BACTERICIDAL IMPLANTS: CHANGING THE LANDSCAPE OF POST-SURGICAL INFECTIONS

Thomas Fuller, Richard A. Wysk, Ph.D. Wayne Sebastianelli, M.D., Paul Cohen, Ph.D., Robert Voigt, Ph.D., Terry Margolis and Jon Zimmerman
ARGENTUMCIDALELECTRICS, INC.
State College, PA 16802

Background: In 2005, there were approximately 850,000 total hip and knee replacements in the U.S. Replacing arthritic joints has improved the quality of life for millions of Americans. Unfortunately, the cost associated with replacement surgery has also grown, along with many other medical costs. In general, improvements in medicine increase the cost of medical delivery. Some of these costs are obvious but others can be obscured. For instance, the surgery itself is a direct cost. The good news here is that the efficiencies of replacement surgery have improved and the direct costs of replacement surgery have actually gone down. A hidden cost for any surgery is the cost of post-operative infection. In the case of joint replacement surgery, about 1.5% of all surgeries result in deep bone infection (Osteomyelitis), and the cost associated with mitigating deep bone infections far exceed the cost of the replacement surgery.

We have developed an indwelling medical implant system that can prevent or eliminate deep bone infections (A Prophylactic Bactericidal Implant – patent pending). The system is capable of operating as a prophylactic device the will inhibit infections from developing or as an active system that can be activated after an infection has been discovered in order to eliminate the infection. The system can be adapted to virtually any joint implant or to most fixation systems used for trauma patients, for a small cost. We see this development as a medical development that actually reduces the total cost of joint replacements as well as for trauma fixation – a rarity in medicine today.

Claim: Bactericidal metals have been used in medicine for over a hundred years. Silver, in particular, has shown amazing bactericidal qualities in laboratory experiments. Unfortunately, it appears that researchers have not been able to develop products, devices and circumstances that routinely exhibit this bactericidal property. Two decades ago, researchers were investigating electrically stimulated silver as a bactericidal. Unfortunately, some successes as well as failures were observed from these investigations.
Today many researchers in this area have been pursuing the use of colloidal or ionic nano silver as a bactericidal. Again, the results of this work have met with mixed success.

We have taken a new look at electrically stimulated silver. First of all, batteries have gotten both smaller and better, and we now have the ability to easily embed a battery in an implant or even in a fixation fastener. The duration of the battery stimulation can also be extended for in many cases years of effectiveness. This compares to a very short duration for nano silvers, which have very short reported periods of effectiveness. We have developed implant devices that can be used for months or years of bactericidal activity that have shown efficacy for a wide variety of bacteria as well as fungi. This development will significantly reduce post-surgical infections and could potentially eliminate medical mitigation cost associated with deep bone infection.

**Our System:** We have designed and tested dozens of devices for bactericidal effectiveness. In our testing, we have found that a critical requirement for bacteria inhibition is getting the bacteria to serve as a conductor for silver ions. This configuration has been tested in vitro for the following bacteria: Staphylococcus Aureus, Enterococcus, Pseudomonas, E. Coli and MRSA. The (bactericidal) metals used for the testing were: silver, copper, stainless steel, cadmium, titanium and gold. The system was also tested for fungicidal properties for Candida Albicans. Electrically stimulated silver showed the broadest effectiveness against all of the bacteria and fungi tested.

Figure 1 shows a prototype hip implant being tested using Pseudomonas. As can be seen in the figure, this configuration created a “cidal dome” around the device, both the anode and cathode. We believe that the device will perform similarly In Vivo to control bacteria and fungus.

![Figure 1. Hip prototype in pseudomonas showing kill region.](image-url)
**Conclusions:** We have developed an anti-microbial device system that can potentially change the landscape of post-surgical infection problems associated with joint replacements as well as for trauma fixations. The cost of fabricating the changes for the bactericidal hip is approximately $20, making it commercially viable to combat the $2B spent annually to mitigate infections from surgical procedures for implant and fixation devices. Our animal testing has shown a 50% efficacy, but continued to show improvements as we learned more about the surgery as well as the device itself. Even with the 50% efficacy for the system, a reduction of $1B in medical remediation costs could be obtained using this technology.

While there is a challenging redesign needed, moving into the fracture fixation devices will open a $1.5B market.