Clinical evaluation of the efficacy of three nitrous oxide scavenging units during dental treatment

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There are environmental health concerns for dental health care providers chronically exposed to trace amounts of waste nitrous oxide (N₂O). This study compared the effectiveness of three N₂O scavenging systems, the Porter/Brown, the Accutron, and the Matrix, in actual time during use in a standardized mock dental treatment protocol that reflected clinical practice while minimizing the influence of confounding variables. At every occasion during the procedure, the Porter/Brown scavenger system left the operator with significantly less N₂O than any of the other scavengers tested. The Porter/Brown removed between 71% and 91% of the N₂O compared to the control (no device).

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Introduced as an anesthetic in 1844, the analgesic, anxiolytic, and psychoactive properties of nitrous oxide (N₂O) make it a nearly ideal agent for use in outpatient sedation for dental procedures. The ADA Council on Scientific Affairs and the ADA Council on Dental Practice have stated that "nitrous oxide continues to be a valuable agent for the control of pain and anxiety." However, there are environmental health concerns for dental health care providers chronically exposed to trace amounts of waste N₂O. Chronic N₂O exposure has been linked to spontaneous abortion and reduced fertility, irritability, headache, nausea, congenital abnormalities, lymphoid malignancies, cervical cancer and hepatic, renal, and neurological disease.4,5

Bruce and Bach investigated the effects of N₂O exposure on operator performance.7 They observed decreased psychomotor performance in visual perception, immediate memory, and cognitive and motor responses in human subjects receiving as little as 50 ppm N₂O over a two hour period.8 Subjects exposed to 25 ppm N₂O did not demonstrate such effects. In a similar study, Cook found no changes in performance until the subjects were exposed to 20% N₂O, or the equivalent of 200,000 ppm.9

The literature reveals a lack of agreement concerning safe limits for the ambient level of N₂O. The National Institute of Occupational Safety and Health (NIOSH) recommends a maximum allowable time weighted average (TWA) of 25 ppm of total N₂O exposure in both the operating room and the outpatient setting.1 It was determined that 25 ppm was achievable in the operating room but not attainable in the dental operator. Therefore, NIOSH chose 50 ppm to be the maximum exposure limit for personnel in the dental setting.10 The American Conference of Governmental Industrial Hygienists recommends a N₂O exposure limit of 50 ppm for an eight hour TWA.11 Among the methods used to control N₂O exposure in the dental office, the ADA emphasizes the routine use of scavenging equipment.12 Levels of ambient N₂O have been reported to be 300–1,000 ppm when scavenging units are not used.13 Further studies have shown that some scavenging systems do not consistently maintain the operator's breathing space to within safety standards.14

Few studies have compared the effectiveness of different N₂O scavenging systems.15 A number of variables related to the delivery of N₂O sedation are difficult to control and complicate such studies. These include the type of dental procedure, mouth breathing, patient movement, mask fit and quality of high-speed evacuation.16 Previous studies have found the Porter/Brown N₂O scavenging system to be superior to others.17 Donaldson reported that the mean ambient N₂O level following use of the Porter/Brown device during a dental procedure was 13.4 ppm.18 These studies, however, involved the collection of gases throughout the dental procedure and a TWA of the N₂O at a specific time, not the actual time of exposure to N₂O by the dental team.

The ADA has published recommendations for controlling N₂O exposure.17 The report stated that dental offices could control N₂O exposure by implementing current recommendations on scavenging equipment maintenance and work practices. However, the level of N₂O in dental offices that follow these recommendations has not been established. This study sought to compare the effectiveness of three N₂O scavenging systems in actual time during their use in a standardized mock dental treatment protocol that reflected clinical practice while minimizing the influence of confounding variables. The hypothesis is that there is no difference in ambient N₂O measurements between the three scavenger units during mock dental treatment.

Materials and methods

Three N₂O scavenging devices were tested following a controlled clinical protocol. The scavenging devices differ in mask design. The Accutron Model No. 32203 Alphax MX (Accutron, Inc., Phoenix, AZ; 800/531-2221) and Matrix MD4 (MDM, Matrix, Orchard Park, NY; 800/847-1000) have one rubber nasal hood with a small plastic scavenging cap perched at the top of it (Fig. 1). The Accutron is disposable after one usage; the Matrix can be autoclaved. The Porter/Brown Model No. 2445-1 (Porter Instrument Company, Inc., Hatfield, PA; 800/457-2001) incorporates two rubber pieces into the mask design and can be autoclaved (Fig. 1). The scavenging units are similar in that the mask is connected to a high evacuation tubing that evacuates ambient N₂O and exhaled air at 45 L/min out of the building.

