An Advanced Aerogel Packaging Solution for Cold-Chain Biologics Materials Handling

Abstract:

Long distance transportation of biologistics is currently limited due to the fact that most containers have a limited time that temperatures inside the containers can be kept steady and at the required low temperature. In some cases expensive and heavy data loggers are used that need to be returned to the vendor upon delivery of the biologistics product. Here, we propose the design, construction, and testing of a light-weight aerogel-based containment package that can be utilized for the safe transportation of temperature sensitive biologics, under sterile environment. Aerogels are currently known as the best insulating material and have demonstrated superior thermal insulating capability compared to materials routinely used in the shipping and storage industry. Its light-weight and biologically-friendly nature makes this material an excellent choice for long-distance transportation and containment of biologistics and the preliminary data acquired in this work will serve as a platform for further growth and utilization/ incorporation of this material in packaging and transportation.

Team Members:

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Expertise, Facilities, and Personnel Contributions:

Sabri: The Nano, Bio, and Space Materials Laboratory of Dr Sabri is an experimental materials physics laboratory located in Manning Hall. The laboratory is equipped with a synthesis room and a separate characterization room containing all the required infrastructure and equipment for synthesizing and testing of the proposed aerogel containment structure. Furthermore, the Sabri lab is equipped with a biologics-grade environmental chamber that can mimic the cell culture environment that the packaging may potentially be exposed to. Sabri has been consistently funded for her materials physics research that involves synthesis and preparation of polymeric devices involving elastomers and aerogels for various applications and industries, mainly with an interest in light-weight devices for insulation and sensing systems. Dr. Marchetta has experience in engineering, design, and construction using a wide variety of materials, including aerogels and polymers. Along with the Sabri Lab facilities, he has space for both experimental and computational studies. The experiment facilities have been modified specifically for testing prototype containers filled with cryogenic liquids. Dr. Marchetta has 20 years of experience using computational models, such as FLUENT, ABAQUS, and COMSOL. He has dedicated workstations for modeling fluid flow, heat transfer, and mass transfer applications. Dr. Marchetta regularly uses the university's high performance computing (HPC) cluster to run his simulations. The on-going collaboration between Sabri and Marchetta has lead to several funded grants and peer reviewed publications with a focus on heat transfer through light-weight structures constructed of aerogels and polymers. The Sabri/ Marchetta team will continue to work closely on the proposed topic and will seek external funding with the preliminary data acquired from this work.

Background and Overview: The shipment of biological materials is challenging due to the regulatory requirements and classification of the shipment for transport. The purpose for such regulation stems from the fear that package of biological may contain infectious pathogens, which if released could cause infection, illness or death. Commodities such as human and animal blood, tissue, body parts are considered dangerous good (HAZMAT) for transport purposes. Clinical research samples, investigational drugs, and clinical supplies are often considered to be similarly classified. Biological commodities are often time, temperature, and impact sensitive. Existing packaging technology for biological materials is often complex in order to meet regulatory and material environmental requirements. Thus, a need exists to develop a safe, reusable, light weight, and inert, cold packaging solution for transporting biological materials. The investigators have extensive experience in developing, designing, and characterizing advanced thermal management systems with performance expectations in the cryogenic temperature ranges, which are well suited for biologistics applications. Aerogels are a relatively new class of materials with unique material properties particularly suitable for thermal insulation and packaging [1-6]. Aerogels are currently the best known solid thermal insulators and have been explored extensively for insulation applications in the aerospace industry, among others [5,6].

