

Comparison of Bacterial Transfer and Biofilm Formation on Intraluminal Catheter Surfaces Among Twenty Connectors in a Clinically Simulated In Vitro Model

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Overview

The risk of bloodstream infection associated with vascular access devices and needleless connectors is of increasing concern. Many questions still remain regarding the potential risk for infection among the various connectors. Disinfection before access is paramount to prevention of microbial ingress but compliance is often poor. This study and the accompanying statistical analysis compare the bacterial transfer rate of 20 needleless connectors and compares biofilm formation within the connectors, catheter hubs, and catheter lumens.

An *in vitro* model was designed to simulate a four times daily antibiotic infusion utilizing the SASH (saline, antibiotic, saline, and heparin) administration method. During each five-day experimental run, each connector's septum was inoculated twice a day with approximately 10^6 colony forming units (CFU) of *Staphylococcus aureus* ATCC #6538. After each inoculation, the connectors were flushed six times and the first and last flush were plated and enumerated for bacteria. The mean log densities (LD) of CFU in the connector, hub, and catheter segment were measured, as well.

Results

The Neutron® and MicroClave® connectors exhibit the overall smallest mean log densities of bacteria in the flush over all flushes and all runs (≈ 3.14 and 3.20 log (CFU/flush)). MicroClave and Neutron were not statistically significantly different, and are the only devices that reside solely in the significant group that had the statistically smallest mean log densities of bacteria in the flush.

Conclusion

The risk of transfer of bacteria through the connector, hub, and catheter lumen and into the bloodstream from a contaminated connector surface is dependent on the type of connector used. Regression analyses suggest that the log (CFU/connector) is the single best predictor of the daily mean LD of bacteria in the flush (among the three predictors: hub, catheter segment, and connector).

INTRODUCTION

Previous studies indicate that the design components of needleless connectors influence the potential for bacteria to pass from the connector surface into the flow path of the connector, catheter hub, and catheter lumen.^{1,2,3} Intraluminal biofilm is a predominant source of catheter-related bloodstream infection (CRBSI) during the maintenance phase of catheterization.

PURPOSE

The purpose of this study was to compare the bacterial transfer rate of twenty needleless connectors through the connector-catheter system and to compare biofilm formation within the connectors, catheter hubs, and catheter lumens.

Intraluminal biofilm is a predominant source of catheter-related bloodstream infection (CRBSI) during the maintenance phase of catheterization.

METHODS

A total of 20 needleless connector designs were evaluated in this study. Four of each connector type were evaluated in three independent runs ($n=9$) with the MicroClave serving as the matched control for every run in a total of 33 runs.

The connector septum was inoculated twice a day with approximately 10^6 CFU *Staphylococcus aureus* ATCC #6538. The inoculated connector was allowed to dry for 30 minutes and then was attached to a 50cm polyurethane peripherally inserted central catheter (PICC).

Each connector-catheter set was flushed with 3.0 ml sterile saline, which was collected and plated (First Flush). The catheter-connector sets were flushed with sterile normal saline (NS) twice more, locked with sterile Brain Heart Infusion Broth (BHI) for one hour and flushed with NS three more times. The last flush was also collected and plated (Last Flush).

The Neutron and MicroClave connectors had statistically significantly smaller mean log densities (LD) of bacteria in the flush, when pooled over all flushes, inoculations, days, and runs, compared to any other of the connector types (≈ 3.14 and 3.20 log (CFU/flush)).

The connector-catheter sets were inoculated a second time each day after the 6th sterile saline flush followed by a second round of flushing, plating, and locks for a total of 18 connector accesses daily, considered to be a routine number of accesses in an intensive care unit.

The entire procedure was repeated each day for five days. On Days 4 and 5, two connector-catheter sets for each connector type were destructively sampled for bacterial counts and microscopy.

Statistical analysis was performed using mixed effect ANOVA and Tukey's tests to determine significant mean differences of log density of bacteria in the flush, hub, catheter segment, or connector amongst the different needlefree connectors. A multiple linear regression was used to determine if any combination of the log density of bacteria in the connector, hub, or catheter segment could significantly predict the log density of bacteria in the flush.

RESULTS

The Neutron and MicroClave connectors exhibit the overall smallest mean log densities of bacteria in the flush over all flushes and all runs (≈ 3.14 and 3.20 log (CFU/flush)). MicroClave and Neutron were not statistically significantly different, and are the only devices that reside solely in the significant group that had the statistically smallest mean log densities of bacteria in the flush.

The Q-Syte[®] and UltraSite[®] had the significantly largest mean LDs of bacteria in the flush compared to any of the other connector types. (≈ 5.37 and 5.15 log (CFU/flush)). The Q-Syte and UltraSite were not statistically significantly different ($p = 0.9101$).

