

Levels of Carbon Dioxide in Helmet Systems Used during Orthopaedic Operations*

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ABSTRACT: The use of isolation helmets has gained popularity as a method of possible protection of the operating-room personnel from diseases that can be transmitted during operative procedures. However, the use of these systems has been associated with a variety of symptoms, including fatigue, diaphoresis, nausea, headache, and irritability. These symptoms have often been attributed to the mental stress of the operative procedure or the physical discomfort of the helmet. As far as we know, no manufacturers include the measured levels of carbon dioxide or the rate of air exchange of their helmet system. A possible common cause of discomfort with helmet systems is the level of carbon dioxide to which the person wearing the device is exposed.

We measured the levels of carbon dioxide in four helmet systems from three different manufacturers during light exercise designed to approximate the exertion during an orthopaedic operation. All but one unit failed to meet the exposure limits recommended by the National Institute for Occupational Safety and Health and the Occupational Safety and Health Administration regarding exposure to carbon dioxide. One unit, the Stackhouse Freedom Aire self-contained system, did meet these standards, but the levels of carbon dioxide in this helmet were more than 1000 per cent greater than the ambient levels in air (440 parts per million compared with 4939 parts per million).

Isolation systems must be evaluated carefully not only for comfort but also for the physiological effects caused by exposure to elevated levels of carbon dioxide. Operating-room personnel who use such systems should be aware that many of the physical symptoms that they experience may be associated with elevated levels of carbon dioxide.

Since their introduction, isolation helmet systems designed for use by surgeons and operating-room personnel during orthopaedic procedures have increased in popularity. These helmets are equipped with battery-operated motor blowers for airflow, air filters, and single-use face shields; they were originally marketed as a way to reduce the rate of infection following total joint arthroplasty. Proponents of the helmet systems suggested that isolation of the operative team and filtration of exhaled air protected the operative site from potential contaminants. The superiority of helmet systems compared with standard laminar airflow systems for protection from infection has never been demonstrated, as far as we know.

Recently, the role of helmet systems has been expanded. Protecting the members of the operative team from potential transmission of disease from infected patients has become an important health concern. One indication of the increased awareness of the risk to health-care workers is that, in operating rooms nationwide, all participants in the procedure are now required to use protective eyewear. Operative helmet systems are now marketed as a protective barrier to prevent the contamination of the operating-room personnel by particles of debris and by aerosolized blood released during orthopaedic procedures.

Those who utilize the helmet systems describe a variety of symptoms, including headache, dyspnea, diaphoresis, cervical pain, and generalized discomfort, both during and after use. Contamination of the air in the helmets and carbon dioxide from the exhaled air are suspected causes of the various symptoms.

When inhaled in elevated concentrations, carbon dioxide causes elevated blood-gas levels that can produce headaches; cardiac arrhythmias; respiratory acidosis; and, in extreme cases, unconsciousness or death⁹. The severity of the symptoms is both concentration and time-dependent. Two federal agencies, the National Institute for Occupational Safety and Health and the Occupational Safety and Health Administration, established a limit to the concentration of carbon dioxide to which employees could be exposed. This limit, an eight-hour time-weighted mean, was set by both agencies as 5000 parts per million, or 0.5 per cent of room air. Employers

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TABLE I
HELMET SYSTEM CONFIGURATIONS

Manufacturer	Model	Helmet Design	Designation*	No. of Inflow Blowers	No. of Exhaust Blowers	No. of Ports†	Fan Speed‡
DePuy	Sterile View	External blowers	DePuy/IO	1	1	2	NA
			DePuy/In	2	0	2	NA
Stackhouse	Freedom Aire	Self-contained	FA/Hi	1	0	NA	High
			FA/Lo	1	0	NA	Low
Stackhouse	Freedom Mark	External blowers	Shark/Hi	2	2	4	High
			Shark/Lo	2	2	4	Low
			Ram/IO/Hi	1	1	2	High
			Ram/IO/Lo	1	1	2	High
			Ram/In/Hi	2	0	2	High
Stryker	Steri-Shield	Self-contained	Stryker/Hi	2	1	NA	High
			Stryker/Lo	2	1	NA	Low

*IO = inflow and exhaust, In = inflow only, FA = Freedom Aire, Hi = high fan speed, Lo = low fan speed, Shark = the shark configuration, and Ram = the ram configuration.
†NA = not available.

are legally required to maintain employees' exposure below the specified level or to limit exposure to higher concentrations.

