

Performance of the BBraun Perfusor Space syringe driver under hyperbaric conditions

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Abstract

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Background: The BBraun Perfusor Space™ syringe driver is already in use by ambulance services and retrieval teams but has not previously been assessed for hyperbaric chamber use.

Methods: Pump flow accuracy was tested at rates between 1 and 40 ml·h⁻¹ using three different brands of 50 ml syringe. Function of the occlusion alarms was assessed using the same syringes. The hyperbaric profile involved pressurisation to 284 kPa at 30 kPa·min⁻¹, 30 min at 284 kPa and decompression at 30 kPa·min⁻¹. Output was recorded from differences in weight of collection containers. A single device was tested.

Results: Performance was highly dependent on the syringe type used, with two of the three 50 ml syringes used demonstrating 'stiction' at both low and high occlusion pressure alarm settings, most marked during pressurisation. On decompression from 284 kPa all syringes alarmed at significantly lower pressures. Because of the stiction problems only the flow measurements for the BBrown Omnifix 50 ml syringes are reported. At a pressure of 284 kPa, the difference between programmed and delivered rates was within the manufacturer's specification of 10%: at 40 ml·h⁻¹ (median variation 1.25%, IQR 0.5–1.7%), 10 ml·h⁻¹ (8.6%, IQR 8–9.2%), 5 ml·h⁻¹ (-8.8%, IQR -1.6–8.8%) and 1 ml·h⁻¹ (-4%, IQR 4–12%). Pressurisation was associated with significantly lower flow rates whilst decompression was associated with significantly increased rates. Limited testing at 405 kPa was also within the manufacturer's specifications.

Conclusion: A BBraun Perfusor Space syringe driver performed within acceptable performance criteria but is highly dependent on syringe type and flow rates. The potential for the device to under deliver on pressurisation and over deliver on depressurisation, however, suggests vigilance and appropriate rate adjustments may be necessary during these phases.

Key words

Equipment; Hyperbaric medicine; Intensive care medicine; Pharmacology

Introduction

Hyperbaric oxygen treatment (HBOT) is indicated in selected patients with critical illnesses, including necrotising soft tissue infections and cerebral arterial gas embolism.^{1–5} Many of these patients are intubated, ventilated and receiving intensive care (ICU) management, including inotropic support. For ICU patients on inotropic support, consistent delivery is dependent on the infusion devices maintaining function under hyperbaric conditions. If the devices are not hyperbaric-approved, the need to change devices imposes the risk of unexpected boluses of inotropes during device changeover and potentially significant morbidity. Haemodynamic instability during HBOT is a recognised entity particularly during compression and decompression. Possible causes of this instability include the physiological response to pressurisation and malfunction of infusion devices.¹

Whilst ICU patients can be managed in a monoplace chamber with infusion devices external to the treatment chamber,⁶ the vast majority of ICU patients are managed in multiplace units. As such, all medical devices should be tested for compatibility within an hyperbaric environment.^{7,8} Previous studies, case reports and letters have demonstrated that some devices fail completely at normal treatment pressures whereas others deliver inconsistent flow rates.^{9,10}

Some of the syringe drivers previously evaluated for hyperbaric use are no longer manufactured but may be still in use.^{11–15}

The primary aim of this project was to evaluate the performance of a current generation syringe driver in wide use and its suitability for hyperbaric chamber use. The BBraun Perfusor Space™ syringe driver (BBPS; BBraun, Melsungen, Germany) is currently used by ambulance services and retrieval teams, including the Royal Flying Doctor Service, but has not previously been assessed for use under increased pressure. The null hypothesis to be tested was that delivery rates of the syringe driver are not influenced by hyperbaric conditions. A secondary hypothesis was that the occlusion alarm function does not alter under hyperbaric conditions so that the alarm settings do not need to be modified for some syringe/pump combinations to be practicable.

In addition, intermittency and obstruction caused by the high static friction relative to dynamic friction between the plunger seal and the syringe wall (combined static friction and sticking or 'stiction') can increase under pressure so that safe drug administration in the hyperbaric environment may require either changes in usual protocols or the exclusion of some driver/syringe combinations.

Methods

All measurements were performed in the inner lock of a rectangular, triple-lock hyperbaric chamber (Fink Engineering, Australia). The researchers were fit for hyperbaric chamber attendance (Australian Standard 4774.2-2002, *Work in compressed air and hyperbaric oxygen facilities*). Testing was conducted solely by the researchers. There were no other human subjects involved in the testing of this device. The Alfred Hospital Research and Ethics Committee were contacted prior to commencing the study and they deemed that no approval was needed as this was an *in vitro* study, no patients were involved in the study and there was no impact on patient care or confidentiality.

