Technical report

The Hyperbaric Protective Tube: A housing for a left ventricular assist device (LVAD) in a multiplace hyperbaric chamber

Jacek Kot[1,3], Piotr Siondalski[2], Ewa Lenkiewicz[3]

[1]*National Centre of Hyperbaric Medicine in Gdynia, Medical University of Gdansk, Gdynia, Poland*
[2]*Department of Cardiac Surgery, Medical University of Gdansk*
[3]*Department of Hyperbaric Medicine and Sea Rescue, University Centre for Maritime and Tropical Medicine, Gdynia, Poland*

Corresponding author: *Jacek Kot, National Centre of Hyperbaric Medicine in Gdynia, Medical University of Gdansk, Poland*
jkot@gumed.edu.pl

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Abstract
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Introduction: During a hyperbaric oxygen therapy (HBOT) session, every medical device that is used within the hyperbaric chamber is exposed to several hazards, including an increased ambient pressure and partial pressure of oxygen. In Europe, all medical devices marketed and/or sold for use in hyperbaric conditions must be tested by the manufacturer and marked 'CE' if approved. At the moment, no left ventricular assist device (LVAD) has been formally approved and CE-marked for HBOT.

Case: A 65-year-old male was referred to our Hyperbaric Centre for HBOT due to a persistent life-threating soft tissue infection of the non-removable wire connecting the external controller with the pump implanted into the left ventricle of the heart (Heartware LVAD). The aim of the intervention reported here was to safely conduct HBOT sessions with this non-CE marked medical device. After risk analysis, the decision was made to isolate the external part of the LVAD (controller and batteries) from the ambient conditions in the hyperbaric chamber by placing it in a pressure-resistant housing that was vented to the external atmosphere. The housing, a 'Hyperbaric Protective Tube' was built and tested, and the resulting operating procedures were practiced by personnel involved in the patient's care. Thirty uneventful HBOT standard sessions were conducted with subsequent clinical improvement of the soft tissue infection, resulting in an extended timeframe for awaiting heart transplantation.

Conclusion: An isolation housing that vents into the dumping system of the hyperbaric chamber allows for the safe use of critical medical devices without prior testing for their compatibility with the hyperbaric environment.

Introduction

Due to environmental conditions, mainly pressure and oxygen content, the use of medical devices in a hyperbaric chamber creates a risk of potential injury to, or even death of the patient in the event of a related malfunction and/or fire in the confined space. The main hazard intrinsically present in every hyperbaric session is the increase of ambient pressure and pressure changes during compressions and decompressions. This hazard can create the risk of malfunction or physical damage to the device. For the most critical devices, the clinical consequences to the patient can be life-threating.

The increased partial pressure of oxygen, arising from the combined fractional amount of oxygen in the hyperbaric air and the absolute pressure within the chamber, introduces the risk of fire if there is overheating or sparking within the device. Even in air-filled chambers, there is a possibility of building local 'oxygen clouds' due to small, but prolonged leakage of oxygen from the breathing units. Paradoxically, the risk of an unnoticed local increase in oxygen fraction can occur more easily in modern large chambers due to the long distance between the leak site (usually the patient's mask) and the oxygen sensor that is usually installed close to the chamber's exhaust. A fire ignited in the oxygen-rich environment is a life-threating situation to all chamber occupants, as well as chamber operators and external bystanders. Detailed reviews of the hazards and risks of introducing medical devices into hyperbaric chambers can be found in other publications,[1,2] or in the descriptive annex of the European Norm for multiplace hyperbaric chambers.[3]

In Europe, all medical devices marketed and/or sold for use in hyperbaric conditions must be tested by the manufacturer and marked 'CE' if approved for specific conditions. At the

Figure 1
Deployment of the HeartWare LVAD (sourced from: https://www.heartware.com/resources)

moment, there are only a few hyperbaric-certified medical devices on the market, all of which are used for intensive care, including monitors, ventilators and electronic pumps and syringe drivers. There is no left ventricular assist device (LVAD) which has been formally approved for hyperbaric use and CE-marked for those conditions.

