An *in vitro* Study to Compare the Antimicrobial Activity of Three Antimicrobial Surgical Incise Drapes
Today’s Panelists

Shawn Matalas
Technical Representative
3M Infection Prevention Division Laboratory

Chou Eyberg
Clinical Research Associate, CCRA
3M Infection Prevention Division Laboratory
Objectives

• Describe the benefits of an antimicrobial incise drape in helping to reduce the risk of surgical site infections

• Discuss in-vitro time kill study results in relation to the antimicrobial activity of three different antimicrobial incise drapes
House Keeping

• Questions
• Mute feature (*7 = unmute, *6 = mute)
• “Chat” feature
• Technical difficulties
• CE credits
• Post session follow-up
Surgical Site Infections

- US - occur in 2% - 5% of patients undergoing inpatient surgery
- ~ 500,000 occur each year
- Add ~7-10 additional postoperative days
- Patients who have SSI have 2-11 times higher risk of death
- Costs vary according to procedure & type of infecting pathogen – estimates $3,000-29,000
- Account for up to $10 billion annually in healthcare expenditures

For most SSI, the source of pathogens is the endogenous flora of the patient’s skin, mucous membranes, or hollow viscera.

Distribution of Top Ranking Pathogens
(January 2006 - October 2007)

<table>
<thead>
<tr>
<th>Pathogens</th>
<th>SSI</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>30.01%</td>
</tr>
<tr>
<td><em>Coagulase Negative Staph (CNS)</em></td>
<td>13.74%</td>
</tr>
<tr>
<td><em>Enterococcus spp.</em></td>
<td>11.21%</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td>5.55%</td>
</tr>
<tr>
<td><em>Eschericia coli</em></td>
<td>9.55%</td>
</tr>
<tr>
<td><em>Acinetobacter baumannii</em></td>
<td>0.60%</td>
</tr>
<tr>
<td><em>Enterobacter spp.</em></td>
<td>4.17%</td>
</tr>
<tr>
<td><em>Candida spp.</em></td>
<td>2.07%</td>
</tr>
</tbody>
</table>

http://www.cdc.gov/ncidod/dhqp/SHEA_Abtract1.html
Quantitatively

- When the surgical site is contaminated with > $10^5$ (100,000) microorganisms per gram of tissue the risk of SSI is markedly increased.

- When foreign material (e.g., implants or sutures) is present at the site contaminating dose decreases (e.g., $10^2$ or 100 microorganisms per gram of tissue)

CDC Guideline for Prevention of Surgical Site Infection, 1999
http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf
Microbial contamination of the surgical site is a necessary precursor of SSI

SSI can be defined as:

\[ \text{Risk of Surgical Site Infections} = \left( \frac{\text{Dose of Bacterial Contamination}}{\text{Resistance of the host (patient)}} \right) \times \text{Virulence} \]


Transient bacteria:

- Low in number on clean unexposed skin
- Do not reproduce
- Attached weakly
- Easily removed
Resident flora:
- Grow
- Reproduce
- Attach firmly
- Are difficult to remove

Stratum corneum
Antiseptics work here
Not Here
Surgical Skin Preps

- Do not sterilize the skin – Only disinfect
- Some residual bacteria may persist
- Skin flora can recolonize during surgery

SSIs (Surgical Site Infections)

An antimicrobial incise drape that provides a sterile operative surface, adheres to wound edges and provides a barrier that isolates the incision from skin flora, reducing wound contamination and the occurrence of SSIs.
Role of Incise Drapes

An incise drape’s barrier is most effective when the drape is securely adhered to the patient’s skin up to the incision edge.

Role of Incise Drapes

- Bacterial regeneration occurs continually on the skin
- Incise drapes create a sterile barrier at the beginning of surgery.
Role of Incise Drapes

Drape Lift has been associated with a six-fold increase in surgical site infection.  

Not all Drapes are Created Equal

• Clear adhesive incise drapes immobilize bacteria.

• An Incise drape with an antimicrobial agent provides added protection.

• The adhesive and antimicrobial agent continuously come in contact with patient’s skin, lowering the bacterial count and helping to reduce the occurrence of SSIs.
Science Behind Choosing an Incise Drape

- Not All Drapes are created equal
- Maximum Barrier protection is obtained when an incise drape adheres securely to the skin surface and wound edges
- Antimicrobial incise drapes may help reduce the risk of wound contamination
An *in vitro* Study to Compare the Antimicrobial Activity of Three Antimicrobial Surgical Incise Drape

Eyberg CI, Morse DJ, Olson LK, Parks PJ. An *in vitro* study to compare the antimicrobial activity of three antimicrobial surgical incise drapes. Poster presented at: 19th Annual Scientific Meeting of the Society for Healthcare Epidemiology of America (SHEA), March 19-22, 2009, San Diego, California
Levels of evidence for antiseptics

