The Development and Validation of a Standard In Vitro Method to Evaluate the Efficacy of Surface Modified Urinary Catheters

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ABSTRACT: Urinary catheters are a critical medical device in modern medicine, used in almost every healthcare setting worldwide. Catheter associated urinary tract infections (CAUTIs) account for 37% of all healthcare associated infections. Many surface modifications, such as antimicrobial coatings, have been proposed but none have resulted in a significant decrease in CAUTI. A variety of test methods exist to evaluate the efficacy of surface modified urinary catheters, but there is no validated in vitro standard method. This thesis reports on a standard test method which aims to replicate two routes which infection can occur, intraluminally and extraluminally, through two quantitative, in vitro models. The first, the Intraluminal Catheter Model (ICM), was devised to evaluate the efficacy of surface modifications to inhibit biofilm growth on the catheter lumen. The ICM was subjected to a rigorous statistical evaluation of its ruggedness, specifically, the amount the log density and log reduction changed with small adjustments to key operational factors. Five operational factors were varied - inoculum concentration, flow of media through the catheter, pH of the artificial urine media (AUM), temperature of the incubator, and biofilm removal technique. The results of the analysis highlighted that biofilm growth is sensitive to changes in pH, which indicates that the growth media must to optimized to increase the method’s ruggedness. The analysis also demonstrated that sonication was more efficient than scraping as a means to harvest biofilm from the catheter surface. With further optimization of the procedure, the ICM has potential to become a useful tool to evaluate the efficacy of surface modified urinary catheters. Three extraluminal models were tested but did not meet the statistical requirements necessary for standardization. Extraluminal infections account for 66% of all CAUTIs, therefore, the in vitro evaluation of a surface modification’s ability to inhibit migration of bacteria along the extraluminal surface of a catheter is critical to fully understand how a modification will perform in the clinical setting. The development of a standardized in vitro method which accurately reflects the physiological conditions of CAUTI with help FDA regulators to compare efficacies across products and to bring more innovative treatments to patients.