Fentonite® – An Effective Antimicrobial Without Cytotoxicity Found with Zinc or Silver

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BACKGROUND

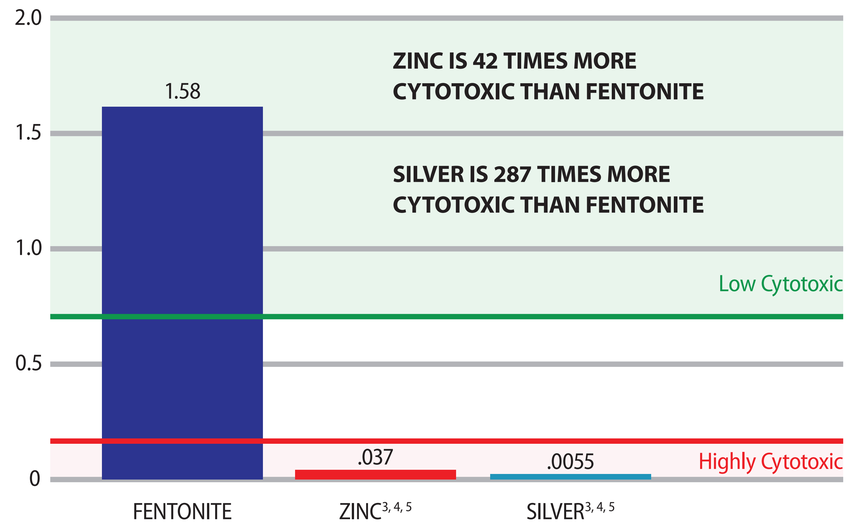
Despite silver wound dressings representing a $1.9 billion dollar industry, research has proven silver-based dressings are not as effective. More importantly. silver is cytotoxic to fibroblast and keratinocytes when used at dosing levels required to meet antimicrobial efficacy standards. Fentonite is a new alternative to silver. It is effective against pathogens while non-cytotoxic to fibroblasts and keratinocytes.

Silver is widely regarded as an effective antimicrobial agent amongst the medical community as evidenced by the wide variety of silver-containing wound care products available. However, a more thorough investigation of the research from in vitro, ex vivo, and in vivo clinical studies paint a more obscured picture of the true safety and efficacy of silver-containing wound care products. In fact, a 2012 international expert working group consensus highlighted studies including two Cochrane reviews that concluded there was a lack of evidence showing improved healing rates with silver dressings.[1] A more recent 2019 comprehensive review of 59 relevant studies about silver in wound care, pointed out that: 1.) "The quality of the published data onthe use of silver in wound care is poor" and 2.) "many of the published studies are funded or even written by manufacturers of silver containing dressings." [2]

The overuse of antibiotics has led to the rise of antibiotic-resistant bacteria, which are now responsible for thousands of deaths each year. In search of a solution, scientists have been looking for new compounds that can kill these dangerous superbugs. One promising candidate is Fentonite, a rare medicinal clay mineral that has shown promise. When exposed to Fentonite, many strains of antibiotic-resistant bacteria were quickly killed. What makes Fentonite so effective is its ability to disrupt the cell membranes of bacteria without harming surrounding cells. Fentonite works with the body's normal defense mechanism, known as the Fenton Reaction. The Fenton Reaction requires a pH below 4 and adequate reduced iron to initiate the cationic exchange.