Proposed Work: The team proposes the development, synthesis, and characterization of a light-weight aerogel-based containment packaging that is inert, biocompatible, and easily sterilized by means of methods accepted and approved by the medical community. During the project period the investigators will synthesize, design, and characterize a prototype aerogel-based medical-grade packaging suitable for transport of biologistics with the capability to be completely sealed in a sterile environment (e.g. culture hood) prior to shipping and transport. Reliable thermal control of environmentally sensitive biological materials is essential component in optimizing cold-chain logistics. Aerogel is considered to be the lightest known solid material and is also an excellent thermal insulator, due to it consisting mostly of air. For example, polyimide aerogels with an average density of 0.137 g/cm^3 have a K value of less than 1 as shown in Table 1. Native silica aerogel on the other hand have a thermal conductivity of about 0.017 W/m-K at room temperature. Aerogels have a unique structure made up of a highly connected open pore system with a very high surface area. Aerogel technologies have become a rapidly developing area for thermal insulation applications. The majority of insulation designs available today are based on beads of native, non-cross linked aerogels packed into a “blanket”. This “blanket” is then wrapped around a container made of another material, such as metal or plastic. Since native aerogels are very fragile, brittle, and inherently hydrophilic, the range of insulation design is severely limited. If the “aerogel blanket” is subject to pressure, the non-cross aerogel beads will crush and fragment further leading to uneven distribution of insulation. A serious drawback of any “blanket” technology is that to accomplish an acceptable level of thermal insulation, multiple layers are required and each layer must be physically isolated from the next layer. An additional weakness of native silica aerogels is that they are strongly hydrophilic. Contact with aqueous solutions can cause the structure to break down creating a major problem for sterilization of aerogel-based components. By crosslinking the aerogel, the mechanical properties of the aerogels can be improved by several orders of magnitude although there is a slight increase in the thermal conductivity as compared to native aerogel. For example, polyamide aerogel has a conductivity of 0.035 W/m-K, which about twice that of the native aerogel. In either case, the conductivities of aerogels are comparatively much lower than traditional construction materials, such as metals, plastics, foams, or cardboard. Additionally, by applying a hydrophobic coating, the material can be made to withstand solvent based sterilization techniques which are important for repeatable use of containers that handle biological materials. The aerogels can also be synthesized into thin moderately flexible sheets which can tolerate the stresses of repeated packaging and transport.

Table 1: Thermal conductivity and calculated error for each aerogel, aerogel+polymer, and polymer only sample at 297K and at 77 K.

297K			**77K**		
Sample	k, mean W/m-K	Error W/m-K	**Sample**	k, mean W/m-K	Error W/m-K
Baseline Samples			**Baseline Samples**		
RTV-655	0.1843	0.0007	**RTV-655**	0.0833	0.0042
PCSA	0.0604	0.0015	**PCSA**	0.0214	0.0026
Encapsulated Microparticle Samples			**Encapsulated Microparticle Samples**		
(RTV-655+MP) 28%	0.2034	0.0009	**(RTV-655+MP) 28%**	0.0849	0.0028
(RTV-655+MP) 57%	0.2285	0.0016	**(RTV-655+MP) 57%**	0.0885	0.0060
(RTV-655+MP) 62%	0.2283	0.0009	**(RTV-655+MP) 62%**	0.0943	0.0042
Encapsulated Block Samples			**Encapsulated Block Samples**		
(RTV-655+Bl) 22%	0.1481	0.0030	**(RTV-655+Bl) 22%**	0.0687	0.0069
(RTV-655+Bl)35%	0.1315	0.0082	**(RTV-655+Bl)35%**	0.0625	0.0053
(RTV-655+Bl)53%	0.1198	0.0049	**(RTV-655+Bl)53%**	0.0492	0.0040

Room temperature vulcanization (RTV) polymers are clear high strength, two-component, elastomeric materials primarily composed of silicone rubber. These types of polymers remain flexible and can be used within a temperature range of 160 to 475 K and have a density in the range of 1.2 – 1.45 g/cm^3. Thermal conductivity of polymers is on average 0.1 W/m K, which still relatively low compared to other commonly used packaging materials and containers [7]. These polymers are made by the addition of a curing agent based on the weight ratio. The low viscosity liquid mixture is poured into a mold and must be exposed to a vacuum to remove trapped air before the silicone is vulcanized. The RTV polymer can be then be completely cured at room temperature or above room temperature and sterilized as previously established by Sabri et al [8].

In the proposed small-scale prototype design, the cross linked aerogels will be synthesized separately in bulk. Then, the appropriate amounts of cross linker and resin will be mixed and outgassed in a vacuum oven. A medical grade RTV polymer mixture will be poured into molds of the appropriate dimensions and partially cured. At this stage, the aerogel will be placed on the polymer mixture and additional polymer will be poured over the aerogel to encapsulate it. The compound polymer/aerogel assembly will be outgassed once more and finally cured at 90C for 1-2 hours. The rigidity or flexibility of the final structure can be controlled by 1) dimensions of the aerogel, 2) thickness of the RTV layer, 3) and the ratio of the crosslinker to the resin, and 4) amount of crosslinking agent for the aerogel synthesis.

