An in vitro Blood Loop to Assess Catheter Thrombogenicity at High Shear Rates

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Abstract

The development of reliable *in vitro* test methods for evaluating thrombogenicity is important for the development of blood-contacting devices. For arterial catheters, blood flow will be high around the device, likely leading to high shear rates. Existing tests primarily assess thrombogenicity of materials at low shear rates, either in static conditions or low flow loops. However, thrombus formation on some materials may form by Shear-Induced Platelet Aggregation (SIPA) within minutes under high shear rates. In this study, we developed and validated a blood loop circuit for thrombogenicity testing under high shear conditions using fresh, whole human blood. The *in vitro* thrombogenicity results were compared to an FDA approved protocol for *in vivo* testing of arterial catheters for thrombogenicity using a swine model as a blinded study. Thrombogenicity was visually assessed using a modified Non-Anticoagulated Venous Implant/ Anticoagulated Venous Implant (NAVI/AVI) scoring scheme of the catheters, tubing and arteries. The amount of thrombus formation developed on the catheters or within the tubing after one hour by the *in vitro* circuit was the same as in the *in vivo* arteries in swine. Consistency between these results substantiates the suitability of employing an *in vitro* blood loop circuit for thrombogenicity of arterial catheters subject to high shear that is comparable to costly, terminal porcine studies.

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