Shape Memory Polymer Foams for Biomedical Devices

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Abstract: Developed in last decade, the shape memory polymers (SMP) have been gaining widespread attention for new product innovation. They are lightweight, have a high strain/shape recovery ability, are easy to process, and required properties can be tailored for a variety of applications.

Recently a number of medical applications have been considered and investigated for polyurethane-based SMP materials. Newly developed SMP foams, together with cold hibernated elastic memory (CHEM) processing, further broaden their potential biomedical applications.

Polyurethane-based CHEM foams are described here and major advantages are identified over other medical materials. Recently, several important applications are being considered for CHEM foams as self-deployable vascular and coronary devices. One of these potential applications, the endovascular treatment of aneurysms, was experimentally investigated with encouraging results and is described in this paper as well.

Keywords: Shape memory polymers, cold hibernated elastic memory, polyurethane, aneurysm.

1. INTRODUCTION

Shape memory polymers (SMPs) constitute a group of high performance smart materials that have recently gained widespread attention. Their potential role in clinical applications has only become recognized in the last 7-8 years. These materials were found to be biocompatible, non-toxic and non-mutagenic. Some simple SMP applications are already used in a clinical setting, whereas others are still in development.

Recently developed polyurethane-based SMP foams combined with cold hibernated elastic memory (CHEM) processing, widen their potential medical applications. The glass transition temperature (T_g) of CHEM foams can be tailored for shape restoration/self-deployment of clinical devices when inserted in the human body. They can be miniaturized and deformed, inserted in the human body through small catheters, and subsequently can recover a larger predetermined shape once in satisfactory position.

In this review paper CHEM foam materials and their potential medical applications are described. Their major advantages over other medical materials are delineated. Also, several important medical applications of CHEM foams are explained here as well.

2. CHEM FOAM STRUCTURES

The concept of "cold hibernated elastic memory" or CHEM has been developed by Sokolowski *et al.* as a new, simple, ultra-light, self-deployable smart structure [1-3]. The CHEM technology utilizes polyurethane-based SMP in open cellular (foam) structures or sandwich structures made of SMP foam cores and polymeric composite skins [4]. The polyurethane-based SMP materials have been under development by Mitsubishi Heavy Industries, Japan for the past 18 years [5, 6]. They offer unique properties for a variety of applications. These materials are polyurethane-based thermoplastic polymers with a unique property of exhibiting large changes in elastic modulus E above and below the T_g.

The material's shape memory function allows repeated shape changes and shape retentions [7]. At temperature above the T_g the material enters a rubbery elastic state where it can be easily deformed into any shape. When the material is cooled below its T_g, the deformation is fixed and shape remains stable. At this stage, the material lacks its rubbery elasticity and is rigid. However, the original shape can be recovered simply by heating the material once again to a temperature higher than T_g. This phenomenon is explained on the basis of molecular structure and molecular movements, and is described elsewhere [8]. The unique properties and major advantages of SMP materials over their predecessors, shape memory alloys (SMA) such as lightweight, large shape recovery up to 400% of plastic strain, excellent biocompatibility, easy processing, low cost and more, are explained in another paper [9].

The CHEM foam technology takes advantage of the polymer's heat activated shape memory in addition to the foam's elastic recovery to deploy a compacted structure. The T_g is tailored to deploy and if needed, one may rigidize a structure in fully deployed configuration [10-12]. The stages for use of a CHEM processing and foam structure are illustrated in Fig. (**1**) and are explained as follows:

1. Original Structure: the original structure is produced/assembled in a room held below T_g.

2. Compaction or Rolling: the structure is warmed above T_g to make it flexible and then compacted and/or rolled up for stowing.