The study population consisted of 12 volunteers. 7 men and 5 women, who ranged in age from 22–44 (mean = 25 ± 3.5). The subjects were selected at random from a population of dental school
volunteers. All subjects met the criteria for Class I of the American Society of Anesthesiology. None used tobacco products; none of the female subjects were pregnant.

The subjects participated in four clinical sessions at one-week intervals. During these sessions, each volunteer was exposed to either one of the three N\textsubscript{2}O scavenger units or to a control that used no scavenger unit. The order of exposure to each of the variables was determined by a randomized computer-generated schedule established by an investigator not associated with the clinical portion of the study. Informed consent was obtained prior to subject participation in this investigation. A pilot study was performed to minimize variation between subjects, calibrate the instruments and the procedures, and expedite reproducibility.

Operatory preparation
All testing was conducted in the same ventilated operatory with an air flow rate that produced six air exchanges per hour. The N\textsubscript{2}O delivery machine was evaluated for proper connections and protection against gas leakage immediately before each experimental session, in accordance with ADA-recommended protocol\textsuperscript{12,14-23.}

Prior to each session, room air was evaluated using an infrared spectrophotometer to determine the baseline value of N\textsubscript{2}O in the operatory.

Patient preparation and clinical monitors
Before each clinical session, each patient was given oral and written instructions including pretreatment and posttreatment dietary restrictions, activity limitations following the study, and a 24-hour contact telephone number. On the day of the study, the subject was seated in a standard dental operator chair. Inhalation mask application and nose breathing technique were explained to each patient.

The patient was encouraged to remain still and to minimize talking and mouth breathing. The room ambient temperature was recorded. Patient blood pressure (BP), pulse, and blood oxygen saturation were recorded electronically by the Passport XC (Datascene Corp., Mani- vale, NJ; 800/288-2121). The patient’s respiratory rate was recorded to establish baseline measurements.

The door to the operatory was closed, the patient was placed in a semi-supine position, and a nasal hood was applied. Oxygen was delivered at a rate of 9.0 L/min. The hood was adjusted for both fit and comfort (Fig. 2). The patient was asked to relax and reminded again to breathe only through the nose. Respiratory rates were recorded again at minutes 3 and 12 of the procedure. A pulse oximeter was used to continually monitor the patient’s oxygen saturation; readings were taken at 3, 12, and 16 minutes.

N\textsubscript{2}O titration
As soon as the patient reported being comfortable with the position of his or her body and the position of the nasal hood, the investigator began titration of N\textsubscript{2}O. A constant gas volume technique was used. N\textsubscript{2}O was adjusted to 1.0 L/min while oxygen flow was reduced to 8.0 L/min. The patient breathed this 11% N\textsubscript{2}O mixture for three minutes. If there were no untoward events and the patient still was comfortable, the flow of N\textsubscript{2}O was increased to 2.0 L/min and the oxygen flow was reduced to 7.0 L/min (22% N\textsubscript{2}O). The patient breathed this new mixture for six minutes, at which time a rubber dam was applied to isolate the maxillary anterior teeth. The dam was held away from the patient’s face using a Young’s frame. The N\textsubscript{2}O flow was increased to 3.0 L/min with a concomitant oxygen flow rate of 6.6 L/min (33% N\textsubscript{2}O). This final N\textsubscript{2}O/O\textsubscript{2} ratio was maintained for nine minutes, during which a sham operative dental procedure was conducted. At the completion of this sham treatment, the N\textsubscript{2}O was secured and the oxygen flow was increased to 9.0 L/min for at least four minutes to purge the N\textsubscript{2}O from the patient. The total length of exposure to N\textsubscript{2}O per subject was 18 minutes.
Table 1. Comparing the baseline vital sign values of the four groups.

<table>
<thead>
<tr>
<th>Group</th>
<th>Systolic BP</th>
<th>Diastolic BP</th>
<th>Respiration rate</th>
<th>Pulse rate</th>
<th>Room air N/O</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Mean</td>
<td>SD</td>
<td>n</td>
<td>Mean</td>
</tr>
<tr>
<td>Control</td>
<td>12</td>
<td>114.8</td>
<td>7.22</td>
<td>12</td>
<td>64.9</td>
</tr>
<tr>
<td>Accuutron</td>
<td>12</td>
<td>117.6</td>
<td>13.43</td>
<td>12</td>
<td>69.8</td>
</tr>
<tr>
<td>Matrix</td>
<td>12</td>
<td>118.4</td>
<td>10.78</td>
<td>12</td>
<td>67.8</td>
</tr>
<tr>
<td>Porter/Brown</td>
<td>12</td>
<td>114.3</td>
<td>10.40</td>
<td>12</td>
<td>64.7</td>
</tr>
<tr>
<td>All</td>
<td>48</td>
<td>116.3</td>
<td>10.69</td>
<td>48</td>
<td>66.8</td>
</tr>
</tbody>
</table>

Fig. 4. Miran 203 sensor adjusted 18 inches from patient's head at the two-o'clock position.