APPARATUS

A single BBPS device was evaluated at ambient atmospheric pressure and under increased pressure, with particular regard to the accuracy of volume delivery. The BBPS is an electromechanical peristaltic syringe driver powered by a stepper motor. The device's external AC power supply was removed and all testing was performed on its internal NiMH battery pack. The syringe driver loaded with a 50 ml syringe of 0.9% saline was tested in the inner lock of the multiplace hyperbaric chamber of the Alfred Hospital Hyperbaric Unit. The syringes evaluated were the BBraun Omnifix 50 ml syringe (BBraun, Melsungen, Germany), the Terumo 50 ml syringe (Terumo, Laguna, Philippines) and the Becton Dickinson 50 ml syringe (BD Luer-Lok, Sydney, Australia). The syringes were connected to a 250 cm Infusomat Space PVC line (BBraun, Melsungen, Germany) which emptied directly into the measuring containers. All air bubbles were thoroughly removed before measurements commenced. The delivered volume was measured using an electronic precision weighing balance (Classic Light PL-L, Mettler Toledo); this is subject to independent, annual quality assurance calibration and accreditation and is considered to be accurate to four decimal places.

Prior to testing, a biomedical engineer (author TS) examined the BBraun syringe driver using the Alfred Hyperbaric Unit testing matrix. This matrix has been used for many new items of equipment and comprises verification of basic suitability and function with test pressurisations to 304 kPa and a pressurisation rate of 10 kPa·min⁻¹.¹⁶ This standardised testing pathway covers our requirements for routine HBOT and is primarily used as a screening tool to identify equipment that may be adversely affected by pressure or pressure changes or represents an ignition risk. In order to complete an oxygen risk assessment, the unit was partially disassembled and an internal inspection conducted to identify any items requiring further evaluation with respect to oxygen enriched environments, including electronic components, the internal battery and any lubricating grease.

FORCE GENERATION TESTING

Performance verification tests were conducted prior to 284 kPa treatment profiles. A calibrated force gauge was used to determine force generated with the pump running at 100 ml·h⁻¹ and the occlusion alarms set at the lowest value (10 kPa or P1) and the highest value (120 kPa or P9). All results were cross referenced with the manufacturer's specifications for allowable tolerances.

OCCLUSION ALARM PARAMETERS

The output line from each pump was connected via a pressure transducer to a tap, the syringe, line and transducer filled with water, all air bubbles flushed and the pressure monitor zeroed against ambient pressure. The pump was started at 100 ml·h⁻¹ and when the flow rate was stabilised the tap was closed. At the moment the pump halted with an occlusion alarm, the pressure reading (measured accuracy 1 kPa) and time duration were recorded.

FLOW RATE ACCURACY

The accuracy of the BBPS syringe driver's flow rates were tested at flow rate settings of 1, 5, 10 and 40 ml·h⁻¹. The volume delivered was collected at 5-min intervals directly into laboratory-supplied sample containers with lids, which were labelled and weighed prior to test dives. Timing was performed by a hyperbaric technician with a stopwatch outside the chamber. Infusion flow rates were determined from differences in weight of the containers and time. After completion of each pressure profile, the test tubes were weighed by the researchers using the precision measuring scales.

HYPERBARIC PROFILE

The hyperbaric profile involved pressurisation to 284 kPa at 30 kPa·min⁻¹, 30 min at 284 kPa and decompression at 30 kPa·min⁻¹. This profile was chosen because it represents standard hyperbaric treatments for emergency and intensive care throughout Australia. The chamber atmosphere was controlled by the outside technicians and internal chamber temperature, humidity and gas composition were monitored and kept within defined limits. Temperature ranged from 24–25°C and humidity from 40–60%. For control purposes, a 30-min sampling phase (six samples) occurred at ambient pressure in the chamber prior to each 'dive' commencing. The syringe driver with a 50 ml BBraun syringe also underwent unmanned tests at 405 kPa whilst programmed to deliver 10 ml·h⁻¹ over a 60-min infusion period.