To the best of our knowledge, the concentrations of carbon dioxide in operative helmet systems have not been reported in the English-language literature. Additionally, no data regarding the concentrations of carbon dioxide in the helmets are provided by the manufacturers. The purpose of the present study was to measure the concentrations of carbon dioxide in com-

mercially available helmet systems marketed for use by surgeons and operating-room personnel.

Materials and Methods

Subjects

Four healthy men who had a mean age of thirty-eight years (range, thirty-four to forty-seven years) participated in the study. Two of the subjects were orthopaedic surgeons who had used several of the available helmet systems in the past, and two were

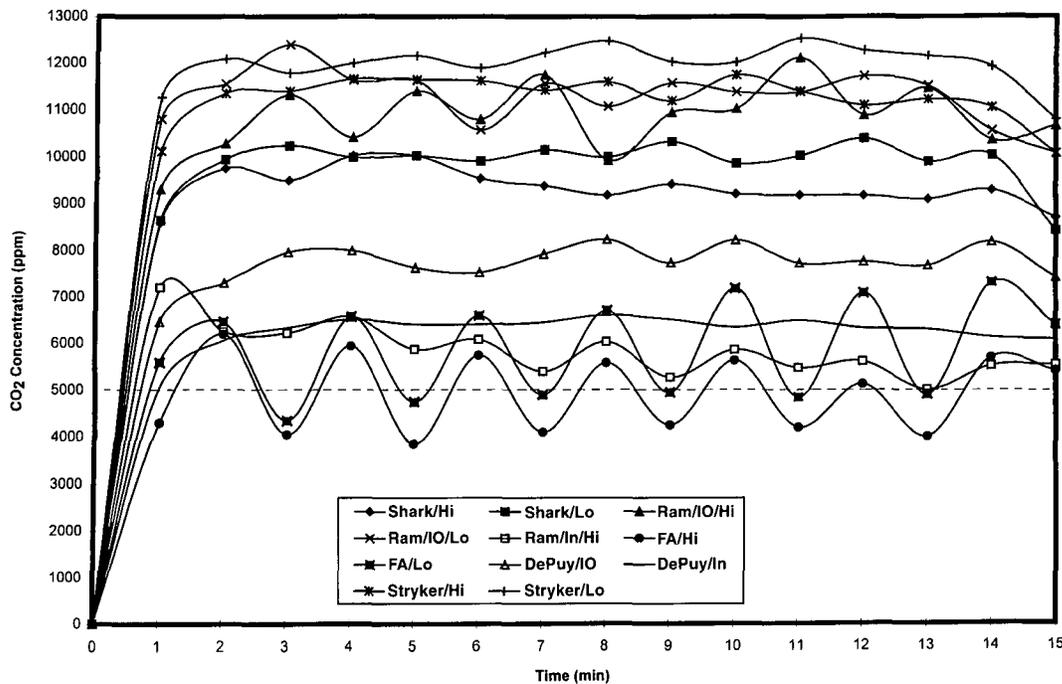


FIG. 1

Graph of the mean concentrations of carbon dioxide for all configurations of the helmet systems that were tested. The concentrations for all systems (ten of the eleven configurations) exceeded the recommended exposure limit proposed by the National Institute for Occupational Safety and Health and the permissible exposure limit proposed by the Occupational Safety and Health Administration of 5000 parts per million (ppm). Shark = the Freedom Mark helmet in the shark configuration, Hi = high fan speed, Ram = the Freedom Mark helmet in the ram configuration, IO = inflow and exhaust, Lo = low fan speed, FA = the Freedom Aire helmet, Stryker = the Steri-Shield helmet, In = inflow only, and DePuy = the Sterile View helmet.