The proposed prototype aerogel/polymer container will measure 3 cm in diameter and will be capable of holding a 3 cm diameter petri dish or vial. The wall thicknesses of the polymer and aerogel will be determined using simulations and experimental tests to optimize both mechanical and thermal performance of the container. Mechanical performance will be assessed by means of stress and strain analysis. The sealed container can be pressurized by embedding a valve stem into the compound material of the container and using compressed air or liquefied gas, such as nitrogen, to stress the container. The resulting displacement measured can be measured using an extensiometer. Thermal performance will be assessed by determining the heat flux through container at varying ambient temperature. The heat flux through the walls of the container can be measured using thermocouples embedded in the compound material of the container. The team does have previous experience in designing and executing such types of experiments [9,10].

The container and contents will be dropped repeatedly from various heights to determine the resistance to impact and high acceleration. Accelerations can be measured by embedding a small accelerometer into the compound material of the container.

The effectiveness and performance of this design for use as a packaging material will be tested and the data collected will serve as preliminary data required for securing further funding from federal agencies.

Previous Work and Data:

The principal investigators have considerable prior experience in their respective areas of study to draw from to complete the goals and objectives of the proposed effort. Dr. Sabri is an experimental materials physicist with 20 years of experience in the synthesis, characterization, and understanding of bulk and surface properties of mesoporous such aerogels and elastomeric materials such as polymers. Dr. Marchetta has 20 years of experience in the design and simulation of fluid, heat, and mass transport systems. The investigators have an ongoing collaboration which has resulted in the development, characterization, and application of novel compound materials for fluid, heat and mass transport systems. In 2010, they were awarded a grant by NASA to develop a new space-qualified material design for the storage container of liquid cryogenic propellants for use in space. This work culminated in the construction of two prototype small scale cryogenic fluid tanks (shown in Fig. 1) which combined the elastomeric properties of the space qualified polymer RTV 655 with the thermal insulation properties of cross-linked polyamide aerogel. These tanks were tested with liquid nitrogen in normal gravity at low temperature (77K). Measurements of the thermal and mechanical behavior of these tanks during these tests showed that they performed reliably at low temperatures.

The investigators also collaborated on a TNSCORE sponsored study to determine to feasibility of using aerogels as an insulating material in industrial burners. It had been shown in previous research by other investigators that many aerogel materials do not perform well at high temperatures (>300 ^{0}C). As such, aerogel was not seriously considered as an alternative insulator for high temperature applications such as combustion chambers. As a component of the TNSCORE grant, the investigators were able to mechanically and thermally characterize the properties of wide range of candidate aerogel materials after they had been exposed to high temperatures. Using this data, the investigators were able to identify which aerogels that were highly resistant to degradation at high temperature and would be most suitable for use as insulating materials for these applications (shown in Fig. 2). This collaboration has resulted in

Fig. 1: Completed polymer/ aerogel aerogel compound tank for NASA grant.

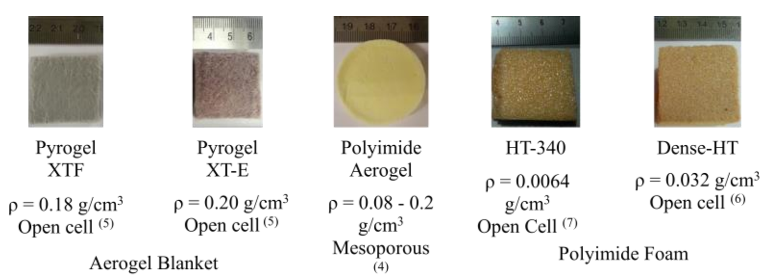

Fig. 2: Variety of aerogels (some synthesized in Sabri lab) tested for a high T combustion environment insulating capabilities.

enhancement of shared measurement and testing capabilities that will benefit the proposed effort to develop and construct a container suitable for handling and transport of sensitive biological materials.

<u>Future Work and Direction</u>:

Aerogel research has grown tremendously in the last decade mainly due to new synthesis protocols that have been developed by the aerogel community, which in turn has made aerogel research safer and less costly. It has been predicted by experts in the field that aerogels will dominate the field of insulation and transportation in the next 10 years simply due to the fact that these materials are the best solid insulating materials known, and, are also the lightest solid currently available. The investigators plan to develop a prototype carrier for biologistics that will take advantage of both properties of this unique material. The preliminary work that will performed by this grant will allow the team collect much-needed feasibility data in this field that can make federal grants more competitive, as a result. The system proposed here is not only attractive and useful for biologistics in the commercial arena, but also highly useful and of interest to defense-related agencies, which is where the follow up grant will be submitted to.

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