Departmental safety protocols mandated constraints on depth, duration and the number of dive profiles able to be completed per week in order to minimise risk of decompression illness in the researcher. The testing durations were calculated to be less than the maximum allowable no

Table 1

Occlusion pressures during pressurisation in a multiplace chamber at 30 kPa.min⁻¹ to maximum pressure 284 kPa and decompression at 30 kPa.min⁻¹; all tests at a flow rate of 100 ml.h⁻¹; P1 (10 kPa) the lowest occlusion alarm setting and P9 (120 kPa) the highest; time-to-occlusion specifications: BBraun 50 ml syringe – 96 s on P1 setting and 13.46 s on P9; Becton Dickinson (BD) 50 ml syringe – 173 s on P1 and 934 s on P9; (mean times and pressures rounded to nearest whole number)

| Test stage | Expected occlusion pressure (kPa) | Syringe | Acceptable range (+/-10%) (kPa) | Time to occlusion (sec) mean (SD) | Measured occlusion pressure (kPa) mean (SD) | Error in occlusion pressure (%) | Comment |
|-----------------------------|-----------------------------------|--------------|---------------------------------|-----------------------------------|---|---------------------------------|------------------|
| Baseline | P1 10 | Terumo 50 ml | 9–11 | 29 (17.3) | 5 (1.6) | -51 | Syringe sticking |
| | | BD 50 ml | 9–11 | 42 (8.4) | 8 (0.3) | -22 | |
| | | BBraun 50 ml | 9–11 | 59 (18) | 11 (3.7) | +13 | |
| P9 120 | P9 120 | Terumo 50 ml | 108–132 | 332 (31.9) | 103 (1.4) | -14 | Syringe sticking |
| | | BD 50 ml | 108–132 | 340 (8.6) | 123 (4.4) | +3 | |
| | | BBraun 50 ml | 108–132 | 319 (6.9) | 113 (2.9) | -6 | |
| Pressurisation [#] | P1 10 | Terumo 50 ml | 9–11 | | | | Fail repeatedly |
| | | BD 50 ml | 9–11 | 20 (6.5) | 8 (2.4) | -20 | |
| | | BBraun 50 ml | 9–11 | 10 (1.2) | 9 (1.1) | -12 | |
| At Pressure* | P9 120 | BBraun 50 ml | 108–132 | 399 (53.7) | 109 (1.4) | -9 | Fail |
| | | BD 50 ml | 9–11 | 9 (7.5) | 7 (0.4) | -32 | |
| | | BBraun 50 ml | 9–11 | 10 (1.2) | 9 (1.0) | -12 | |
| Decompression [#] | P1 10 | BBraun 50 ml | 108–132 | 98 (1.6) | 110 (0.6) | -8 | |
| | | BBraun 50 ml | 9–11 | 7 (3.3) | 8 (1.4) | -25 | |
| | | BD 50 ml | 9–11 | 5 (1.0) | 5 (0.9) | -45 | |
| | P9 120 | BBraun 50 ml | 108–132 | 4 (6.8) | 116 (0.6) | +4 | |

Table 2

Flow rates (ml.h⁻¹) delivered at different stages of hyperbaric exposure using a new BBraun 50 ml syringe for each test (see text for details of pressure profile); baseline – normobaric pressure; data normally distributed except for that at pressure; * $P < 0.001$

| Set flow (ml.h ⁻¹) | Baseline | | Pressurisation | | At pressure | | Decompression | |
|--------------------------------|-----------------------------------|----------|-----------------------------------|-----------|-----------------------------------|-----------------|-----------------------------------|-----------|
| | Actual flow (ml.h ⁻¹) | % diff | Actual flow (ml.h ⁻¹) | % diff | Actual flow (ml.h ⁻¹) | % diff | Actual flow (ml.h ⁻¹) | % diff |
| 40 | 40.3 (0.1) | 1 (0.9) | 32.4 (2.7)* | -14 (0.1) | 41.1 (0.7) | 1 (-0.7–11.3) | 43.4 (2.5) | +5 (0.2) |
| 10 | 10.6 (0.1) | 6 (5.2) | 10.5 (0.2)* | -14 (0.2) | 10.9 (0.3) | 9 (8 to 9.2) | 14.1 (0.9) | +41 (4.5) |
| 5 | 4.8 (0.2) | -5 (5.1) | 3.6 (0.6)* | -28 (0.3) | 4.4 (0.2) | -9 (-8 to -9.2) | 7.6 (1.1) | +52 (5.0) |
| 1 | 1.0 (0.1) | 0 (0.2) | 0.7 (0.3) | -16 (0.5) | 1.1 (0.1) | -4 (-4 to -12) | 1.4 (0.9) | +20 (4.1) |

decompression limit (NDL) duration for the dive depths under study in accordance with Canadian Defence and Civil Institute of Environmental Medicine (DCIEM) tables currently utilised by Hyperbaric Units in Australia.

