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The Oxygen Index of Surgical Drape Materials

ABSTRACT: An effective method for minimizing operating room fires is to use materials that are least flammable in air and in oxygen-enriched atmospheres (OEA). The objective of this study was to characterize the flammability of commonly used surgical drapes by measuring the minimum concentration of oxygen ($[O_2]$) required to support a candle-like flame on the test specimen, the oxygen index (OI) [1]. Under the conditions studied, the OI was 17.8 for woven cotton towels (Huck), 18.5 for non-woven cellulose draping, and 22.8 for polypropylene draping. These data demonstrate that materials commonly used for surgical draping have an OI less than or near the O_2 content of ambient air (21%), making them particularly susceptible to fire in the localized OEA of the operating room. Quantitative measures, such as the OI, are useful for determining the relative flammability of materials and their consideration should play an important role in optimizing operating room safety.
KEYWORDS: operating room, fire, surgical drape, oxygen index, flammability

Introduction

The primary function of a surgical drape is to create a sterile field around an incision during surgery and to provide a contamination barrier. Typically, the drape is placed over the patient and an incision is made through an opening in the drape. Surgical drapes are either woven or non-woven. Woven drape materials are usually cotton, including linen, and are almost exclusively polyester coated. Non-woven drapes are usually polymeric, most commonly polypropylene. Surgical drapes are required to perform a unique set of functions such as delineated in the standard proposed in the European Committee for Standards (CEN) EN 13795 Part 2 document. The scope of that proposed standard includes the statement that the standard "is intended to prevent the transmission of infectious agents between patients and clinical staff during surgical and other invasive procedures." Test methods are proposed to determine the following: resistance to microbial penetration, cleanliness, linting, resistance to liquid penetration, bursting strength, tensile strength, and adhesion for fixation for the purpose of wound isolation. None of these proposed test methods address fire safety. In consideration of the 50-100 reported operating room fires per year, the flammability of surgical drapes requires further study and information dissemination [2].

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While relatively rare, the potential for and severity of operating room fires is enhanced due to oxygen-enriched atmosphere (OEA) created by O_2 administered to the patient during surgery. In OEA, combustible materials ignite more readily and burn more vigorously creating dangerous potential for an ignition source to lead to a violent flame. Consequently, the operating room staff likely face greater difficulty containing and extinguishing the fire, exposing both the staff and patient to serious injury or death [3]. OEA are reportedly involved in 74% of operating room fires [2]. Therefore, an effective method to minimize operating room fires is to utilize materials that are least flammable in air and in OEA. A proper fire risk assessment requires an understanding of the combustion characteristics of relevant materials in OEAs.

Three components are required for fire: an ignition source, an oxidizer, and a fuel. In operating room fires, the ignition source is commonly an electrosurgical unit or laser and the oxidizers present include O_2 and nitrous oxide [2]. Surgical drapes are a source of fuel in the majority of operating room fires, as estimated from data reported to the Food and Drug Administration and investigations by Emergency Care Research Institute (ECRI) [2]. The $[O_2]$ that exists in and around these drapes is not well characterized or understood. However, it has been reported that OEA up to 50% routinely exist under the drapes, particularly in surgery involving the head and neck where supplemental O_2 is administered by nasal insufflation [4, 5]. These localized O_2 pockets likely account, at least in part, for the prevalence of drapes as fuel in operating room fires. Despite being recognized as a primary source of fuel, little is known about the relative safety of the various materials from which surgical drapes are manufactured.

In a previous study, the response of drape materials to CO_2 laser ignition was investigated in air and OEAs (50% and 95% O_2) [6]. The focus of that study was the time required to ignite a material, which was shown to decrease strongly with oxygen concentration and to vary with material type. Another pertinent measure of flammability, addressed in the present study, is the minimum $[O_2]$ in a gas mixture required to support candle-like flame on a test specimen, the oxygen index (OI). The objective of this study was to measure the OI of commonly used surgical drapes manufactured from non-woven cellulose, woven cotton, and polypropylene.

Materials and Methods

The procedure was consistent with ASTM D2863 with minor modifications as described below [1].