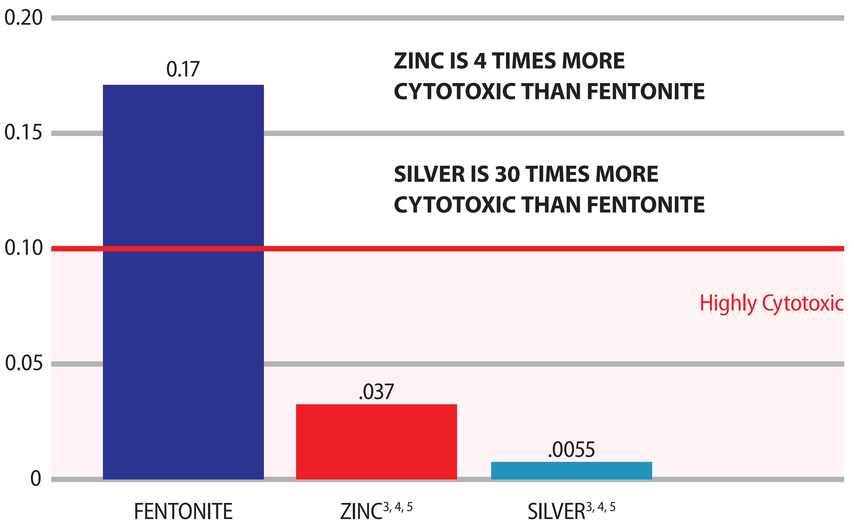
HUMAN FIBROBLAST SURVIVAL RATE IN COMMON ANTIMICROBIAL INGREDIENTS

TC50 is a measure used to determine how cytotooxic a drug or compound is to certain types of cells. Typically, compounds that are considered highly cytotoxic have TC50 concentrations below .10 mg/mL, while compounds are considered relatively low cytotoxic with TC50 above .7 mg/mL



HUMAN KERATINOCYTE SURVIVAL RATE IN COMMON ANTIMICROBIAL INGREDIENTS

TC50 is a measure used to determine how cytotooxic a drug or compound is to certain types of cells. Typically, compounds that are considered highly cytotoxic have TC50 concentrations below .10 mg/mL, while compounds are considered relatively low cytotoxic with TC50 above .7 mg/mL



TESTING FACILITY

ImQuest BioSciences

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MATERIALS AND METHODS

Fentonite (test article) was stored at room temperature upon arrival. The test article was weighed (400 mg) and resuspended in 1 ml of sterile water. For the NHEK cytotoxicity evaluations, 500 µL of each prepared test article was added to 500 µL of assay medium. For the HFF cytotoxicity evaluations, 250 µL of each prepared test article was added to 750 µL of assay medium. Two hundred microliters (200 µL) of the 200 mg/ml solution (NHEK) or 100 mg/ml solution (HFF) were transferred to 800 µL of assay medium (1 :5 dilution) for a total of nine serial dilutions. One hundred microliters of each 2x concentration were added in triplicate wells to the cells containing 100 µL of fresh assay medium for cytotoxicity evaluation. Staurosporine was purchased from Sigma Aldrich (St. Louis, MO) and evaluated as a positive control compound in the cytotoxicity assays.

CYTOTOXICITY EVALUATIONS

HFF Cell Culture - Normal human foreskin fibroblasts (ATCC SCRC-1041) were cultured in DMEM supplemented with 10% heat-inactivated fetal bovine serum, 2 mM Lglutamine, 100 U/ml penicillin and 100 µg/ml streptomycin. Cells were seed in flat bottom 96 well microtiter plates at 5 x 103 cells per well and incubated at 37°C/5% CO2 overnight for adherence. Following overnight incubation, cell culture medium was removed and replaced with 100 µL per well of medium. Compound was added in triplicate wells to the cells at 100 µL per well. Compound plus medium allow was evaluated in a single well per concentration as a colorimetric control.

NHEK Cell Culture - Normal human epidermal keratinocytes (Lonza 00192906) were cultured in KGM Gold Keratinocyte medium with supplied growth supplements. Cells were seed in flat bottom 96 well microtiter plates at 2 x 104 cells per well and incubated at 37°C/5% CO2 overnight for adherence. Following overnight incubation, cell culture medium was removed and replaced with 100 µL per well of medium. Compound was added in triplicate wells to the cells at 100 µL per well. Compound plus medium allow was evaluated in a single well per concentration as a colorimetric control.

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