STATISTICAL ANALYSIS

Descriptive statistics were calculated for all variables. Normality of data was assessed by the skewness/kurtosis test for normality and the Shapiro-Wilk test. Paired Student's *t*-tests were performed to test for differences in programmed and delivered volumes for each of the administration sets. Non-normally distributed data were reported as median and interquartile range and compared between groups by the Kolmogorov-Smirnov and Kruskal-Wallis tests. A general linear model (ANOVA) and a Scheffe post hoc test to isolate differences were fitted to the standardised values to determine the effect of day of testing on the accuracy of volume delivery.

Results

OCCLUSION ALARM TESTS

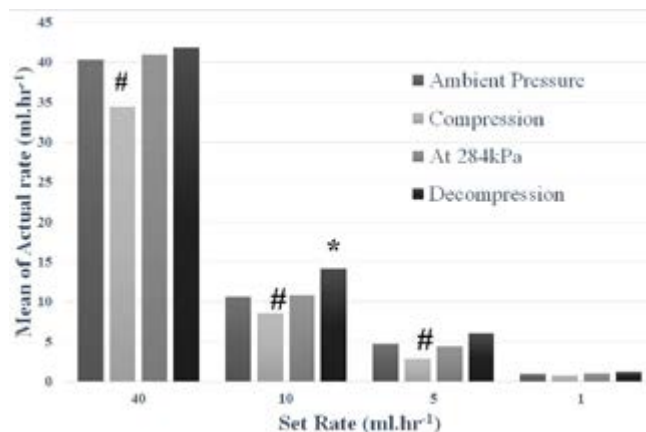
The force generated by the syringe driver at 100 ml·min⁻¹ was 12.85 (SD 0.2) Newton on the lowest occlusion alarm setting and 71.9 (SD 0.2) Newton on the highest occlusion alarm setting. Both values were within the manufacturer's specifications. Performance was highly dependent on the syringe type used (Table 1). The Terumo and Becton Dickinson 50 ml syringes demonstrated significant stiction on pressurisation to 284 kPa. The performance of these syringes was unacceptable and all further testing was performed with the BBraun 50 ml syringe. The BBraun syringe had a markedly stiffer barrel and the plunger O-rings were further apart causing less lateral plunger movement than the Terumo or BD syringes. In addition, the plunger end has ridges which may reduce slippage of driver on plunger. The BBraun syringes performed within the manufacturer's specifications (+/- 5%) and were clinically acceptable during pressurisation, at 284 kPa and on decompression. On the lowest occlusion pressure setting, BBraun syringes alarmed at a significantly lower pressure (-12%, *P* = 0.01) and earlier time (*P* = 0.01) at 284 kPa. On the high occlusion pressure setting during decompression, BBraun syringes alarmed at a significantly lower pressure (-25%, *P* = 0.01) and earlier time (*P* = 0.01).

ACCURACY OF VOLUME DELIVERY

Following the unacceptable occlusion testing, all flow rate calculations reported are exclusively for the BBraun 50 ml syringe. Measured flow rates were dependent on the flow rate set and the stages of pressurisation (Figure 1). During pressurisation mean flow rates decreased by 13.9%, 13.6%, 28% and 16% on the 40 ml·h⁻¹, 10 ml·h⁻¹, 5 ml·h⁻¹ and 1 ml·h⁻¹ settings, respectively. At 284 kPa the rate increased

Figure 1

Calculated delivered rates during hyperbaric testing of a BBraun Space syringe driver with 50 ml BBraun syringe of 0.9% saline; normobaria; pressurisation at 30 kPa·min⁻¹; 284 kPa; decompression at 30 kPa·min⁻¹; rates calculated from volume delivered over 5-min increments; statistically significant variation from set rates are marked as under-delivery (#) and over-delivery (*)



by a median of 1.2%, 8.6% and 4% at 40 ml·hr⁻¹, 10 ml·hr⁻¹ and 1 ml·hr⁻¹ respectively and decreased by 8.8% at 5 ml·hr⁻¹. All rates at 284 kPa were within the manufacturer's allowable flow rate tolerance for the BBPS of 10%. On decompression, increases of 4.7%, 41%, 52% and 20% occurred (Table 2). There was no day-to-day variation in performance (*F* = 0.866, *P* = 0.55).

At 405 kPa the syringe driver with a 50 ml BBraun syringe set to deliver 10 ml·hr⁻¹ had a calculated actual flow rate of 10.06 ml·hr⁻¹ (+ 0.6% of target).

