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An Economical Alternative for the Secondary Container Used for Transporting Infectious Disease Substances

Joseph G. Mandella, Jr.
Robert P. Garner

Civil Aeromedical Institute
Federal Aviation Administration
Oklahoma City, Oklahoma 73125

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16. Abstract

The safe containment of biological specimens during air transport is of growing concern as the number of shipments and hazards associated with such material increases. The purpose of this study was to examine the durability of adhesive-closure polyethylene (PE) bags upon exposure to altitude. The tests consisted of two phases. The objective of the first phase was to identify the most appropriate combination of bag composition, thickness, and size. The second phase was to determine the most appropriate packing techniques to be used with the bag best suited for air transport. Both phases consisted of a hypobaric chamber being taken to a simulated altitude of 45,000 feet. The PE bags contained specimens packaged in International Air Transportation Association approved containers. Initial tests indicated that differences in material composition and thickness did not significantly alter the ability of the PE bags to withstand the pressure differential. The second test phase suggested that the most effective means of preventing bag rupture upon exposure to altitude was to use oversized bags, evacuated of any residual air as completely as possible.

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AN ECONOMICAL ALTERNATIVE FOR THE SECONDARY CONTAINER USED FOR TRANSPORTING INFECTIOUS DISEASE SUBSTANCES

INTRODUCTION

Over the last two decades, technological advances have expanded laboratories' abilities to analyze biological specimens or substances. A number of areas benefit from having diagnostic capabilities available, including accident investigation, criminal and forensic identification, medical diagnosis, and screening for employment. Since the increased analytical accuracy of tests of biological specimens has found greater applicability in the aforementioned areas, the number of laboratories, the number of samples analyzed, and the number of samples transported to and from laboratories for analysis have increased.

The potential for infection is an inherent risk in the handling and transport of biological specimens. Transport regulations require that infectious and non-infectious specimens be packaged differently. An infectious substance is defined in the Code of Federal Regulations (CFR) 49, Paragraph 173.134. The specific tests and guidelines covering the packaging of such materials for transport are found in CFR 49, Paragraph 178.609 (*Test requirements for packagings for infectious substances (etiologic agents)*), and Paragraph 173.196 (*Infectious substances (etiological agents)*). These regulations are consistent with the Infectious Substances and Packaging Instruction 602, issued by both the International Air Transport Association (IATA) and the International Civil Aviation Organization (ICAO).

Currently, the United States Department of Transportation (DOT) recognizes ICAO packaging instructions for infectious substances. In brief, this requires a primary receptacle with leak proof seal, a leak-proof secondary packaging, and absorbent material separating the primary and secondary containers. Changes in the regulations regarding transport of infectious substances are being considered by the DOT Research and Special Programs Administration. The Research and Special Programs Administration issued a Notice of proposed rulemaking and notice of public meeting addressing infectious substances on December 21, 1994. These proposed regulatory changes would effect the CFR 49, paragraphs 171, 172, 173, and 178.

One potential problem covered by regulations is the accurate and reliable assessment of specimen infectiousness when being packaged for shipment. Awareness and sensitivity to this issue have been heightened by the Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) epidemic. In response to these concerns, consideration has been given to requiring all specimens be packaged as if they were infectious. Such regulations could lead to a significant increase in packaging cost. Part of this additional cost comes from the expense of the rigid containers that have been used for the secondary packaging of infectious substances.

The purpose of these tests was to evaluate the ability of polyethylene (PE) bags to withstand an internal pressure differential consistent with IATA and ICAO regulations for the transport of infectious substances. During the testing, we also wanted to identify packaging techniques that would enhance the utility of the polyethylene transport bags to serve as secondary containers for the transport of infectious substances. The work supplements research at the FAA Civil Aeromedical Institute (CAMI) that is aimed at optimizing medical equipment and supplies for use in air ambulance and regular air carrier transport settings.

METHODS

A hypobaric chamber was used to create the internal pressure differential specified in the transport regulations. The testing was divided into two phases. The first phase was designed to identify which physical characteristics (size, type of PE, and extrusion process) derived from the bag manufacturing process best withstood a pressure differential without rupturing. The second phase was to evaluate if packing materials and techniques have an influence on bag performance. Incorporated in both phases was the evacuation of the hypobaric chamber in steps equivalent to 5,000 foot increments, to an altitude of 45,000 feet above sea level (Figure 1). At each 5,000 foot increment, ascent was halted and the condition of the bags was recorded. Atmospheric pressure, temperature, and relative humidity were recorded electronically during all of the altitude tests.

