In Vitro Antimicrobial Efficacy Testing of a Needless Connector's Septum Manufactured with Silver and Chlorhexidine

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Statement of Purpose

Health care providers are at risk for contracting a blood-borne disease by contact with infected bodily fluids. Needleless I. V. connectors (NCs) were designed to prevent one form of such contact – needlestick injuries. Since the introduction of the NC, the occurrence of needlestick injuries has been greatly reduced; however, this introduction has been accompanied by an increase in catheter-related bloodstream infections (CRBSI). A common feature of NCs is an elastomeric septum that is punctured during activation and provides a physical barrier between the catheter lumen and the environment. Contamination of this septum has been implicated as a source of such infections; accordingly, an antimicrobial eluting septum is a potential solution to decrease the occurrence of CRBSI associated with NCs. The purpose of this study is to determine whether the addition of antimicrobial agents to the septum of a NC demonstrates reduction in microorganisms in an *in vitro* assay of septum contamination.

Methods

The elastomeric septum of a NC [InVision-Plus® CS™ (RyMed Technologies, Inc., Franklin, TN) see arrows in Figure 1] was combined with two antimicrobial agents, silver and chlorhexidine using a proprietary method developed at Bacterin International, Inc. A septum (n=3), a control and treated set, was challenged by pipetting, on the top of a septum, a 10 µL solution of saline containing approximately 10^5 CFU of one of the organisms, *E. coli* or *S. aureus* (see Figure 1). At time zero and 30 minutes the septa were vortexed for 15 seconds in 1.0 mL normal saline and appropriate dilutions were plated on sheep blood agar plates to determine the number of viable colonies. At 30 minutes the 10 µL drop has not completely evaporated: It takes approximately 50 minutes for the 10 µL to dry (by visual inspection). The plates were incubated at 37 °C overnight, enumerated, and log reductions between treated and control septa calculated.

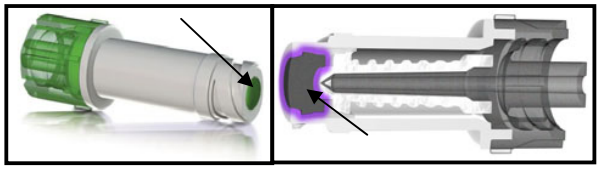

Figure 1: InVision-Plus® with Neutral Advantage™ (left). InVision-Plus® CS™ (right).

Figure 2: Septa with a 10µL droplet containing approximately 10^5 CFU

Results and Discussion

Results are shown in Figure 3. The 30 minute time point for the treated septa showed a minimum of 4 log reduction for *E. coli* and *S. aureus*. The CFU count for the treated septa were reduced to the limit of detection.

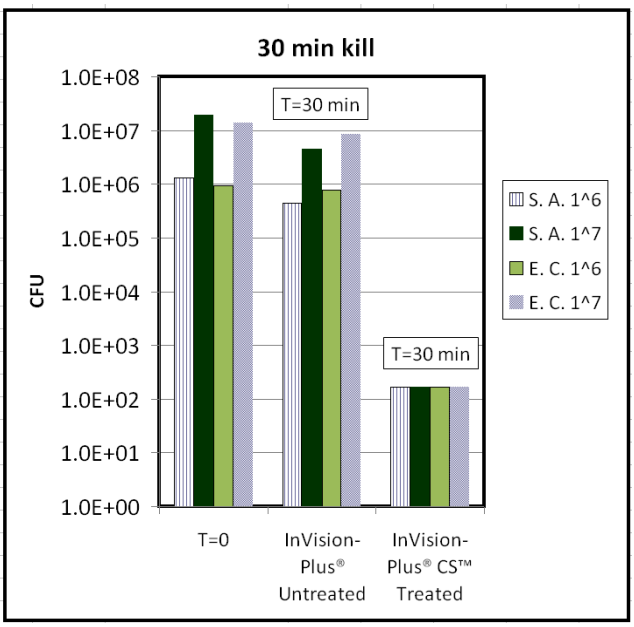

Figure 3: InVision-Plus® with Neutral Advantage™ Technology needleless connector (left). InVision-Plus® CS™ (right) (RyMed Technologies, Inc., Franklin, TN).

Conclusions

This study demonstrates the that application of two antimicrobial agents, silver ions and chlorhexidine, to the septum of a NC, results in a meaningful log reductions versus untreated control in an *in vitro* assay of bacterial contamination. Such a reduction in bioburden on the surface of the septum is expected to translate into a reduction in organism counts exiting at the distal end of the device and into the attached catheter. While the reduction in bioburden of the treated septum is demonstrated herein, the clinical efficacy of this treatment strategy has not been established.

References

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2. Menyhay SZ, Maki DG; Disinfection of Needleless Catheter Connectors and Access Ports with Alcohol May Not Prevent Microbial Entry: The Promise of a Novel Antiseptic-Barrier. *Infect Control Hosp Epidemiol* **2006**, *27*, 23.