Comparison of Bacterial Transfer and Biofilm Formation on Intraluminal Catheter Catheter Surfaces Among Eight Connectors in a Clinically Simulated in vitro Model

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INTRODUCTION

The use of needleless connectors is an important strategy in the prevention of needlestick injuries for healthcare workers and caregivers of patients with vascular access devices. The design components of the connector influence the potential for bacteria to pass from the connector surface into the flow path of the connector, catheter hub and catheter lumen. Intraluminal biofilm becomes 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 eight needleless connectors through the connector-catheter system and to compare biofilm formation within the connectors, catheter hub, and catheter lumen.

METHODS

A total of 8 needle-free connectors were evaluated in this study. Three of each connector type were evaluated in three replicate runs (n=9) with the MicroClave® serving as the matched control for every run in a total of 12 runs.

MicroClave® (ICU Medical Inc.)

SmartSite® (CareFusion Corp.)

ClearLink® (Baxter Inc.)

Invision® (RyMed Technologies Inc.)

MaxPlus® (CareFusion Inc.)

Q-Syte™ (BD and Co.)

One-Link® (Baxter Inc.)

Bionector® (Vygon Inc.)

METHODS

The connector septum was inoculated twice a day with 10^6 CFU *Staphylococcus aureus* ATCC # 6538. The inoculated connector was allowed to dry for 30 minutes and then was attached to a catheter.

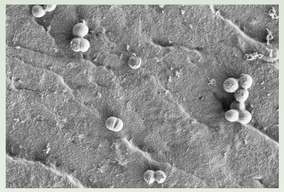

Figure 1. Scanning electron microscopy (SEM) of connector septum 30 min after inoculation. Bacteria are observed in cell division and early stages of biofilm formation.

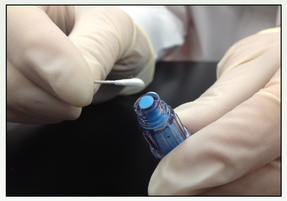

Figure 2. For surface inoculation controls, the connector was swabbed in order to determine the concentration of bacteria on the connector septum.

Each connector-catheter set was flushed with 3.0 ml sterile saline which was collected and plated (First Flush). The catheter-connector sets were sterile normal saline (NS) flushed twice more, locked with sterile Brain Heart Infusion Broth (BHI) for 1 hour and NS flushed three more times. The last flush was also collected and plated (Last Flush).

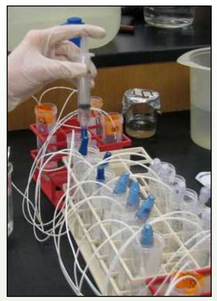

Figure 3. The connector-catheter set were placed in conical vials between flushes. The technician is flushing one of the connector-catheter sets.

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, inoculation and flushing, was repeated each day for 5 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 analysis 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 needle-free 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 mean log densities (LD) of the surface inoculations averaged across all days were statistically equivalent as long as mean differences as large as 0.37 were assumed to be negligible. For each day individually, the mean LD of the surface inoculum (averaged across the two inoculations for each day) were shown to be statistically equivalent as long as mean differences as large as 0.81 were assumed to be negligible.

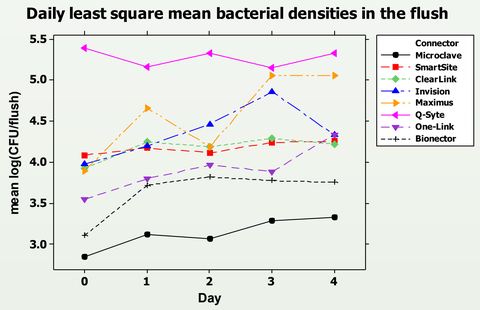

Table 1. The mean log density (LD) in the daily flush for the MicroClave connector was significantly smaller compared to any of the other connector types tested (p<0.0005).

The Q-Syte had the significantly largest mean LD of bacteria in the flush compared to any of the other connector types. (p <0.0005).

Mean Flush for all Days and all Flushes								
	Least Square Mean (Log CFU/flush)	Significant Groups						
Microclave	3.128	A						
Bionector	3.637		B					
One-Link	3.907		B	C				
ClearLink	4.176			C	D			
SmartSite	4.176			C	D			
Invision	4.368				D	E		
Maximus	4.573					E		
Q-Syte	5.276							F

Table 2. The least square mean for all flushes for all days was calculated. The color scheme indicates the significant groups (p< 0.05).