TABLE
MEAN CONCENTRATION OF CARBON DIOXIDE FOR ALL

Concentration	Stryker/Lo	Ram/IO/Lo	Stryker/Hi	Ram/IO/Hi	Shark/Lo
Mean CO ₂ and stand. error	11,977 ± 115	11,296 ± 151	11,241 ± 133	10,842 ± 188	9855 ± 145
Minimum CO ₂	10,788	10,063	10,063	9300	8413
Maximum CO ₂	12,538	12,400	11,750	12,117	10,388

*The values are given in parts per million. Stryker = the Steri-Shield helmet, Lo = low fan speed, Ram = the Freedom Mark helmet in the ram configuration, IO = inflow and exhaust, Hi = high fan speed, Shark = the Freedom Mark helmet in the shark configuration, DePuy = the Sterile View helmet, In = inflow only, and FA = the Freedom Aire helmet.

industrial hygienists who had no previous experience with the helmets. The subjects were not blinded with regard to the helmet system and configuration that were used for each test.

Helmet Systems and Configurations

At the time of the testing, three companies manufactured and marketed four helmet systems for use in orthopaedic operating rooms. The systems tested were the Freedom Mark helmet (Stackhouse, Riverside, California), the Freedom Aire helmet (Stackhouse), the Steri-Shield helmet (Stryker Instruments, Kalamazoo, Michigan), and the Sterile View helmet (DePuy, Warsaw, Indiana). The systems were classified by design (a self-contained unit with integrated blowers or a helmet with a separate external blower connected by hoses) and by ventilation pattern (inflow alone or inflow and exhaust). Each system could be modified by changing the ventila-

tion pattern, fan speed, or number of hoses connected to the external motor blowers (ports). Each configuration that was tested was given a designation based on the modifications (Table I). With the Freedom Mark system, one or two hoses could be attached to each blower and the configuration was designated as either shark (four ports) or ram (two ports)¹³.

The helmet configurations that were selected for testing were recommended by the sales representatives, the manufacturer's literature, or the operating-room personnel. The equipment used for testing was randomly selected from operating-room inventory or was provided by the manufacturer or the sales representatives. The same helmet and motor blowers were used by each subject for every modification of the configuration of that helmet. No further modifications or adjustments were made to any system before testing.