Discussion

This study has shown that the performance of the BBraun Perfusor™ Space device is dependent on the set flow rates and on the make of syringe used. We have reported here only the volumes delivered with the 50 ml BBraun syringe. In general, the device delivered small increases in volume infused at 284 kPa compared with rates at ambient pressure. These were statistically significant and may be clinically significant. The major changes in delivery occurred on compression (under-delivery) and decompression (over-delivery). Whilst modest errors in the average rate of infusion may not be critical, transient interruptions and unintended boluses could be clinically relevant. When inotropes are being infused, this could seriously impact a critically ill patient. Noradrenaline has a half-life of 1–2 min and a standard dilution for adults is 60 µg·ml⁻¹ delivering 1 mcg·min⁻¹ at 1 ml·h⁻¹. Variations in delivery of 10–40% would mean the actual rate is 0.6–0.9 µg·min⁻¹ on compression and 1.1–1.4 µg·min⁻¹ on decompression. For paediatric inotrope infusions, the standard dilution is 30 µg·ml⁻¹ delivering 5 mcg·kg⁻¹·min⁻¹ at 1 ml·h⁻¹ and the variation may be more relevant.

There have been only three syringe drivers tested for use in multiplace hyperbaric chambers (Terumo, Graseby and Atom 235).^{9,13,16} The Atom syringe pump is now discontinued and the Terumo and Graseby drivers have been superseded. The Fresenius Pilote Hyperbaric (Vial Infusion Technology) syringe pump is CE-marked but not FDA-cleared for use in multiplace hyperbaric chambers. The battery powered Argus 600 syringe pump (Codan Triplus) has been used successfully at the Karolinska Hyperbaric unit but has not undergone rigorous peer review.¹⁷

A number of syringe characteristics affect the volume infused under pressure. It is likely that deformation of the syringe during pressurisation and decompression significantly impacted on delivery.^{18–20} The thinner barrel, lack of O-rings on the plunger and a non-serrated plunger end of the Terumo syringe permitted torsion of the plunger and an asymmetrical alignment resulted in significant stiction and delivery failure. A contributing factor is the gas space between the two sealing rings of many types of syringes, which is air filled and hence subject to Boyle's Law forces. On pressurisation, distortion of the plunger seal occurs causing it to bind more tightly against the syringe barrel and trigger the occlusion alarm to stop the infusion. In general, the larger the syringe and the lower the flow rate the more pronounced the stiction effect. In our series, the changes in flow rate were most marked at low set flow rates and stiction may have played a significant role in exceeding occlusion alarms and under-delivery of saline.

Using the same type of infusion device in the ICU, during transport and in the hyperbaric chamber not only reduces delays before treatment starts but also removes the need for interruption of dose-critical infusions and reduces the risk of change-over errors.^{21,22} On balance, the risk associated with over- or under-delivery during compression and decompression is likely to be markedly less than the risk of inadvertent boluses on transfer from one infusion system to another prior to treatment. The under-delivery on compression, however, may well compound the haemodynamic changes occurring as a result of exposure to hyperbaric oxygen. Cardiovascular responses to hyperbaric hyperoxia include a rate-dependent reduction in cardiac output and systemic vasoconstriction with an increase in peripheral vascular resistance and a decrease in pulmonary vascular resistance.^{23,24} This results in a decrease in heart rate, cardiac output, and cardiac work, possibly related to baroreceptor stimulation.²⁵ All left ventricular performance indices decrease, without a change in preload or afterload. Pulmonary vascular resistance decreases whilst pulmonary arterial pressure does not change.²⁶ Although these effects are well tolerated in normal individuals, patients undergoing HBOT can have compromised cardiac function as evidenced by reports of acute pulmonary oedema (with one death) during monoplace HBOT in three patients with markedly reduced left ventricular ejection fractions.²⁷

LIMITATIONS

A limitation of this study is the use of only one syringe driver during testing. Some variability in performance between devices could be expected but it is likely this would be small. Our standard compression rate (30 kPa·min⁻¹) to a treatment pressure permitted only five minutes to document syringe performance on compression and decompression. As such there were fewer observations during this phase of the study and less precision in the estimate of effect size. The potential for sampling bias thus exists. We also did not test the dynamic performance of the driver following transfer through the medical lock at pressure. This is a possible clinical scenario, and it is possible that the rapid rate of pressurisation could affect subsequent performance at pressure by causing mechanical distortion.

Conclusions

The BBraun Infusor™ Space syringe driver performs within acceptable performance limits but is highly dependent on syringe type and set flow rates. From a clinical perspective, the errors in overall volume delivery were relatively small and should be interpreted as clinically acceptable error and of clinically insignificant risk to patients. However, the potential for the device to under-deliver on pressurisation and over-deliver on depressurisation suggests vigilance and appropriate rate adjustments may be necessary during these phases. This is important in order to avoid adverse shifts in haemodynamics, compounded by physiological responses related to exposure to hyperbaric oxygen.

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