Recent Advances in Polymeric Heart Valves Research

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ABSTRACT
Heart valve replacement is fast becoming a routine surgery worldwide, and heart valve prostheses are today considered among the most widely used cardiovascular devices. Mechanical and bioprostheses have been the traditional choices to the replacement surgeries. However, such valves continue to expose patients to risks including thrombosis, infection and limited valve durability. In recent years, advances in polymer science give rise to an important new class of artificial heart valve made predominantly of polyurethane-based materials, which show improved biocompatibility and biostability. These polymeric heart valves have demonstrated excellent hemodynamic performance and good durability with excellent fatigue stress resistance. Advancements in the designs and manufacturing methods also suggested improved in the durability of polymeric heart valves. Animal studies with these valves have also shown good biocompatibility with minimal calcification of the valve leaflets. With these promising progresses, polymeric heart valves could be a viable alternative in the heart valve replacement surgeries in the near future.

Keywords: Bioprostheses, Calcification, Hemodynamic, Polyurethane, Reynolds Shear Stress

INTRODUCTION
Existing commercial prosthetic heart valve designs can be classified into two groups: bioprosthetic, or tissue valves, and mechanical heart valves. The former is made from a combination of synthetic materials and chemically treated animal tissue mainly porcine in origin, whereas the latter is manufactured entirely from synthetic materials. In the 1960s, Dr Charles Hufnagel performed one of the earliest successful mechanical heart valve surgeries where six of the eight patients who received a caged ball heart valve survived the operation (Hufnagel, Gillespie, Conrad, Mercier, & Evangelist, 1966). However, current artificial heart valves are still exposed to risks of thrombosis and thromboembolism, tissue overgrowth, infection, anti-coagulant related hemorrhage, and valve failure due to material fatigue or chemical change (Black, & Drury, 1994; Yoganathan, 2000; Starr, Fessler, Grunkemeier, & He, 2002; Korossis, Fisher, & Ingham, 2000).
One major drawbacks associated with the implantation of mechanical heart valves is the need for daily chronic anticoagulation therapy to reduce the risk of thrombosis and thromboembolic complications. These patients are exposed to an increased risk of bleeding, infection, and/or autoimmune response (Walker, & Yogathan, 1992). Blood flow through mechanical prostheses can lead to high turbulent stresses that may damage and/or activate blood elements and initiate platelet aggregation. Platelet aggregation can lead to thrombus formation with disastrous consequences for the patient. Thrombi may even detach from the valve and become lodged in a downstream blood vessel, thus reducing or even cutting off the blood supply to vital tissues.

An alternative to mechanical valves is using tissue valves which utilize the concept of a trileaflet configuration with one central orifice that mimics the design of the native valve. These valves have a lower potential for blood element damage than their mechanical counterparts. Nevertheless, the mechanical properties of tissue valves appear to degrade more rapidly, and they are prone to calcification (Black & Drury, 1994). Often, implanted tissue valves do not last for more than ten years, and reoperation is necessary.

The polyurethane (PU) trileaflet polymeric heart valve is the latest development in prosthetic heart valve research (Hyde, Chinn, & Phillips, 1999). The design is based on the natural aortic valve and is inherently appealing from a hemodynamic viewpoint. Although this particular valve design is still in a developmental stage, preliminary studies have shown excellent forward flow hemodynamic properties equivalent to that of a tissue heart valve and promise a durability comparable to that of a mechanical heart valve (Bernacca, Mackay, Wilkinson, & Wheatley, 1995; Jansen et al., 1991). However, recent animal trials involving polymeric valves have reported problems mainly related to tearing of the leaflets and thrombus formation occurring along the stent region of the valve (Wheatley et al., 2001). In addition, results of long-term in vivo evaluation have suggested that calcification could be a limiting factor to long-term function of polymeric valves (Bednar & Frater, 1991). The leaflets and basal attachments, such as the commissural region of the polymevalves, have experienced extrinsic calcification associated with surface microthrombi that appear to be independent of structural defects suggesting that the flow characteristics inside the polymeric valve may be a contributor to the observed blood clots.

This review will discuss the recent development of polymeric heart valves, particularly on its choice of materials. Much attention will also focus on the in vitro hemodynamics characterization these polymeric heart valves. The review will also discuss the in vivo experiments involving these polymeric heart valves and their susceptibility to calcifications.

Introduction of Polymeric Heart Valves

Pioneering works in polymeric heart valve replacement in human was first reported in 1958 (Roe, Owsley, & Boudoures, 1958). This is followed by a single trileaflet silicone rubber (SR) aortic valve implanted in several patients between 1960 and 1962 (Roe, Kelly, Myers, & Moore, 1966). The clinical trials were discontinued due to the high occurrence of thromboembolic events. The choice of material is an important factor in the development of polymeric heart valve. The chosen polymer should have acceptable characteristics with regard to biocompatibility, hemocompatibility, anti-thrombogenicity, resistance to degradation and calcification (Daebritz et al., 2004; Gallacher, Aguirre, Kasyanov, Pinchuk, & Schoephoerster, 2006). Since then, several synthetic polymers have been tested as leaflet materials, including silicone, polyofelin rubber, Silastic, SR-impregnated Dacron mesh, polytetrafluoroethylene (PTFE) and PU.

In 1960s, silicone was considered a choice due to its great flexibility and biocompatibility. However, in clinical investigations, formation of thrombosis and thickening of valve leaflets were found. Silicone suffered from structural
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