Materials

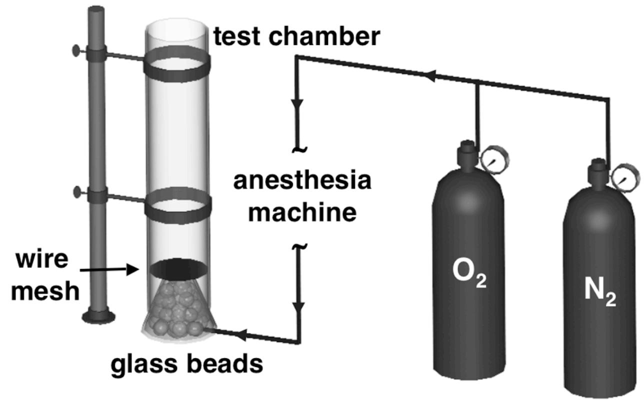
Compressed O_2 and N_2 cylinders of greater than 99% purity were obtained from Praxair (Danbury, CT) and Airgas (Radnor, PA). Natural gas, used as the fuel source for the flame igniter, was from a house supply line. The materials tested were non-woven cellulose draping from Allegiance Healthcare Corporation (McGaw Park, IL), woven cotton towels from Medical Action Industries (Arden, NC), and polypropylene draping from Kimberly-Clark (Roswell, GA). To emulate the condition of the materials at the time of use in the operating room, specimens were removed from sterile packaging on the day of testing.

Experimental Set-up

A heat-resistant glass tube (Pyrex; 600 mm tall x 70 mm inside diameter) was used as a test chimney (Figure 1a). The O_2/N_2 gas mixture entered the chimney through a base containing 5 mm diameter glass beads to evenly distribute the gas. An Ohmeda Modulus anesthesia machine (Ohmeda Medical, Madison, WI) controlled the flow of N_2 and O_2 to obtain the desired [O_2] and maintain an upward flow rate of ~40 mm/s within the test chimney. A galvanic O_2 analyzer (Mini-OX I; Mine Safety Appliance Co.; Pittsburgh, PA) was used to measure the [O_2] within the test chimney immediately prior to testing. A flame igniter (2.3 mm diameter) with an ~10 mm flame was inserted into the chimney as an ignition source. In accordance with the standard, the method of ignition used was propagating ignition.

A custom aluminum support frame was used to secure 150 x 50 mm test specimens and lower the upper end of the specimen ~100 mm past the top of the chimney (Figure 1b). The frame contained reference markings for the purpose of assessing location of ignition, period of burning, and extent of burning. In accordance with ASTM standard D2863, a burn response ("X") was recorded when the period of burning exceeded 180 seconds or the flame maintained on the specimen propagated the 80 mm between reference marks on the frame [1]. A no burn response ("O") was recorded if neither condition was met.

(a)



(b)

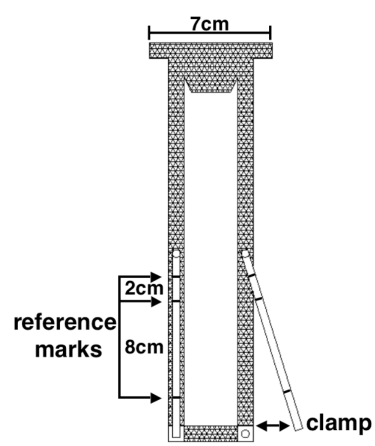


FIG. 1— (a) experimental set-up and (b) specimen support frame

Measuring the Oxygen Index

The $[O_2]$ (expressed as % by volume) for the first test of each material was selected based on the burning behavior of the material in air. Depending on whether the material burned rapidly, unsteadily, or not at all in air the first test was performed at 18%, 21%, or 25% O_2, respectively. The $[O_2]$ was adjusted for each successive specimen until an "X" response and an "O" response were recorded within 1% O_2 of each other. Of these two, the $[O_2]$ that lead to an "O" response was designated as the preliminary OI of the material.

The next series of tests, designated as the N_L series, began with an $[O_2]$ equal to the preliminary OI of the material. The $[O_2]$ in subsequent tests was increased or decreased by 0.2% (step size; *d*) from the preceding test depending on whether that test gave an "O" or an "X" response, respectively. Testing continued until a response different from the first in the N_L series was recorded. Four additional tests using the same criteria and step size were performed.

Calculating the Oxygen Index

A correction factor (k) was determined from the ASTM standard based on the last five tests and the number of like responses from tests in the N_L series [1]. The OI was calculated according to the formula:

$$OI = C_F + kd$$

where (C_F) is the $[O_2]$ used to test the final specimen and (*d*) is the step size. The estimated standard deviation (σ*) of the $[O_2]$ from the last 6 measurements was calculated as:

$$\sigma^* = \left[\frac{\sum_i (C_i - OI)^2}{5} \right]^{1/2}$$

where (C_i) is the $[O_2]$ used for each of the last *i* tests (*i*=6). The estimated standard deviations were used to assess confidence in the OI measurement. Specifically, σ* was compared to the step size and it was confirmed that $\frac{2\sigma^*}{3} < d < \frac{3\sigma^*}{2}$.