In case of the need to expose any non-CE marked medical devices to a hyperbaric environment, the medical user should perform the risk assessment him or herself and take full responsibility for any residual risk created by using such a device.[4]

Aim

A 65-year-old male patient was referred to our hyperbaric centre for hyperbaric oxygen treatment (HBOT) to treat a persistent soft tissue infection of the non-removable wire connecting the external controller of the LVAD (HeartWare Inc., Framingham, MA, USA) with the magnetic pump implanted into the left ventricle of the heart. The LVAD was implanted to enhance left ventricular function which was critically impaired by an ischaemic cardiomyopathy. The aim was to bridge the patient to heart transplantation. Regardless of the good clinical status of the patient, the local infection was classified as life-threatening, since there was no physical possibility of replacing the line without replacing the complete set of implanted parts. The aim of this study was to prove that the in-chamber use of encapsulated equipment would allow effective function of this medical device not approved for hyperbaric exposure.

Methods

The HeartWare LVAD consists of the implanted magnetic pump, connection cable and an external controller with a power supply comprised of two independent, high-power batteries (Figure 1).

The implanted portion was not considered a risk for the patient, as it does not have any gaseous closed spaces. On the contrary, the external controller with the power supply, which cannot be safely disconnected for testing or therapeutic purposes, was considered potentially dangerous.

An extensive literature review was done, and only single-case reports published on the use of LVADs in patients treated with HBOT were found.[5–8] In all those cases, the manufacturers were included in the risk analysis, the power supply was removed and stayed outside the chamber, and the controller was exposed to the hyperbaric environment (up to 2.5 atmospheres absolute (atm abs), 253 kPa pressure). In our case, there was no direct contact with the manufacturer, and we had no access to a spare LVAD in case of malfunction of the controller during tests.

Therefore, a formal risk analysis was conducted according to published guidelines.[9] Due to the lack of detailed technical information about the external controller and the batteries, the risk of exposing it to hyperbaric pressure was considered unacceptably high. Therefore, the decision was made to separate the external part of the LVAD from the ambient conditions in the hyperbaric chamber. This would be done by enclosing the LVAD controller with the power supply in a pressure-resistant housing, the Hyperbaric Protective Tube (HPT), which was vented to the external atmosphere to keep the internal pressure at 101.3 kPa (1.0 atm abs). The facility staff prepared a general assembly diagram (Figure 2) for the housing with the following main properties:

- capable of enclosing the external controller with batteries within the housing;
- allowing the connection cable to pass through the housing wall without any mechanical damage;
- allowing connection to the hyperbaric chamber dump system opened to the external environment to ensure the internal pressure is kept at the normobaric level (101.3 kPa), regardless of any leak into the housing around the connection cable;
- include a valve to control the inflow of ambient air into the housing to decrease internal temperature;
- capable of monitoring internal pressure in order to alert the user in case pressure builds up over 121.6 kPa arbitrarily considered the safety cut-off point for any electronic device);
- designed so that the weakest point of the housing should be able to withstand 709 kPa (equivalent to 60 metres' sea water (msw) depth and the working pressure should be at least 253 kPa (equivalent to 15 msw).

