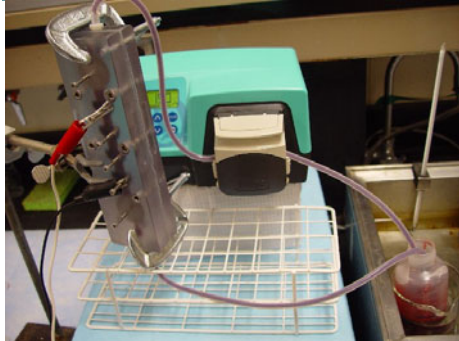


Rapid Screening of Pyrolytic Carbon Leaflets and Fully Assembled Heart Valves for Blood Compatibility

Presenting Authors Brian Pederson¹, Rachel Nachreiner¹, Kyle Brandy², Debra Cocking Johnson², and Gundu HR Rao²
ATS Medical¹, Minneapolis, Minnesota, 55447 and Biomedical Engineering Institute², University of Minnesota 55455.

Statement of Purpose: Over one million artificial heart valves have been implanted in the United States of America and approximately 80,000 adults undergo procedures every year to repair or replace damaged heart valves. Mechanical heart valve patients must remain on continuous anticoagulation therapy. There is considerable interest in developing improved heart valves that can be used safely with anti-platelet drugs.

Methods: Methodologies have been developed for rapid screening of mechanical valve leaflets as well as fully assembled heart valves for blood compatibility and thrombogenicity. For individual leaflet screening, we have developed customized flat chambers which house four leaflets.



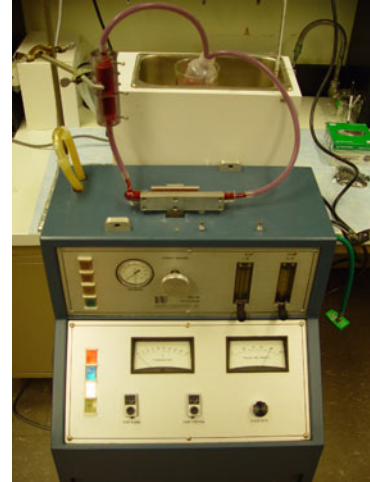
Controlled flow of human blood over these leaflets is achieved using a Watson Marlow, (Boston MA.) pulsatile pump.



In addition we have developed a customized chamber to test fully assembled heart valves and to compare with those manufactured by different companies.

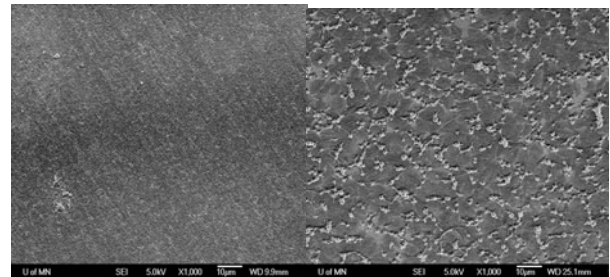
Controlled pulsatile flow of blood through these valves is achieved by using Max 100 Oxygenator (Waters

Instruments, Rochester, Minnesota), as shown in the next figure.



At the beginning of each study, the blood is tested for the normal response using optical whole blood aggregometry (Chronolog Corp, Haverton, PA). After exposing samples to blood for a maximum of 45 minutes, samples are washed with a buffer and fixed with glutaraldehyde and examined by scanning electron microscopy (SEM) or light microscopy.

Results / Discussion: At the normal shear rate, comparable to arterial pressure, platelet adhesion, activation, spreading and micro-aggregates are observed on these test surfaces.



Results of preliminary studies and the details of the methodologies used for testing will be presented.

Conclusions: The methods developed for rapid screening of pyrolytic carbon leaflets and fully assembled heart valves for human blood compatibility studies are simple and easy to perform. These methods can be effectively used for testing surface modifications of pyrolytic carbon leaflets for blood compatibility. In these whole blood perfusion studies the in vivo effect of antiplatelet drugs on in vitro interaction on modified biomaterial surfaces can be evaluated.

References: 1. Rao GHR, Escolar G, White JG: Epinephrine reverses the inhibitory influence of aspirin on platelet vessel wall interactions. *Thrombosis Research* 44:65-74, 1986.

2. Jen CJ, Tai YM: Morphological study of platelet adhesion dynamics under whole blood flow conditions. *Platelets* 3, 145-153, 1992