Phase 1. The polyethylene bags being tested were of varying size, physical materials, and thicknesses (Table 1). Bag composition consisted of linear low density polyethylene (LLDP) or low density polyethylene (LDP) combined with 5% ethylene vinyl acetate (EVA). Theoretically, LLDPE is a stronger polymer than LDPE, due to the manufacturing

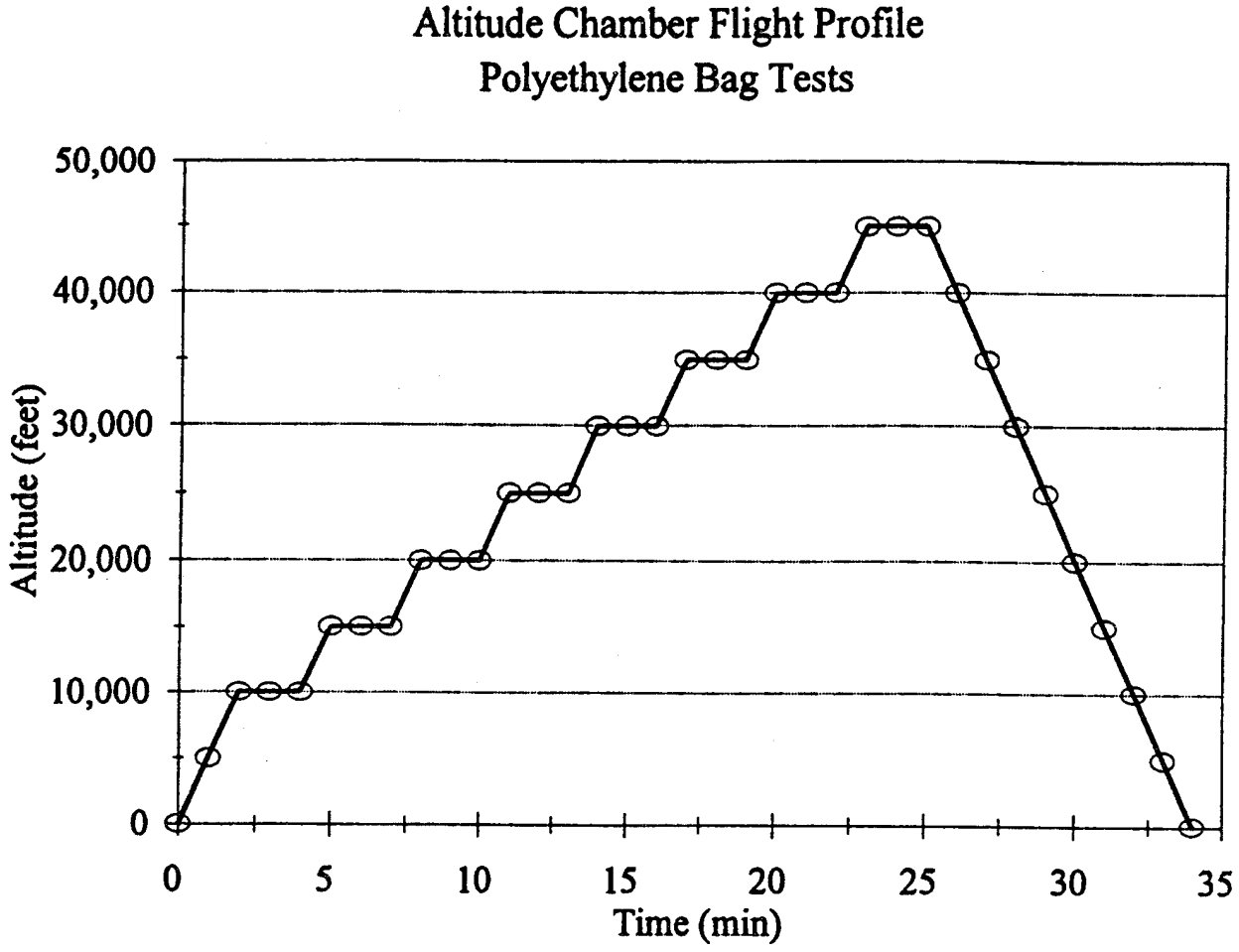

Figure 1. Altitude chamber profile used for the two-phase testing of polyethylene bags. Approximately two minutes were spent at each equivalent altitude.

process resulting in better hydrogen bonding of the polymers. Phase 1 included the following packaging conditions (treatments): (a) bag sealed without adding or removing any air, (b) bag sealed after air removed by squeezing, and (c) bag sealed after being filled to capacity with air. To mimic containment of infectious specimens, a 90 cc water-filled specimen bottle was included in each bag under packaging conditions a, b, and c. All test bags included an adhesive closure.

Phase 2. Two types of LDPE bags with inside dimensions of 12.5 x 17.63 and 14.25 x 21.0 were subjected to three packaging conditions. The conditions included: (a) sealed bag containing a hard foam rack but no test tubes, (b) sealed bag containing a soft poly-foam rack without test tubes, (c) sealed bag containing a soft poly-foam rack half full of test tubes and air removed by squeezing.

Bag #	Inside Dimensions	Outside Dimensions	Material/ Thickness
1	6.125 x 11.125	6.75 x 11.50	LLDPE / 0.00225
2	4.25 x 8.25	5.00 x 9.00	LDPE / 0.00200
3	8.25 x 10.25	9.00 x 11.00	LDPE / 0.00200
4	13.25 x 16.50	14.00 x 17.00	LDPE, Co-Extruded 0.00350
5	11.50 x 17.13	12.5 x 17.63	LDPE, Co-Extruded 0.00350
6	11.50 x 17.13	12.5 x 17.63	LLDPE / 0.00225
7	14.25 x 21.00	14.25 x 21.00	LDPE, Co-Extruded 0.00350
8	14.25 x 21.00	14.25 x 21.00	LDPE / 0.00225
9	15.125 x 20.00	15.375 x 21.00	LDPE/ 0.00300

Table 1. Dimensions and materials tested during phase 1 of this project. All bags contained approximately 5% ethylene vinyl acetate (EVA). LLDPE-linear low density polyethylene, LDPE-low density polyethylene.