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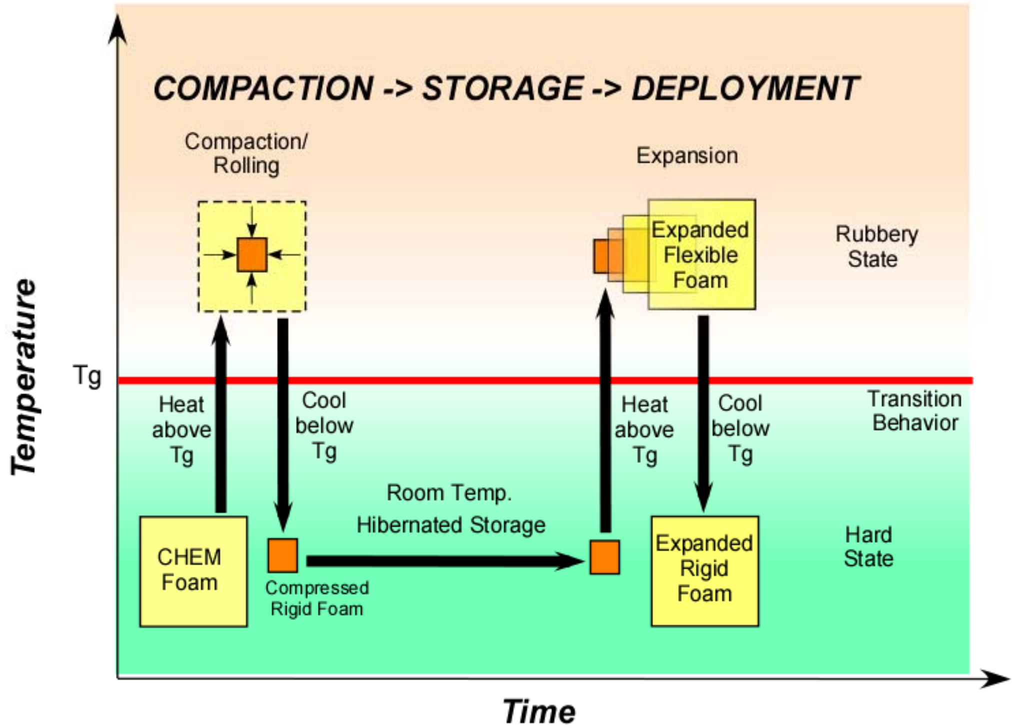

Fig. (1). Cold hibernated elastic memory (CHEM) processing cycle.

3. Hibernation (storage): the compacted/rolled structure is cooled to ambient temperature to achieve the hibernated stowage. As long as the temperature is maintained below T_g, no external forces are needed to keep the structure compressed.

4. Deployment: the compacted/rolled structure is warmed above T_g. The memory forces and foam's elastic recovery cause the structure to naturally deploy back to its original shape and size.

If needed:

5. Rigidization: the deployed structure is cooled by ambient temperature and becomes rigid.

The advantage of this technology is that structures, when compressed and stored below T_g, are a small fraction of their original size and are lightweight (two orders of magnitude lighter than aluminium).

The foam configuration ensures lower mass, higher speed of deployment and higher full/stowed volume ratio when compared with solid SMP materials. Similar to solid SMP, the wide range of T_g can be selected for deployment/shape restoration including a T_g slightly below the human body temperature of ~37°C. Thus allowing a wide variety of potential biomedical device applications [13, 14].

Consequently some biomedical applications are being considered and investigated for polyurethane-based CHEM foams. They are described in the following section.

3. MEDICAL CHEM APPLICATIONS

One property of particular interest to the medical world is that polyurethane-based SMPs were found to have excellent biocompatibility. Standard cytotoxicity and mutagenicity tests have been conducted on these materials with excellent results [14]. Another attractive feature is that the T_g can be tailored for shape restoration/self-deployment of different clinical devices when contacted or inserted in the human body.

Properties that CHEM foams add to SMP properties, including a wide range of porosities, lightweight, high full/stowed volume ratio and precision of original shape restoration, suggest that they have a potential to be used in functional and deployable elements of different clinical devices.