A total of eleven helmet configurations were tested

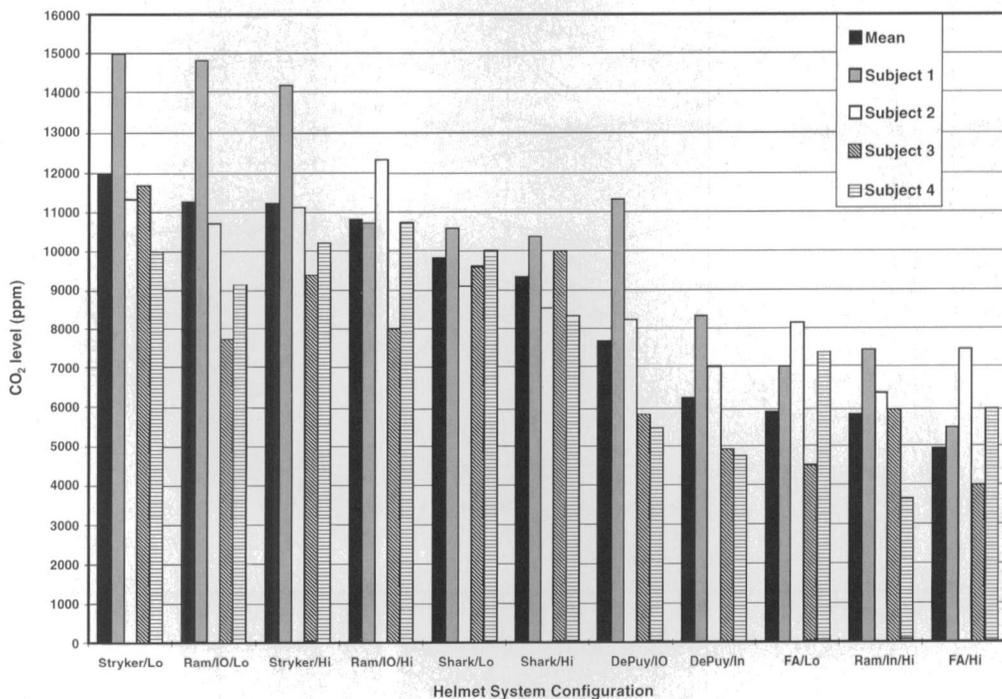


FIG. 2

Graph of the mean concentrations of carbon dioxide and the individual results for each helmet system and for each subject. Stryker = the Steri-Shield helmet, Lo = low fan speed, Ram = the Freedom Mark helmet in the ram configuration, IO = inflow and exhaust, Hi = high fan speed, Shark = the Freedom Mark helmet in the shark configuration, DePuy = the Sterile View helmet, In = inflow only, and FA = the Freedom Aire helmet.

II
TEST SUBJECTS ACCORDING TO HELMET CONFIGURATION*

Shark/Hi	DePuy/IO	DePuy/In	FA/Lo	Ram/In/Hi	FA/Hi
9339 ± 105	7718 ± 116	6269 ± 96	5908 ± 267	5861 ± 145	4939 ± 218
8600	6463	5063	4350	5000	3850
10,025	8238	6613	7313	7200	6200

by each subject, for a total of forty-four tests (Table I).

Testing Protocol

All subjects completed a health-screening questionnaire from the National Institute for Occupational Safety and Health, and all consented to the testing protocol. The oral temperature of each subject was measured before and at the end of each testing period. The pulse rate and the blood-oxygen saturation were recorded with a pulse oximeter throughout the testing period to observe the effect of the exercise protocol and the helmet system on the cardiovascular system and possibly to indicate any unrelated cause of the production of excess carbon dioxide. As the concentration of carbon dioxide in inspired air increases, the alveolar-to-capillary ratio of carbon dioxide decreases, resulting in less favorable diffusion of carbon dioxide from the blood. The body compensates with a number of physiological changes, including an increase in respiratory depth and rate and an accompanying increase in cardiac output¹¹. Previous studies have not shown a correlation between the levels of carbon dioxide in the blood and the physiological changes and symptoms that we described². Exposure limits are based only on ambient levels in air.

Studies of the effect of concentrations of carbon dioxide and that of arterial PCO₂ have demonstrated that PCO₂ increased and the pH of the blood decreased at levels of inspired carbon dioxide ranging from 1 to 5 per cent greater than normal². A 5 per cent increase in carbon dioxide in the air resulted in an approximately 15 per cent increase in arterial PCO₂. There is a linear relationship between changes in the arterial PCO₂ and the amount of carbon dioxide in the air². Therefore, carbon dioxide was monitored only in the helmet system. The concentrations of ambient carbon dioxide were monitored and measured by industrial hygienists (A. S. E., G. E. B., and S. W. L.) from the National Institute for Occupational Safety and Health who were familiar with the protocol and the equipment.

The subjects performed light exercise (less than four kilocalories used per minute) while standing at an upper-extremity ergometer (Uppercycle, model 841; Engineering Dynamics, Lowell, Massachusetts) for fifteen minutes. This protocol approximated the level of exertion during an orthopaedic operative procedure (such as a total hip or knee arthroplasty) that requires the use of powered hand instruments and moderate manual labor. The ergometer was set at a workload of

twenty watts, and the subjects maintained an exercise rate of sixty rotations per minute with the hand cranks. The subjects wore operative scrub suits and standard operating-room gowns over the helmet hoods as recommended by the manufacturers. One-piece combination face shields and gowns (so-called togas) were not used during testing. The subjects were allowed to speak *ad libitum* during the testing.

An air-sampling probe was positioned just anterior to and caudad to the subject's right ear, out of the direct path of the inflow air or exhaled breath. A five-minute pilot test without a helmet was performed for each subject to verify that exhaled air was not in direct line with the probe. The concentration of carbon dioxide was measured with a portable infrared analyzer (model RI-411A; Gastech, Newark, California). The concentration of ambient carbon dioxide in room air was monitored continuously with a second analyzer in the testing room and was recorded at the beginning and the end of each testing period. The analyzers were calibrated at the beginning of each day with known standards of carbon dioxide.

