REFERENCE MATERIAL

BALLARD™ TURBO-CLEANING* CATHETER CLOSED SUCTION SYSTEMS MICROBIOLOGY REPORT

*Formerly known as Trach Care - 72 Catheter

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Ballard™ Turbo-Cleaning Catheter Closed Suction Systems Microbiology Report

ABSTRACT

A Ballard Turbo-Cleaning Catheter (formerly known as Trach Care - 72) - code 227, was compared to a standard Ballard Closed Suction System - code 2210. Two hundred forty catheters were equally divided then challenged with four common bacterial pathogens, which cause ventilator-associated pneumonia. The catheters were challenged by simulating the suctioning procedure over 24 to 72 hours at various time intervals. Bacterial counts of the catheter tips were performed at 24 and 72 hours. The Turbo-Cleaning catheter has less colonization of the catheter tip at 72 hours than the current double-swivel elbow Trach Care catheter has at 24 hours.

TEST METHOD

All testing was conducted by Nelson Laboratories. Four species of bacteria were used with the catheters. These four bacteria were chosen as representative/common respiratory pathogens, representing approximately 47% of nosocomial pneumonias[i].

They are:

Staphylococcus Aureus ATCC #6538
Pseudomonas Aeruginosa ATCC #27853
Klebsiella Pneumonia ATCC #23357
Escherichia Coli ATCC #8739

A simulated mucus solution was prepared and divided into four containers. Each container of simulated mucus was inoculated with one species of organism at $1 \times 10^7 \pm 0.5 \log_{10}$ CFU/ml. This level simulates the level of colonization in the respiratory secretions of a patient with pneumonia[ii, iii]. The inoculum was stored at room temperature and new inoculum was prepared every 24 hours.

An AEROS Mobl-Vac III vacuum system and a sterile saline vial was attached to each catheter. The vacuum level was set to 120 ± 5 mm Hg with the catheter control valve open. Each catheter was dipped into the inoculum approximately 5 centimeters. Inoculum was suctioned approximately 30 centimeters up the catheter. The catheter was then removed from the inoculum.

The catheter tip was cleaned, by applying suction and retracting the catheter, until the black band is visible in the protective sleeve. The regular catheters were cleaned with saline by the usual method of squeezing the saline vial to dispense. The Turbo-Cleaning catheter includes a manifold restrictor, which closes under vacuum to allow the vial to empty into the catheter-cleaning chamber without squeezing the vial.

TEST METHOD CONT.

Twelve simulated use suctionings were performed every 24 hours, using the following schedule on each day: 12:00, 13:00, 15:00, 16:00, 18:00, 19:00, 21:00, 22:00, 06:00, 07:00, 09:00, 10:00. At 12:00 following the last suctioning time point the catheter was extended and the first 2 centimeters of the tip was aseptically removed and bioburden measured. Catheter bioburden was measured at 24 and 72 hour time points. Catheters were tested in groups of five replicates per catheter per test per week.

Bacteria grow at an exponential rate, so to improve accuracy, the data was converted into Log (CFU) before the analysis was performed. This is consistent with USP guidelines for antimicrobial effectiveness testing[iv]. Statistical analysis was performed using SAS® statistical software[v]. Conclusions are based on a level of confidence of 95%.

RESULTS[v]

A. The Turbo-Cleaning catheters, at 72 hours show over a (89%) reduction in mean catheter tip colonization compared to the control 2210 catheters at 24 hours ($P < 0.001$).

Figure 1 - Shows the overall reduction **(see next page)**.

Figure 2 - Subdivides Figure 1 by organisms **(see next page)**.

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FIGURE 1 - 2210 AT 24 HOURS VS 227 TURBO-CLEANING CATHETER AT 72 HOURS. ALL ORGANISMS COMBINED.

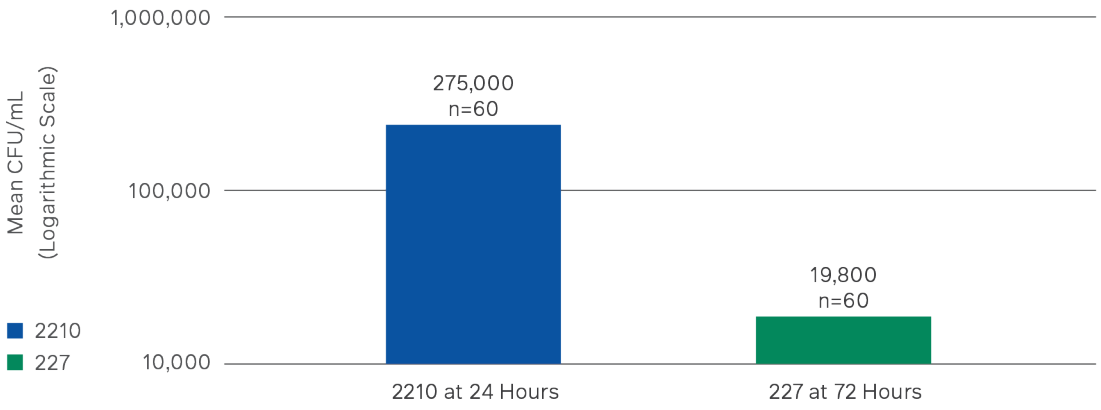
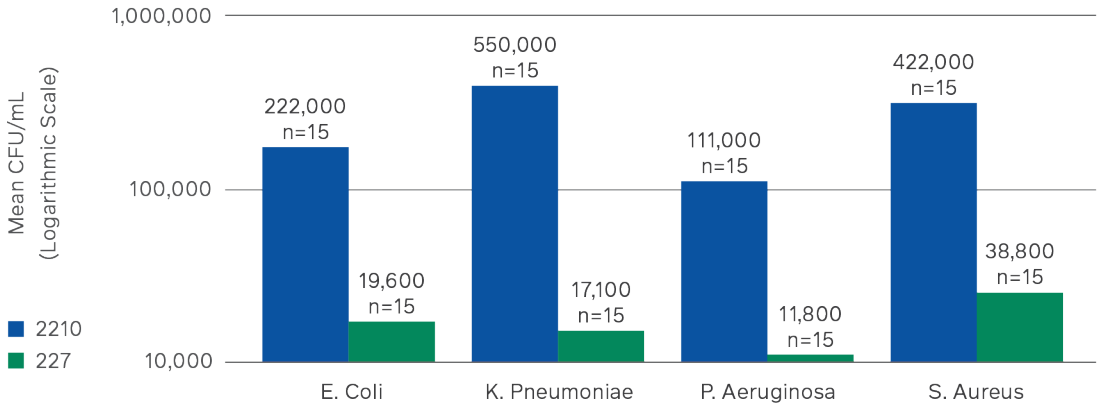


FIGURE 2 - REDUCTION BY ORGANISM.



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[ii] Jerome Pugin, Raymond Auckenthaler, Nabil Mili, Jean-Paul Janssens, P. Daniel Lew and Peter M. Suter, "Diagnosis of Ventilator-associated Pneumonia by Bacteriologic Analysis of Bronschosocopic and nonbronchoscopic "Blind" Bronchoalveolar Lavage Fluid" American Review of Respiratory Disease 143 (1991): 1121-1129.

[iii] Judd Shellito, M.D., "Application of Bronchoalveolar Lavage to the Diagnosis of Pulmonary Infection": Clinical Pulmonary Medicine vol. 1. No. 3 (May 1994): 144-153.

[iv] U.S. Pharmacopeia (USP) 24, <51>

[v] SAS version 6.09, SAS Institute Inc. Cary, North Carolina

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