TABLE 1: DAILY LEAST SQUARE MEAN BACTERIAL DENSITIES IN THE FLUSH

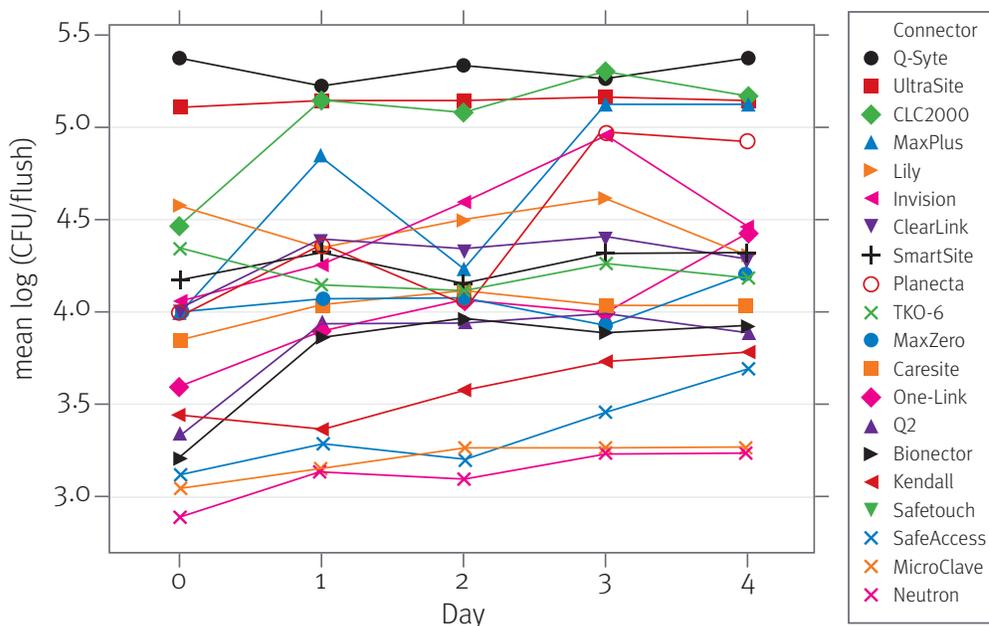


TABLE 2: LEAST SQUARE MEAN FLUSH FOR ALL DAYS AND ALL FLUSHES

Connector	Significant Groups*	Least square mean (log (CFU/flush))
Q-Syte	A	5.37
UltraSite	A	5.15
CLC2000	A B	5.04
MaxPlus	B C	4.66
Lily	C D	4.46
Invision	C D	4.45
ClearLink	C D E	4.26
SmarSite	C D E	4.26
Planecta	C D E	4.24
TKO-6	D E	4.22
MaxZero	D E F	4.08
Caresite	E F G	4.00
One-Link	E F G	3.99
Q2	G H	3.75
Bionector	F G H I	3.72
Kendall	H I	3.55
Safetouch	H I J	3.50
SafeAccess	I J	3.32
MicroClave	J	3.20
Neutron	J	3.14

*color scheme indicates significant groups (p < 0.05)

DISCUSSION

The risk of transfer of bacteria through the connector, hub, and catheter lumen and into the bloodstream from a contaminated connector surface is dependent on the type of connector used. The results of this study validate that biofilm formation in the catheter

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hub and internal lumen can result from bacterial transfer through a needleless connector. It further demonstrates that detached or planktonic bacteria shed from the biofilm are subsequently flushed into the bloodstream with infusion. Regression analysis indicates that biofilm formation within the connector was the best predictor of the number of bacteria flushed into the bloodstream (R-squared=95%). Thus the use of a connector with a low microbial transfer rate may minimize the risk of bloodstream infection. It also points to the use of consistent and effective disinfection methods of the connector and catheter hub prior to access as a critical strategy for prevention of CRBSI. The data also suggests that the common classification related to features of connectors such as split septum and mechanical valve is an unreliable approach for device selection based on infection risk.

MicroClave and Neutron connectors were shown to have a significantly lower bacterial transfer rate than any of the other connectors tested.

tested. In addition, the frequency of connector exchange may be dependent on the bacterial transfer potential of each device design. Data from this study also indicates that the common classification of split septum and mechanical valve is an over-simplification and an unreliable approach for device selection based on infection risk.

CONCLUSIONS

The risk of transfer of bacteria from a contaminated connector surface through the hub and catheter lumen and into the bloodstream is dependent on the type of connector used, and the MicroClave and Neutron connectors were shown to have a significantly lower bacterial transfer rate than any of the other connectors

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