Bag		Tmt	1	2	3	4
1	LLDPE, 5% EVA	a	+	+	+	+
		b	+	+	+	+
		c	38	33		40
2	LDPE, 5% EVA	a	+	+	+	+
		b	+	+	+	+
		c	+	+	+	23
3	LDPE, 5% EVA	a	+	+	+	+
		b	+	+	+	+
		c	+	+	+	+
4	LDPE, 5% EVA	a			28	28
	Co-Extruded	b			+	+
		c				+
5	LDPE, 5% EVA	a	+	27	25	21
	Co-Extruded	b	+	+	+	+
		c	27	+	+	28
6	LLDPE, 5% EVA	a	38			+
		b	41	45	+	38
		c	38			+
7	LDPE, 5% EVA	a	45			+
	Co-Extruded	b	45	40		38
		c	23	+		+
8	LDPE, 5% EVA	a	32	39	45	
		b	41	+	45	
		c	42	30		
9	LDPE, 5% EVA	a	+	+	+	+
		b	+	+	+	+
		c	+	+	+	+

Table 2. Results from phase 1 testing. Four separate tests were performed for each treatment. Blank slots in the table represent a test scenario that was either not performed or where bag performance was inconclusive. The number represents the altitude in thousands of feet at which the bag failed. A plus sign (+) indicates that the bag did not fail during the test. Treatment codes are as follows: a - no air removal, b - hand evacuation of air, and c - bag filled to capacity with air.

RESULTS

A summary of the data collected during phase 1 is presented in Table 2. There did not appear to be any major differences related to bag manufacturing techniques. The smaller bags tended to withstand the induced pressure differential better than the larger bags. Bag number 9 was a vented bag that contained a filter through which air molecules could escape, but infectious materials would be contained. The size of the venting of this particular bag was not disclosed by the manufacturer. Therefore, it is difficult to imagine a scenario in which this bag could be used with confidence for the transport of infectious substances. A summary of the data collected during phase 2 is presented in Table 3. As can be seen from Table 3, if a soft foam rack was not evacuated before being packaged in the LDPE bags, bag rupture always occurred (treatment b). However, if the air was evacuated from the soft foam by squeezing during packaging, the LDPE bags did withstand the induced pressure differential.

Bag	Size & Type	Tmt	1	2	3	4
1	12.5 x 17.63	a	+	+	+	+
	LDPE, 5% EVA	b	35	39	39	40
		c	+	+	+	+
2	12.5 x 17.63	a	+	+	+	+
	LDPE, 5% EVA	b	37	45	41	40
		c	+	+	+	+
3	14.25 x 21.00	a	43	+	+	+
	LDPE, 5% EVA	b	32	34	35	35
		c	+	+	+	+

Table 3. Results from phase 2 testing. Treatment codes are as follows: a - hard foam rack, no test tubes, b - soft foam rack with no test tubes, and c - soft foam rack with test tubes, air hand evacuated.

DISCUSSION

The purpose of these tests was to evaluate polyethylene bags and associated packaging techniques. The goal was to determine if the bags could withstand an internal pressure differential consistent with the transport requirements for secondary containers of infectious substances, as defined by ICAO. Phase one of the testing attempted to identify the manufacturing parameters that yielded the sturdiest bag. Although there was not a definitive performance difference, LDPE and LDPE, Co-Extruded bags seemed to tolerate a high-altitude-induced pressure differential better than LLDPE. When normalized for size there was not a large performance difference between the LDPE and LDPE, Co-Extruded bags. This probably reflects an increased bag surface area per unit volume of air contained. The most important influence on bag performance was the packaging technique utilized.

Evacuation of air is very important. Obviously, the less air contained within a bag, the less potential volume expansion available for a given pressure differential. This fact also has implications for the packing material used for the primary container. A hard foam rack contains little, if any, air within its structure. Unfortunately, there is no convenient mechanism for evacuating air contained in empty test tube or bottle compartments. The soft foam rack contains a large volume of air within its structure. However, the air contained in the foam structure and empty compartments can be evacuated relatively easily by squeezing before the bag is sealed. If using soft foam racks, the transporter must recognize the extreme importance of proper instruction for packagers to use correct procedures.

If used properly, polyethylene bags and their derivatives can perform to ICAO standards for secondary containers for the transport of infectious substances. Therefore, the bags have the potential to be used as an alternative to rigid secondary containment vessels. The use of a bag as a secondary containment vessel may significantly reduce shipping costs associated with the transport of large numbers of samples. Cost savings would be particularly dramatic if regulatory bodies introduced future guidelines requiring any biologic or pathologic specimens to be shipped as if they were infectious.

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