Continuous voltage output (corresponding to the concentration of carbon dioxide) from the helmet analyzer was sent to a datalogger (model DL3200; Metrosonics, Rochester, New York) for storage. The data were subsequently downloaded, and graphs of the concentration of carbon dioxide as a function of time were plotted. Statistical analysis was performed with analysis of variance and Duncan multiple-range tests.

Results

The concentrations of carbon dioxide in all of the helmet systems exceeded the exposure limit of 5000 parts per million proposed by both the National Institute for Occupational Safety and Health and the Occupational Safety and Health Administration (Table II) (Figs. 1 and 2). Ten of the eleven helmet configurations resulted in a mean concentration of carbon dioxide of more than 5000 parts per million, and six of these resulted in a mean concentration of approximately 10,000 parts per million, or two times higher than the exposure limit.

The highest concentrations of carbon dioxide were measured in the systems that used both inflow and exhaust blowers (bidirectional airflow). The four helmet configurations with unidirectional airflow (inflow blowers only) resulted in a mean carbon-dioxide concentration of 5744 parts per million, whereas the seven configurations with bidirectional flow resulted in a

mean concentration of 10,324 parts per million. This difference was significant ($p < 0.001$).

The fan speed also contributed to the levels of carbon dioxide. All systems equipped with a variable-speed fan were found to contain higher concentrations of carbon dioxide when the fan was on low speed than when it was on high speed, but this difference was not found to be significant with the numbers available.

The design of the helmet (self-contained or external-blower) was not found to have a significant influence on the concentration of carbon dioxide, with the numbers available. The highest concentration of carbon dioxide measured in the study was found in a self-contained unit and the next highest was in an external-blower unit.

The number of inflow and exhaust ports was a significant determinant of the concentration of carbon dioxide ($p < 0.01$). Regardless of the fan speed, the concentration with the shark (four-port) configuration was lower than that with the ram (two-port) configuration when the same bidirectional airflow pattern and the same motor blowers were used.

The mean ambient carbon dioxide in room air was 440 ± 59 parts per million (range, 250 to 575 parts per million). No physiological differences were noted during the eleven test sessions for any subject. The blood-oxygen saturation was never lower than 94 per cent in any subject. The pulse rates increased with the level of exercise and were consistent from session to session. No subject had a difference between the oral temperature before the test and that after it.

Discussion

Operative helmet systems are currently used by surgeons during orthopaedic procedures, particularly joint replacements. Although we are not aware of any evidence in the literature that supports the ability of these systems to decrease the rate of infection following hip and knee arthroplasties, the system serves as a protective barrier for the surgeon and the operating-room personnel. A large number of orthopaedic surgeons continue to recommend and to use the helmets. Many of these same advocates, however, consider the helmets to be uncomfortable and report headaches, dyspnea, diaphoresis, irritability, and cervical pain after wearing a helmet for the duration of a procedure. Two of us (M. H. R. and M. G. S.), who are orthopaedic surgeons, have experienced these symptoms, as have our colleagues. Our hypothesis was that increased concentrations of carbon dioxide could be responsible for the symptoms. To our knowledge, this is the first study to measure the concentration of carbon dioxide in the helmet systems.

Carbon dioxide is a naturally occurring, odorless gas found in the atmosphere at concentrations of approximately 300 parts per million¹². Carbon dioxide can affect the central nervous, respiratory, cardiovascular, and renal systems⁹. It has anesthetic properties and was used

in the early nineteenth century as an anesthetic during operations on animals¹. Physiologically, carbon dioxide is a key factor in the control of respiration and cerebral circulation and can act as a powerful cerebral vasodilator^{5,7,9}. High concentrations (300,000 parts per million)⁴ can result in a loss of consciousness in twenty-eight seconds, and low concentrations (15,000 to 30,000 parts per million) have been shown to cause confusion, an increased rate of ventilation, headache, respiratory acidosis, and an increased consumption of oxygen^{3,6,9,10,14}.

Luft et al. studied tolerance of exercise in carbon dioxide-rich environments. They found that a concentration of carbon dioxide of 19,000 parts per million increased the rate of ventilation as well as the consumption of oxygen by their subjects. Those authors concluded that a concentration of 19,000 parts per million was sufficient to affect an individual's capacity for exercise. Although that study was performed on healthy male volunteers, the authors noted that persons who have underlying respiratory, cardiac, or renal insufficiency demonstrate a decreased ability to tolerate exercise at lower concentrations of carbon dioxide and are at a greater risk for symptoms and physiological manifestations.