Minimally invasive surgery has made possible the insertion of small devices and materials by laparoscopes. Alternatively, they can also be inserted via the endovascular route. These new approaches have made essential the miniaturization of devices, designed to pass through small skin apertures.

CHEM foams can be miniaturized, deformed and inserted in the body through small catheters. Under the body heat, they can be precisely deployed and recover a much larger predetermined required shape when in satisfactory position [14]. A CHEM foam porosity can be adjusted to the needs of the application. Also, the CHEM technology provides a simple end-to-end process for stowing and deployment, and avoids the complexities associated with other methods for deployment of medical devices.

CHEM foams may find use in medical applications, such as vascular and coronary grafts, orthopedic braces and splints, and medical prosthetics and implants.

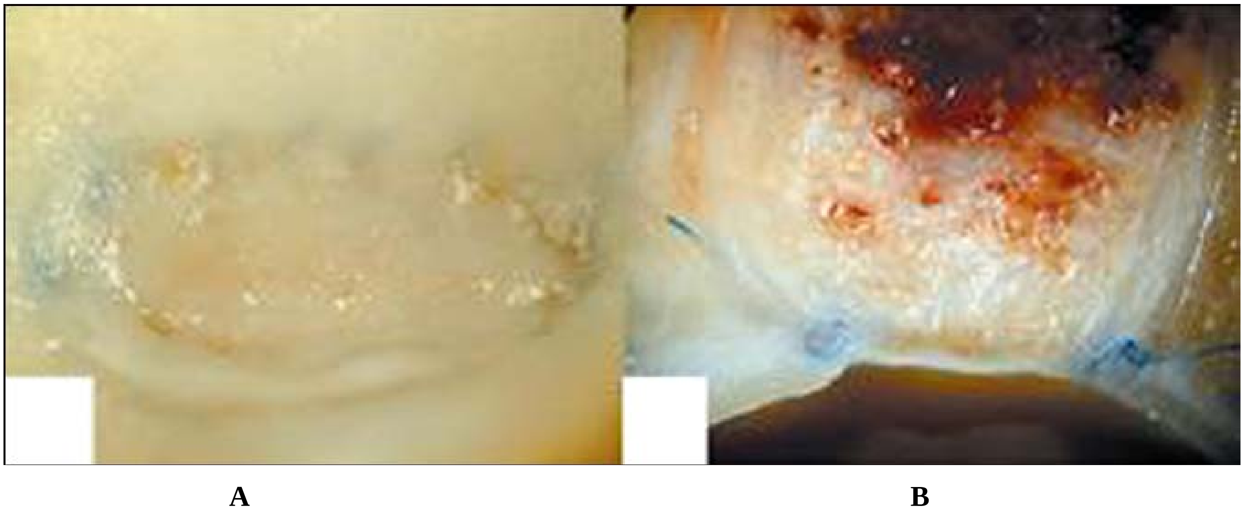

Fig. (2). Experimental aneurysm occluded with CHEM. Macroscopic photographs showing good neointimal formation over the neck of the aneurysm at the CHEM interface. (**A**) Aneurysm neck '*en face*'. (**B**) Axial section of the aneurysm [17].

CHEM foams are considered to be used for orthopedic braces and splints from that can be custom fit. By heating the shape memory component above its T_g and then deforming it, a desired fit can be obtained and sustained after cooling. Recently, Wache *et al.* have conducted a feasibility study and preliminary development on a polymer vascular stent with shape memory as a drug delivery system [15]. They could be used to design artificial grafts for replacing diseased arteries or serve as a scaffold for tissue engineering. The CHEM may possibly be used as a three-dimensional matrix to support bone growth *in vitro* and *in vivo*. CHEM foams could be appropriate for both soft and hard tissue engineering, due to its T_g and large difference of elastic modulus.

Potential vascular uses of SMP foams include the removal of blood clot (thrombus) from the arterial network. Feasibility studies and preliminary (*in vitro*) demonstrations on SMP, conducted by Metzger at al., were optimistic [16].