• *In vitro*
  • Log reduction in skin flora
  • Kill rate
  • Bacterial capture/immobilization

• *In vivo*
  • Reduction in wound contamination rate
  • Reduction in surgical site infection rate
Prospective, Randomized, Clinical Trial of An Antimicrobial Drape vs. no Drape in Reducing SSI

Sample Size Calculations:

- Hypothesis: antimicrobial drape vs no drape, no effect on SSI reduction,
- Assumption: surgery with 1% infection rate
- Goal: To demonstrate 25% difference in infection rate reduction
- For alpha = 0.05, and power of 80%,
  \[ N \sim 44,000 \]
- For alpha = 0.05, and power of 90%,
  \[ N \sim 60,000 \]
An *in vitro* Study to Compare the Antimicrobial Activity of Three Antimicrobial Surgical Incise Drapes

- **Objective:** To compare the *in vitro* ability of 3 antimicrobial incise drapes to reduce known population of microorganisms
- **Study site:** An independent test lab
- **Study design:** Prospective, controlled, comparative
- **Drapes tested:**
  - 3M™ Ioban™ Antimicrobial Incise Drape
  - ACTI-Gard® Antimicrobial Incise Drape
  - ISO-Drape™ Incise Drape featuring Microban™ Antimicrobial Protection
  - 3M™ Steri-Drape™ 2 Incise Drape
Microorganisms tested:

- Staphylococcus aureus (MRSA)
- Staphylococcus epidermidis (MRSE)
- Enterococcus faecium (MDR)
- Enterococcus faecalis (VRE)
- Streptococcus pyogenes
- Enterobacter cloacae
- Escherichia coli
- Klebsiella pneumoniae
- Pseudomonas aeruginosa
- Serratia marcescens
- Candida albicans
- Candida parapsilosis
Test Procedure

ASTM E2315-03

- Inoculate surface of the adhesive side of drape samples with microorganism
- Incubate 30, 60 and 90 minutes
- Transfer test material to a blender containing neutralizing broth
- Plate dilutions
- Count survivor colonies
Comparing Antimicrobial Incise Drape With Incise Drape without Antiseptic Agent In Log Reduction

- S. aureus MRSA
- S. epidermidis MRSE
- E. faecalis VRE
- E. faecium MDR
- S. pyogenes
- E. cloacae
- E. coli
- K. pneumoniae
- P. aeruginosa
- S. marcescens
- C. albicans
- C. parapsilosis
MRSA and MRSE

Pathogens frequently associated with increased incidence of SSI and morbidity in surgeries commonly using incise drapes

Shams WE and Rapp RP. Methicillin resistant staphylococcus infections: an important consideration for orthopedic surgeons. *Orthopedics* 2004; 27(6):565-568
Test Results

In vitro Time-Kill of MRSA at 90-minute Exposure

Microbial Log Reduction

loban | ACTI-Gard | Microban | SD 2
Test Results

In vitro Time-Kill of MRSE at 90-minute Exposure

[Diagram showing microbial log reduction for different products]
Study Result

In vitro Time Kill (logarithm)

* No organisms were recovered from any of these samples at this time point, so the standard deviation was 0.00.
Conclusion

- At no time point, did any of the other drapes kill any of the microorganisms better than Ioban.
- After 90 minutes, Ioban Drape was significantly better than ACTI-Gard and Microban in reducing the microbial counts of all 12 microorganisms.
- ACTI-Gard and Microban were not significantly better than Steri-Drape in reducing any of the microorganism tested at all time points tested.
Study Limitation

In vitro study

This is a surrogate endpoint, the clinical relevance is unknown, and cannot be used as an indicator of the reduction of surgical site infections
Frequently Asked Questions

Question: Some surgeries are longer than 90 minutes, why not include kill time longer than 90 minutes?

Answer:

• The test material + the inoculum dry out after 90 minutes
• In this study, Ioban killed 99.999% of MRSA after 90 minutes. Even if we can conduct the study > 90 minutes, the increase in % kill is likely not significant
Frequently Asked Questions

Question: If we use prepping solution to disinfect the skin, why do we need to use an antimicrobial incise drape? Isn’t it sufficient to use a clear incise drape?

Answer:

• Surgical prepping solutions disinfect, not sterilize skin
• Incise drapes with adhesive immobilize bacteria\(^2\)
• The study we have just discussed demonstrated in an \textit{in vitro} testing, some antimicrobial incise drapes are efficacious in reducing bacterial counts

Frequently Asked Questions

Question: Why can’t we test the bacterial kill in surgery in real world conditions on a patient’s skin?

Answer:

Depending on individual, when you remove an incise film, part of the epidermal cells may be removed, exposing bacteria that were not originally on the skin’s surface, but below the epidermis.
Thank You

Questions

To ask via the phone, you must unmute your phone first: (*7 = unmute, *6 = mute)

To ask via the internet, please use the chat feature on the left hand side of your screen.