Figure 2

Construction of the LVAD housing. 1 – transparent acrylic tube; 2 – tube base; 3 – tube flange; 4 – removable lid; 5 – hard synthetic seal; 6 – eight wingnut fasteners (for practical purposes replaced by hand-screws); 7 – quick connector to the dumping system; 8 – valve for venting; R in the View 'W' – machined conduit in the housing cover for connection cable

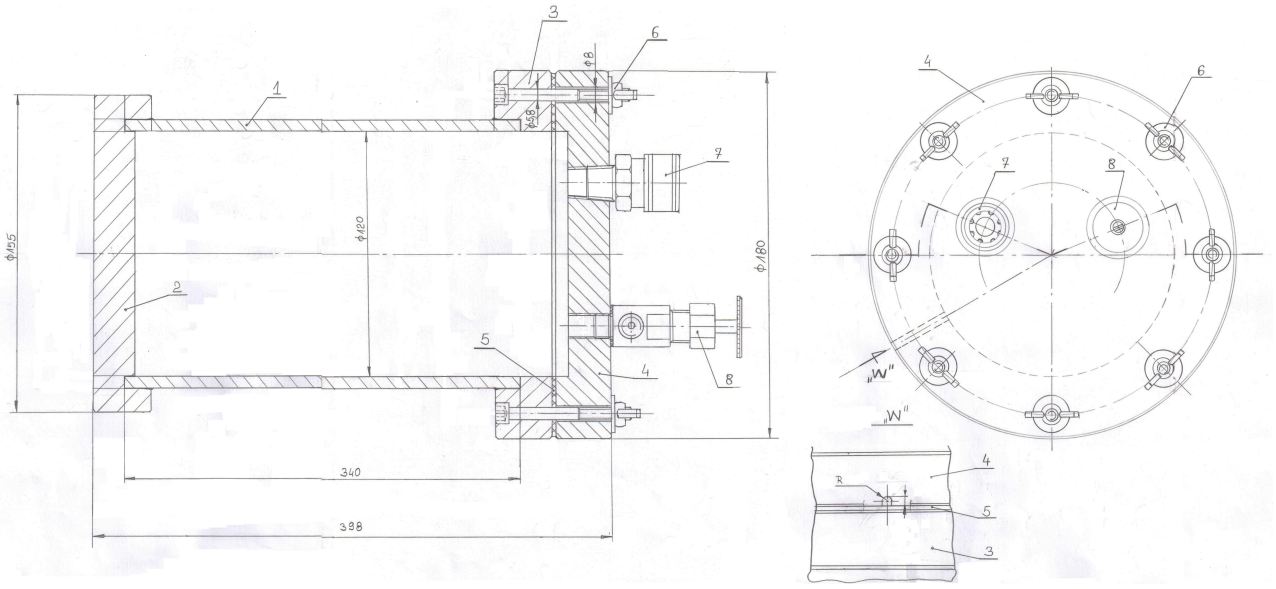


Figure 3

The housing with the enclosed HeartWare LVAD in the hyperbaric chamber. Inside there is the LVAD external controller with batteries and a diving computer showing only the date and time of exposure, which means that the internal pressure is in the normobaric range (1.0–1.2 atm abs). The other diving computer is located outside the housing confirming that the pressure inside hyperbaric chamber is 2.5 atm abs (14.9 msw on the display)

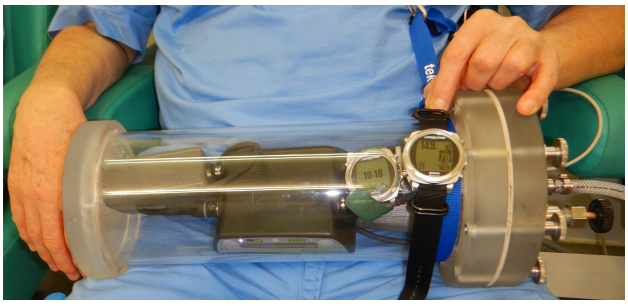
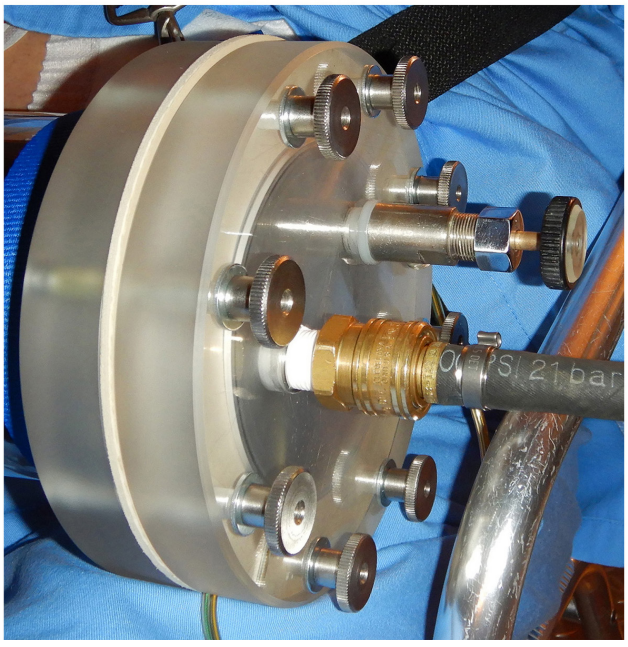