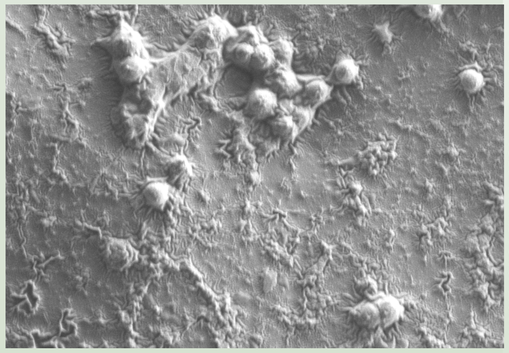

Figure 4. Biofilm colony on the septum of a needleless connector after 96 hours.

RESULTS

Hub Days 3 and 4							
	Least Square Mean (Log CFU/hub)	Significant Groups					
MicroClave	1.594	A					
One-Link	1.694	A	B				
ClearLink	1.853	A	B	C			
Maximus	2.101	A	B	C	D		
SmartSite	2.095		B	C	D	E	
Q-syte	2.925			C		E	F
Bionector	2.905				D	E	F
Invision	3.14				D		F

Table 3. The least square mean for the destructive sampling of the catheter hubs was calculated for Days 3 and 4 combined. The color scheme indicates the significant groups (p< 0.05)

Catheter Segment Days 3 and 4			
	Least Square Mean (Log CFU/segment)	Significant Groups	
MicroClave	0.845	A	
One-Link	1.14	A	B
ClearLink	1.194	A	B
Maximus	1.426	A	B
Invision	1.541		B
SmartSite	1.58		B
Bionector	1.646		B
Q-Syte	1.797		B

Table 4. The least square mean for the destructive sampling of the catheter segments was calculated for Days 3 and 4 combined. The color scheme indicates the significant groups (p< 0.05).

Connector Days 3 and 4				
	Least Square Mean (CFU/connector)	Significant Groups		
MicroClave	2.544	A		
One-Link	2.592	A	B	
ClearLink	3.005	A	B	C
SmartSite	3.274		B	C
Maximus	3.902	A		C
Q-Syte	3.936	A		C
Bionector	3.481			C
Invision	3.79			C

Table 5. The least square mean for the destructive sampling of the connectors was calculated for Days 3 and 4 combined. The color scheme indicates the significant groups (p< 0.05).

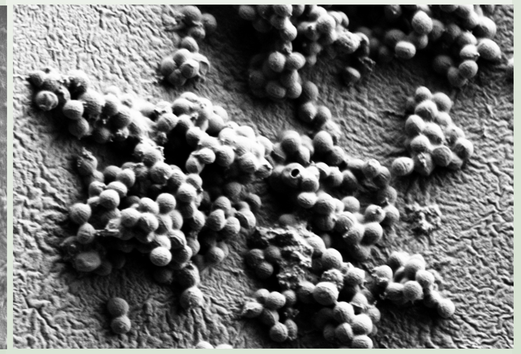

Figure 5. Biofilm formation on the intraluminal surface in the flow path of the needleless connector in Figure 4. The bacteria was transferred into the connector on access with the flush syringe.

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 validates that biofilm formation in the catheter hub and internal lumen can result from bacterial transfer through a needleless connector (Figures 3-5). It further demonstrates that detached or planktonic bacteria shed from the biofilm are subsequently flushed into the bloodstream with infusion.

The regression analysis indicates that biofilm formation within either the connector or the catheter hub were good predictors of the number of bacteria flushed into the bloodstream (R^2=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.

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. The MicroClave had a significantly lower bacterial transfer rate than any of the other connectors.
- Biofilm formation in the catheter hub and internal lumen can result from bacteria transferred through a needleless connector.
- Biofilm formation within either the connector or the hub are good predictors of the number of bacteria flushed into the bloodstream.
- The frequency of connector exchange may be dependent on the bacterial transfer potential of each device design.
- The common classification of split septum and mechanical valve is an over-simplification and an unreliable approach for device selection based on infection risk.

REFERENCES

1. Ryder M, James GA, Pulchini E. deLancy, Bickle L, Parker A. Differences in bacterial transfer and fluid path colonization through needlefree connector-catheter systems in vitro. The Society for Healthcare Epidemiology of America. Dallas, TX. April 2011.

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