

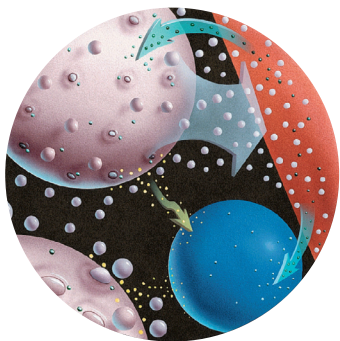
Edwards Vantex Central Venous Catheter with Oligon Material

Evaluation of Antimicrobial Effectiveness

Vantex Whitepaper 02 Antimicrobial Effectiveness

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Introduction

Central venous catheter (CVC) induced nosocomial infections continue to be a serious medical problem. The pathogenesis and spread of catheter-related infections is multifactorial; the main source may be a result of skin organism migration along the catheter tract, while hub contamination may lead to intraluminal colonization and produce bloodstream infection. A new catheter material called Oligon has been developed which claims to prevent bacterial growth. The aim of this study was to examine the effectiveness of the Oligon material with and without a heparin coating *in vitro* in preventing growth of the most common nosocomial organisms.

Test Method

Antimicrobial efficacy of the Edwards Vantex Central Venous Catheter, constructed of the Oligon material, with and without heparin coating,* was tested against conventional polyurethane CVCs. The test methodology involved a minimum of 3 logs of organism challenge to a tube containing a catheter segment submerged in diluted saline solution containing culture medium. This method was selected to simulate actual *in vivo* clinical application at the point of insertion through subcutaneous tissues, with ≤ 1 mm fluid surrounding the catheter. Catheter segments were exposed to the solution environment with microorganism inoculations for 7 days. The microorganism concentrations were evaluated by serial dilution, pour-plate and membrane filtration after 6, 24, 48, 72 and 168 hours (7 days).

Broad-spectrum microorganisms selected from the American Type Culture Collection (ATCC) catalogs were used to assess the antimicrobial activity of the Oligon material with and without heparin coating. The selection of organisms was based on those representative of the most common microorganisms associated with indwelling central venous catheter infection, referenced in peer-reviewed articles and abstracts, and representing a broad spectrum of gram-positive and -negative bacteria, as well as yeast.

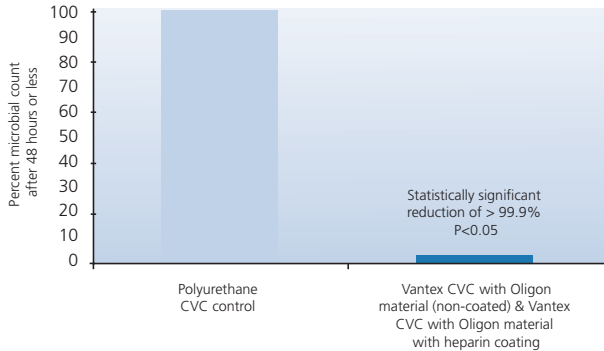
- *Candida albicans*
- *Enterococcus faecalis*
- *Staphylococcus epidermidis*
- *Enterobacter aerogenes*
- *Corynebacterium diphtheriae*
- *Staphylococcus aureus*
(Gentamicin & Methicillin Resistant Strain)
- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*
- *Acinetobacter calcoaceticus*
- *Klebsiella pneumoniae*
- *Serratia marcescens*
- *Escherichia coli*

Test Results

Bacterial reduction of polyurethane control catheters vs. Vantex Central Venous Catheter with Oligon material with and without heparin coating:

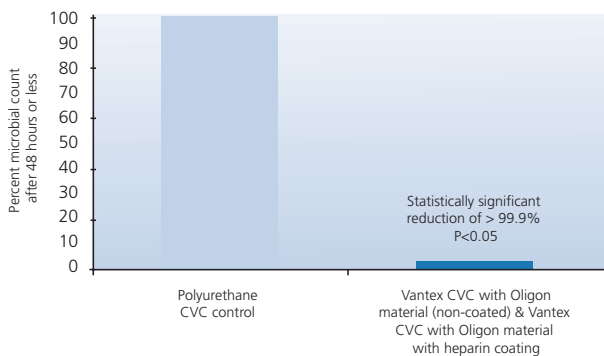
Gram-Positive Organisms Challenged (> 3 logs)

Staphylococcus aureus, Staphylococcus epidermidis, Enterococcus faecalis, GMRsA, Corynebacterium diphtheriae



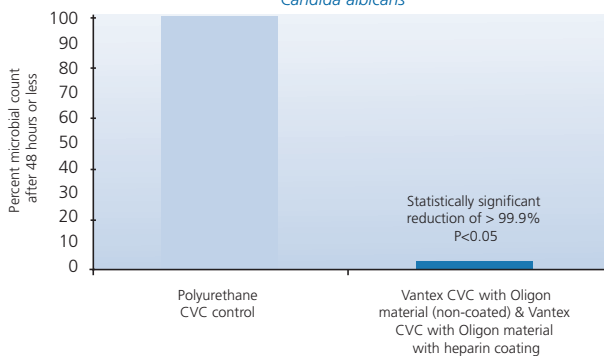
Gram-Negative Organisms Challenged (> 3 logs)

Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Serratia marcescens, Enterobacter aerogenes, Acinetobacter calcoaceticus



Yeast Organism Challenged (> 3 logs)

Candida albicans



Conclusion

As was observed in the testing, the Vantex Central Venous Catheter accomplished a significant decrease in concentration for all microorganisms tested, as compared to the polyurethane control catheters. Because the antimicrobial agents are incorporated into the material, both the inside and outside of the catheter are capable of reducing the spread of organisms, potentially reducing the incidence of catheter-related nosocomial infection.

References

- 1 Russell LM, Weinstein RA. Antimicrobial-coated central venous catheters—icing on the cake or the staff of life? Crit Care Med. 1998;26:195-196.
- 2 Milder FL. Antimicrobial action of oligodynamic iontophoretic polyurethane. Implimed, Inc., Watertown, Mass. June 1995.

Antimicrobial activity on the Oligon surface and inner lumens of the catheter during handling and placement has been demonstrated through *in vitro* testing against organisms commonly associated with nosocomial infections. The activity of the antimicrobial agents is localized at the catheter surfaces and is not intended for treatment of systemic infections.

In vitro testing demonstrated that the Oligon material provided broad spectrum effectiveness (≥ 3 log reduction from initial concentration within 48 hours) against the organisms tested: *Staphylococcus aureus, Staphylococcus epidermidis, Klebsiella pneumoniae, Enterococcus faecalis, Candida albicans, Escherichia coli, Serratia marcescens, Acinetobacter calcoaceticus, Corynebacterium diphtheriae, Enterobacter aerogenes, GMRsA* and *Pseudomonas aeruginosa*. The impact of Oligon material on infection rates has not been demonstrated.

*Contact inhibition of microbial growth on surface of catheters. Effective against organisms commonly associated with nosocomial infection, e.g., *S. epidermidis*.

Antimicrobial activity associated with AMC THROMBOSHIELD (an Antimicrobial Heparin Coating) has been demonstrated using *in vitro* agar diffusion assays against the following organisms: *Staphylococcus epidermidis, Staphylococcus aureus, Enterococcus faecalis, Candida albicans, Escherichia coli, Serratia marcescens* and *Acinetobacter calcoaceticus*.

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