising physician. Our research does not condone a universal acknowledgement that all ports are immune to structural integrity problems. We also do not hypothesize that similarly constructed ports would exhibit the same results. In this study, we considered only five models from a single manufacturer. Care should be taken to consider the medical necessity in maintaining an intact port clinically in a patient at all times. For individuals with ports who maintain interest in deep water diving, it is recommended that they consult with their vascular specialist prior to engaging in that activity.

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