Results

The qualitative burning behaviors of the three materials in ambient air were distinctly different. The non-woven cellulose ignited readily and burned with a luminous flame that released visible smoke. The woven cotton towel did not ignite as readily as the cellulose, and burned more slowly with more of a smoldering spread rather than a flaming spread. However, both materials burned in air, and therefore the first test in the procedure for determining the OI was 18% O_2 for these materials. The polypropylene did not burn steadily in air. Rather, the material appeared to shrink away from the ignition source as it was brought near the sample. Therefore, the first test was conducted at 21% O_2 for polypropylene.

Under the conditions studied here, the OI was 17.8 for woven cotton towels, 18.5 for non-woven cellulose draping, and 22.8 for polypropylene draping (Table 1). The corresponding estimated standard deviations 0.22, 0.30 and 0.19 were within the allowable range 0.13 –0.3 for the 0.2% step size used in all tests.

TABLE 1—Oxygen Index (OI) Measurements

	N_L series measurements					N_{L+1}	N_{L+2}	N_{L+3}	N_{L+4}	C_F	**OI**
Woven Cotton Towel											
$[O_2]$	17.4	17.6	17.8	18.0	18.2	18.2	18.0	17.8	17.6	17.4	**17.8**
Response	O	O	O	O	⇒	X	X	X	X	O	
Non-woven Cellulose											
$[O_2]$	17.9	18.1	18.3	18.6	. . .	18.6	18.4	18.2	18.4	18.6	**18.5**
Response	O	O	O	⇒	. . .	X	X	O	O	O	
Polypropylene											
$[O_2]$	22.5	22.7	. . .	. . .	. . .	22.7	22.5	22.7	22.9	22.7	**22.8**
Response	O	⇒	. . .	. . .	. . .	X	O	O	X	O	

Discussion

The purpose of this study was to quantitatively assess the flammability of commonly used surgical drapes. The OI of woven cotton towels was determined to be 17.8, non-woven cellulose draping to be 18.5 and polypropylene draping to be 22.8. Most importantly this study calls attention to the consequences of the fact that drape manufacturers do not consider fire risk as a primary design objective.

Ideally, surgical drapes should be able to withstand ignition in OEAs up to 50% [4, 5]. Unfortunately, presently available materials do not meet this objective. More practically, surgical drapes should be able to withstand ignition in air. If a material that has an OI less than or equal to 21% is ignited (such as woven cotton and non-woven cellulose), a flame can propagate away from the ignition point and ultimately encompass the entire drape, yielding devastating results. Utilizing a drape with an OI greater than 21% (such as polypropylene) would prevent such a scenario.

The OI data presented here is useful information but should not be considered in isolation. It must, instead, be integrated into an overall fire risk assessment in which other fire test results are considered. Combustion characteristics vary depending on fuel characteristics (spatial orientation, geometry, mass, etc.), ignition source characteristics, oxidant concentration and other characteristics such as degree of ventilation, which would likely vary from the laboratory to the clinical setting. For example, in conditions where polypropylene burns (i.e. supported by an adjacent burning material or in an $[O_2]$ above its OI), it may melt and release flaming droplets which could cause patient burns or ignite other materials.

It is also important to note that the oxygen index of a material is independent of other flammability characteristics such as time to ignition and behavior in oxygen concentrations above that of its OI. A study of laser ignition of surgical drape materials determined that the time to ignition in air was shorter for non-woven cellulose (2.7 sec) than woven cotton towel (11.9 sec) [6]. In 50% O_2, polypropylene ignited virtually instantaneously (0.14 sec) while non-woven cellulose and cotton had longer ignition times (1.1 and 2.3 sec, respectively) [6].

Additional quantitative studies such as flame spread rate and toxicity of combustion products will likely, in conjunction with the OI and other measures, offer better direction in decision making as to which drape to use in a particular clinical application. Ideally, materials that are more resistant to flammability, easily extinguished, and serve the same antiseptic functions of drapes currently used should be considered. Until such drapes are available, it is the responsibility of the anesthesiologist to consider the risk: benefit ratio attendant to nasal oxygen insufflation during monitored anesthesia care, particularly during procedures involving the head and neck. By decreasing the amount of oxygen present in the surgical field, temporary compensation can be achieved for the unacceptable oxygen indexes of currently available surgical drapes.

Acknowledgments

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