In all cases, patients were alert and responsive throughout the treatment period. The patients were able to independently maintain a patent airway and respond appropriately to physical stimulation and verbal commands at all times. The concentrations, flow rate, and duration of administration of oxygen and N/O were documented. No patients experienced any discomfort at any time during the procedure. No treatment was aborted due to an untoward reaction.

Sham procedure
The sham dental operation simulated tooth cavity preparation (Fig. 3). A "dummy" bur was used in a high-speed handpiece. The "dummy" bur is incapable of cutting action and serves only to stabilize the handpiece bur chuck during operation. The handpiece ran for one minute in the subject's mouth at full speed with a standardized flow of coolant/irrigation water. An assistant applied high-speed evacuation at the same time. After a 15 second break, the handpiece was run again for another minute, followed by another 15 second break and a final one minute run. Following the completion of handpiece operation, the patient continued to breathe the gas mixture until it was secured.

Documentation and clinical measurements
A portable infrared spectrophotometer sensor (Miran 203, Irwensee, Foxboro, MA; 866/746 6477) was calibrated professionally prior to the study. The instrument's sensor was placed opposite the dentist at a height of 18 inches above the patient's nose at the two-o'clock position (Fig. 4). The sensor position simulated that of a dentist or technician on the other side of the dental chair. This position has been used previously and was chosen to minimize interference with spectrophotometer accuracy due to carbon dioxide and water vapor exhaled by the investigator. The spectrophotometer was calibrated using a N/O filter before each clinical trial. Ambient N/O concentrations, registered by the spectrophotometer, were recorded at baseline, 3, 9, 10, 13, and 18 minutes and after 4 minutes of 100% oxygen (Fig. 5). The recorder remained blinded during the entire course of the clinical trials.

Clinical control
All volunteers participated in a clinical control session in which the study design was duplicated with one exception: no scavenging system was employed. During these sessions, the researchers breathed through portable oxygen units.

Results
Baseline differences
The first analysis compared the baseline values of the four groups. Summary descriptive statistics are shown in Table 1. The four groups did not have a different
diastolic BP (F(3, 44) < 1, p = 0.7298), systolic BP (F(3, 44) = 1.2, p = 0.3243), respiration rate (F(3, 44) = 1.9, p = 0.1385), pulse rate (F(3, 44) < 1, p = 0.6428), or room air N\textsubscript{2}O (F(3, 44) < 1, p = 0.6948).

Ambient N\textsubscript{2}O levels (ppm) were analyzed using the repeated-measures crossover approach of Iones and Kenward to compare the scavengers across time. The analysis uses the baseline as a covariate (the baseline N\textsubscript{2}O values were taken to be the average of the room air level and the zero-minute level) and uses subjects as their own control. The model also included effects for scavenger, minutes, a scavenger minutes interaction, and period, meaning that the N\textsubscript{2}O values at 3, 9, 10, 13, 18, and 22 minutes were compared using the baseline as a covariate. The subjects were tested during four experimental periods. A cross-over design also must assess whether there is any significant difference associated with the first through the fourth observation period; there was not for this study (F(3, 249) = 1.11, p = 0.3470).

The means for each group at each data collection time are shown in Table 2 and illustrated in Figure 5. The N\textsubscript{2}O flow rate is shown in Figure 6. As the N\textsubscript{2}O flow rate increased, the ambient N\textsubscript{2}O level also increased until after 10 minutes. There was a significant increase in N\textsubscript{2}O levels between 3 and 9 minutes overall, between 9 and 10 minutes overall, and within each scavenger (p < 0.0001) for both intervals. The decrease in ambient N\textsubscript{2}O at the 13 minute measurement can be explained by the high volume evacuation used during the sham operation. There was a significant decrease in N\textsubscript{2}O levels between 10 and 13 minutes overall and also within each scavenger (p < 0.0001); and a significant decrease in N\textsubscript{2}O levels between 18 and 22 minutes overall and also within each scavenger (p < 0.0001).

