The Effect of Surface Roughness on Activation of the Coagulation System and Platelet Adhesion: An In-Vitro Study with the Baylor Gyro 710 Pump

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The Baylor Gyro 710© centrifugal blood pump had demonstrated excellent anti-thrombogenic characteristics in several long-term in-vivo experiments. The surface roughness of LVAD is an important factor and seems to be closely related to cell trauma. Quality assurance and quality control of the metal surface finishing, however, is a time consuming and expensive process during the mass production procedure. Currently, no specifications have been formulated that regulate the quality of the surface finishing in blood pumps. The present study investigated the effect of minor surface roughness differences on the activation of the coagulation cascade and platelet thrombus formation in a pre-production impeller-type blood pump.

Methods
Three identical Baylor Gyro 710© centrifugal blood pumps were manufactured that deviated slightly in the surface roughness quality. The average surface roughness was determined in a laser scanning profilometer and was visualized by scanning electron microscopy (SEM). The surface roughness was 0.1, 0.2 and 0.3 µm, respectively. Whole blood was anticoagulated with 1.0 IU/ml heparin (ACT 250 ± 28 sec.) and was circulated for 60 min. in an artificial circulatory system. After perfusion, the impeller of the pump was carefully removed and incubated with a monoclonal mouse anti-human CD 41 antibody. Platelet adhesion onto the impeller was quantified spectrophotometrically using a secondary enzyme linked anti-mouse-IgG antibody. ELISA was also used to quantify fibrinogen and von Willebrand factor (vWF) adsorption to the titanium surface. Levels of prothrombin fragment F1+2 and thrombin-antithrombin-complex (TAT) were measured to reflect thrombin generation and the activity of the coagulation system.

Results
Compared to the 0.1 µm surface, platelet adhesion increased by 40 % and 76 % on the 0.2 µm and 0.3 µm surface, respectively (p<0.01). The evaluation of adsorbed prothrombotic plasma proteins yielded similar results: fibrinogen and vWF deposition increased significantly (p<0.01) on less carefully treated surfaces. In addition, consistently higher prothrombin F1+2 fragment and TAT concentrations were observed when the blood was exposed to inferior quality surfaces. However, the levels remained within physiological range.

Conclusion
Although all three pump-surfaces were within commonly accepted quality levels, the results identified significant deterioration in the anti-thrombogenic characteristics. Enhanced adsorption of prothrombogenic plasma proteins seems to amplify platelet adhesion and platelet thrombus formation on imperfect surfaces. We conclude that rigorous internal QA/QC is necessary and propose to specify and regulate the surface roughness of LVAD by international standards.

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