Although our results showed the concentrations of carbon dioxide to be lower than 19,000 parts per million, concentrations as high as 16,300 parts per million were measured. Exposure to concentrations as low as 10,000 parts per million has been shown to result in widespread physiological alterations, including acidosis and adrenal cortical exhaustion¹¹. According to the Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health, 5000 parts per million is the limit for prolonged exposure. Ten of the eleven helmet configurations resulted in a mean concentration of carbon dioxide that was higher than the recommended exposure limit, and six of the configurations resulted in a mean concentration that was close to or more than 10,000 parts per million. This exposure limit was established as an occupational guideline: a time-weighted mean that should not be exceeded. While most orthopaedic procedures last two to five hours, surgeons and operating-room personnel who participate in, and wear a helmet during, multiple procedures daily may be at risk for overexposure.

The airflow pattern was the most important design factor affecting the concentration of carbon dioxide. The concentrations in the systems with a unidirectional flow pattern (inflow only) were significantly lower than the concentrations in the systems with bidirectional airflow (inflow and outflow) ($p < 0.001$). Although the rates of flow through the blowers are the ultimate determinant of the volumes of inflow and exhaust, these rates are fixed by the manufacturer and were not measured in this study. The concentrations of carbon dioxide clearly demonstrate that the exhaust blowers in the bidirectional flow units were ineffective at removing the ex-

haled air and the inflow blowers were unable to provide an adequate supply of fresh air. To compensate for the lack of exhaust blowers, one system (the Freedom Aire helmet) incorporates a porous filter in the back of the hood both to filter inflow and to allow exhaust air to be eliminated easily. This passive exhaust configuration with a single inflow blower resulted in the lowest concentrations of carbon dioxide and, when the fan was on high speed, it was the only system in which the mean concentration was less than 5000 parts per million. The unidirectional systems that did not include a filter for passive exhaust had higher concentrations of carbon dioxide than the system that had a filter, but the concentrations were still significantly lower than those for the bidirectional systems ($p < 0.01$). However, even the unidirectional system with the filter had a concentration of carbon dioxide that exceeded the level of ambient carbon dioxide in the room by more than 1000 per cent. Other manufacturers have subsequently adopted and produced helmet systems that use a single inflow fan with a passive exhaust filter.

There were several limitations of this study. Although the fifteen-minute exercise protocol was believed to be an adequate representation of the level of activity during a routine joint-replacement procedure, actual conditions and the duration of the use of the helmets vary. Use of the systems for a two to three-hour period may increase concentrations of carbon dioxide even more. In every test, the concentration of carbon dioxide was elevated immediately and was sustained throughout the test-period; therefore, a longer duration of use was not ex-

pected to lower the elevated concentration. Monitoring during an actual operation was not feasible because the need for additional personnel and equipment in the operating room in order to measure the concentrations was potentially detrimental to the outcome of the procedure. Another limitation of the study was that our sample of four test subjects was small and homogeneous; however, most orthopaedic surgeons are men, and the study population was thought to represent the population at risk adequately.

The adverse effects of several hours (or more) of exposure to the concentrations of carbon dioxide that were measured in the helmets during this study are slight in healthy individuals who do not have any underlying pulmonary, cardiac, or renal disease. Surgeons and operating-room personnel who have normal acid-base balances should be able to compensate for the increased concentrations of carbon dioxide in the alveoli and blood that can occur during and after use of the helmets. Individuals with underlying abnormalities who choose to wear helmets during operative procedures should be aware of the increased risks that may be associated with increased concentrations of carbon dioxide. In addition, symptoms such as headache, fatigue, irritability, and decreased tolerance of exercise may impair the efficiency and technical abilities of the surgeon and operating-room personnel during a procedure. We encourage manufacturers to modify the designs of these helmet systems, and we believe that additional studies of the effect of elevated concentrations of carbon dioxide on operating-room personnel are warranted.

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