The repeated measures ANOVA results for the interaction between scavenger-time indicated that the differences between the four scavenger conditions were not constant at each time point (F(3, 249) = 1.39, p = 0.2784). Therefore, the four scavenger conditions were compared at each time point. Each of the scavenger groups differed significantly from the others. The Porter/Brown unit was the most efficient, followed by the Accumet and the Matrix. At every time interval during the procedure, the Porter/Brown scavenger left the operator with significantly less N\textsubscript{2}O than any of the other methods. The Porter/Brown scavenger remained between 71 and 91% of the N\textsubscript{2}O compared to the control.

Oxygen was assessed at three time points during the procedures. The means are shown in Table 3. Blood oxygen saturation was analyzed with repeated measures ANOVA. There was no significant interaction between the four scavenger methods (F(4, 44) = 1.36, p = 0.2683), no significant change across time (F(2, 88) = 1.39, p = 0.2274), and no significant interaction between group and time (F(6, 88) = 2.07, p = 0.0644). The average blood oxygen saturation value (expressed as a percentage) using any of these four methods was 99.1% (SE = 0.37%).

**Discussion**

The significant finding of this study was that at all times during the clinical trials, N\textsubscript{2}O levels were significantly lower using the Porter/Brown scavenger than either the Matrix or Accumet devices during mock dental treatment. The Porter/Brown unit...
Brown scavenger removed between 71% and 91% of the N₂O compared to the control. The Porter/Brown maintained ambient N₂O levels below 50 ppm; the other units did not. This study confirms the results of previous studies indicating that the Porter/Brown scavenger performed better than the other two scavenging systems. These findings are of significant to dental health care providers.

A distinct advantage of the Porter/Brown mask design is that a tight fit is not critical. The outer mask design is open, permitting effective evacuation of the escaping gas to occur around a loosely fitted nosepiece. The Porter/Brown outer mask encompasses the entire inner nasal hood, unlike the Accutron and Matrix, where the outer scavenging caps are perched on top of the nasal hood. Due to the close proximity to the nose and mouth, the Porter/Brown scavenging hood readily captures escaped N₂O. Also noted in this study was that the rubber lining at the periphery of the Porter/Brown nasal hood is very soft and pliable. A better adaptation on the nasal hood to the face was achieved with the Porter/Brown mask due to the soft, pliable rubber hood. This finding also was noted in unsolicited comments from the subjects. With a better seal, one would expect fewer leaks and less release of N₂O into the ambient room air.

It also was observed that as the N₂O flow rate increased, the ambient N₂O level also increased. The only notable exception was the precipitous drop in ambient N₂O levels when high volume evacuation was introduced. This finding is consistent with that of Carlson et al, who used thermocouples to document N₂O escape during dental procedures.

An interesting observation is the sharp increase in ambient N₂O during the 9-10 minute interval, which corresponds to time of rubber dam placement. This rapid spike in ambient N₂O was consistent for all three scavenger units and the control. This result could have been anticipated when one considers that as the mouth is opened during rubber dam placement, a plume of N₂O is allowed to escape the oral cavity, rapidly increasing ambient N₂O levels recorded by the Miiran sensor.

Christensen et al evaluated procedural influences on ambient N₂O levels. They concluded that rubber dam isolation did not significantly affect the levels of ambient N₂O, even though the reported TWA of ambient N₂O decreased from 192 ppm to 109 ppm following rubber dam placement. The results of this study conflict with their results in that during our sham dental treatment, ambient N₂O levels increased during the period of rubber dam placement regardless of which scavenger unit was used. This finding confirms the result of McGlothlin et al, who demonstrated with infrared imaging that rubber dam placement simply redirected the flow of N₂O out of the sides of the rubber dam. However, this effect was reversed rapidly when high volume evacuation was introduced.

Conclusions
1. Under mock dental treatment conditions, the Porter/Brown scavenger system reduced ambient N₂O levels over the time of N₂O delivery to levels below those recommended by the American Conference of Governmental Industrial Hygienists (50 ppm).
2. Supplemental high volume oral evacuation significantly reduced ambient N₂O levels during dental procedures.
3. Rubber dam application and the corresponding opening of the oral cavity increased ambient N₂O levels. Supplemental high volume oral evacuation can mitigate this effect.
4. The four groups showed no significant difference in diastolic or systolic BP, respiration rate, or pulse rate.
5. N₂O administration did not significantly affect blood oxygen saturation. The average pulse-oximeter (blood oxygen saturation) reading using any of these four methods is 99.1%.
6. The clinical evaluation of the efficacy of three N₂O scavenging units during dental treatment, from most efficient to least efficient, was Porter/Brown, Accutron, and Matrix.

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References


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