SILVER BASED ANTIBACTERIAL IN SILICONE LINER MATERIAL
Klaus-Peter Anhalt, Susann Hesse, Chuck Polta
Otto Bock HealthCare GmbH, Otto Bock HealthCare LLC

INTRODUCTION
Healthy humans can produce between 0.8 L and 10 L of sweat a day. Due to the presence of bacteria, the components of this perspiration can break down into unpleasant odors.

Under ideal conditions, bacteria such as Escherichia coli can divide / double every 20 minutes. In the warm moist conditions of the socket environment this bacterial presence may quickly lead to liner odor.

The antibacterial effects of silver have long been known (e.g., silver coins used to prolong the shelf life of food). More recently, antimicrobial additives have entered use in commercial products where bacterial odor and sweating are common (e.g., running shoes, anti-microbial wicking sockliners). These antibacterial treatments claim to prevent bacterial growth in and on the treated materials, thus reducing associated odors.

We will investigate whether a silver based antibacterial additive (Skinguard\textsuperscript{TM}), when formulated into silicone liners, protects them from bacterial contamination and resultant odors while maintaining standard liner function.

METHOD
Biological, mechanical and user evaluations are all utilized.

Subjects: 19 users of traditional silicone based liners participated in the evaluation.

Apparatus: Mechanical testing was performed on a standard load frame (Instron / MTS).

User evaluation was conducted by way of a patient survey comparing standard and antibacterial silicone liners.

Procedures: Biological testing includes; JIS Z 2801:2000 (antimicrobial efficacy), ISO EN 10993-5:2007 (cytotoxicity), and ISO 10993-10 (skin irritation / sensitization, 50 subjects).

Mechanical Testing conducted according to ASTM D638 (tensile properties), and ASTM 1938 (tear propagation).

In addition, an 8 week user evaluation was conducted with participants wearing the antibacterial liners.

Data Analysis: Test results compared to data from standard (no antibacterial additive) silicone.

RESULTS
The test material with antibacterial additive showed significant reduction in bacterial count.

<table>
<thead>
<tr>
<th></th>
<th>Silicone without antimicrobial</th>
<th>Silicone with antimicrobial</th>
</tr>
</thead>
<tbody>
<tr>
<td>E. coli</td>
<td>0.00%</td>
<td>99.87%</td>
</tr>
<tr>
<td>S. aureus</td>
<td>0.00%</td>
<td>&gt; 99.99%</td>
</tr>
</tbody>
</table>

Table 1. Reduction in bacteria after 24 hours.

Additionally the antibacterial liner material tested as both non-cytotoxic and non-irritating to skin.

Mechanical properties of the antibacterial silicone were comparable to the standard control silicone.

The user survey indicated 49% of participants observed a reduction in liner odor, and an 84% overall “equal or better than existing liner” rating.

DISCUSSION
Addition of the antibacterial additive appeared to reduce both bacterial growth and reported liner odor. Basic liner properties were maintained.

CONCLUSION
A silver based antimicrobial additive can be effective in reducing bacteria in/on the liner. This reduction in bacterial count can manifest as reduced odor.

CLINICAL APPLICATIONS
It is estimated that approximately 1/3 of amputees experience odor associated with their prosthesis. Antibacterial liners may help reduce this proportion.

REFERENCES
M Wilson, Microbial Inhabitants of Humans: Their Ecology And Role In Health And Disease, 2005.