Figure 4

The housing lid. There are eight hand screws visible with a connector to the dumping system (black hose) and connection cable passing through the housing (at the lowest point)



An external commercial company manufactured the HPT from acrylic plastic according to the supplied drawings with internal dimensions that were capable of holding the HeartWare LVAD (cylindrical shape approximately 40 cm length and 12 cm diameter). Then, a full battery of tests was conducted internally by the hyperbaric facility staff, up to the test pressure of 6 atm abs (equivalent to 50 msw depth). A procedure for enclosing the LVAD in the housing unit in an uninterruptible manner without any disconnection was developed, and the staff were trained for standard and emergency situations. The patient was informed about the therapeutic plan and gave informed consent for the non-standard approach with unknown probability of critical failure.

Results

During each HBOT session, the LVAD controller with batteries and the diving computer used for monitoring the internal pressure were enclosed in the HPT (Figure 3), with staff double-checking that the connection cable was placed

in the machined conduit in the housing head to ensure there was no crushing. Eight screws were lightly tightened to avoid asymmetrical tension to the housing head (Figure 4).

The chamber was pressurized to 121 kPa, and the internal gauge (a diving computer) was checked to confirm that internal pressure was not increasing. The final check of the dumping system was done by opening the venting valve. The sound of air passing into the housing unit was heard with no indication of increasing internal pressure. Then, the venting valve was closed, and the chamber was pressurized to the treatment pressure (253 kPa). During proper operation at treatment pressure, the internal gauge in the HPT did not indicate any increase of pressure above atmospheric (1.0 atm abs) (see diving computers in Figure 3). Thirty uneventful standard HBOT sessions (100% oxygen for 70 minutes at 253 kPa, excluding compression and decompression) were conducted in an air-filled multiplace hyperbaric chamber with subsequent clinical improvement of the soft tissue infection. This facilitated an extended period to await heart transplantation.

Discussion

Where it is necessary to use a non-approved medical device in hyperbaric conditions exceeding those in the manufacturer's technical specification, there are several options available for the medical user, including: checking the resistance of a device to the external conditions (sealed medical devices, e.g., implantable devices); checking the compatibility of devices with specific hazards (e.g. syringe drivers/pumps, ventilators); and enclosing the device within an external case that is resistant to the in-chamber environment. In all cases, risk analysis and mitigation should be conducted by experienced personnel to keep the residual risks as low as possible. The process should be documented and approved by the facility or by hospital authorities. All problems should be discussed with the patient in detail to facilitate informed consent. Personnel must be informed and trained for both standard and emergency operating procedures.

Conclusions

Using the HPT, an external, not-perfectly-isolating housing unit with venting to the dumping system of the hyperbaric chamber allows the option of putting medical devices with unknown susceptibility to the environmental factors associated with HBOT into a pressurized environment.

After careful risk evaluation and training of personnel involved, such a housing allows for the safe use of critical medical devices, without prior testing for their compatibility with or exposure to the hyperbaric environment.

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