The formation or lodging of thrombus in the arterial network supplying the brain, typically causes the ischemic strokes. The stroke is the third leading cause of death and the principal cause of long-term disability in North America. The strokes can by caused also by the intracranial aneurysm. However, present endovascular interventions on aneurysms have important drawbacks, such as a significant incidence of residual lesion, deficient healing at the neck, recanalization or recurrences. Therefore, the search for new and more effective methods has been continued. The CHEM foam materials have appealing characteristics for the design of endovascular devices. Their unique properties suggest that they have a large potential to be used as an embolic agent and filling material to occlude aneurysms.

The CHEM foams were experimentally investigated for endovascular treatment of aneurysm at CHUM Research Center, Notre-Dame Hospital, Montreal, in collaboration with École Polytechnique, Montreal with encouraging results (Fig. **2**).

Lateral wall venous pouch aneurysms were constructed on both carotid arteries of 8 dogs. The aneurysms were occluded per-operatively with CHEM blocks. Internal maxillary arteries were occluded via a 6F transcatheter technique using compressed CHEM blocks. Angiography and pathology were used to study the evolution of the occlusion and neointimal formation at the neck of experimental aneurysms after 3 and 12 weeks. The CHEM extract demonstrated no evidence of cell lysis or cytotoxicity and no mutagenicity. The efficient vascular embolization was confirmed in the aneurysms and good neointimal formation over the neck of treated aneurysms was demonstrated at the CHEM interface. Maxillary arteries embolized with CHEM foam remained occluded at the time of sacrifice (3 weeks). The major conclusion of the investigation was that the foamy nature of this new embolic agent favors the ingrowth of cells involved in neointima formation and new embolic devices for endovascular interventions could be designed using CHEM's unique physical properties.

Presently, most commercially available stents are made of metallic materials. There are several designs of these minimally invasive vascular stents intended for coronary applications including tubular mesh, slotted tubes and coils. A common after-effect of stent implantation is restenosis. The use of the shape memory polymer stent as a drug delivery system leads to significant reduction of restenosis and thrombosis. An improved biological tolerance in general is expected when using biocompatible SMP materials.

The CHEM materials could be used in a variety of different medical devices and diagnostic products as deployable elements of implants from vascular grafts to components of cardiac pacemakers and artificial hearts [18, 19]. Present memory metals such as NiTi are being used as components of different devices and provide a mean of inserting a thin, wire-like device contained in a needle like casing through a small incision. This device can regain a more complex shape once the casing is removed.

SMP foams with much higher shape recovery/packaging capability can be inserted through small incision or non-invasive way by catheters and subsequently regain their original large shape/size by the body heat and then stay there to perform a desired function. The CHEM stent represents also an innovative alternative to the conventional stent due to less costly manufacturing compared to metal stents. Compared to the production of conventional metal stents, the production costs could be reduced by more than 50%.

4. SUMMARY

The unique attributes of polyurethane-based SMP materials like shape memory effect, biocompatibility and other properties make them a worthy technology for numerous potential self-deployable medical products. Presently, some SMP applications are already used in medical world, others are under development.

Recently developed SMP foams together with cold hibernated elastic memory (CHEM) processing, further widen their potential medical applications. Future progress in the development of different CHEM materials, configurations and delivery systems will be evaluated and tested *in vitro* and *in vivo*. The best systems will be selected for design and development of novel, second generation medical devices including devices for the treatment of aneurysms by endovascular embolization.

The author believes that SMP materials and CHEM foams will significantly and positively impact the medical device industry. They have unique characteristics that enable the manufacture of devices not possible currently. Their applications may usher in an era of simple, low-cost self-deployable medical devices. The SMP/CHEM stent will cost much less than conventional complex stents. He hopes that the SMP/CHEM technology will continue to gain attention and will open the door for the design and construction of novel important medical products and devices.

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