

# Treatment for Diabetic Foot Ulcers

Fact: 80% of all Foot Ulcers result in foot and limb infections. The World Health Organization (WHO) has mandated all countries to promote their medical establishments to innovate and find solutions to the growing problem of diabetic foot infections. New Technology is required as antibiotics are not keeping up with the resistance of the bacteria.

In the USA alone 170,000 diabetic foot and limb amputations continue each year. This is an indication of innovation failure. This lack of innovation is stunning when considering the USA's own health agencies have funded over \$5-10 Million annually to major universities. Researchers have produced little innovation and medical technology.

## Reasons for Lack of Medical Innovation

1. **High Cost:** There is a difficulty in financing the high costs of research and the production of new antibiotics tailored to treat emerging strains of bacterial infections.
2. **Lengthy Development Time** compared against the rapid bacterial mutations discourages investment and research.
3. **Misdirected Research** by bio-chem educated investigators who see little value in technology outside of their main educational field, in spite of mandates from the WHO for a “*Multidisciplinary / Tech-Driven Strategy*”.
4. **General Population's Declining Health** cause shift away from real infection research. Now the emphasis has changed to focus on people's diet and lack of exercise that contributes to the rise in diabetes.

## Suggestions for Innovation in 2026:

1. Bacteria develop a **Strong Cell Wall** to prevent entry of foreign antibodies into its membrane. **Solution:** Use a treatment that ignores the cell wall and defeats the bacteria by attacking the cell membrane from the inside..
2. Choose a treatment that does not stimulate the bacteria to immediately develop a resistant pathogen. **Solution:** Consider a **Drug-Free / Quasi-Drug** treatment.
3. Choose a treatment that acts **Immediately**, not days or weeks, to overtake and stop the growth of the infection. **Solution:** Use a treatment that exploits the fundamental flaw of bacteria that allows bacteria to survive and rapidly grow.
4. Use a treatment that Penetrates bacterial biofilm to reach the bone.

## Medical Innovation 2026:

It is common knowledge that bacteria absorb iron for its own biological needs. This fact represents an opportunity that innovation can exploit. The bacteria *biosynthesizes* this iron to form it into iron nanoparticles. Iron nanoparticles are *paramagnetic*.

*Paramagnetic nanoparticles* will easily heat inside the bacteria cell membrane when exposed to **Magnetic Hyperthermia (AMF)**.\*

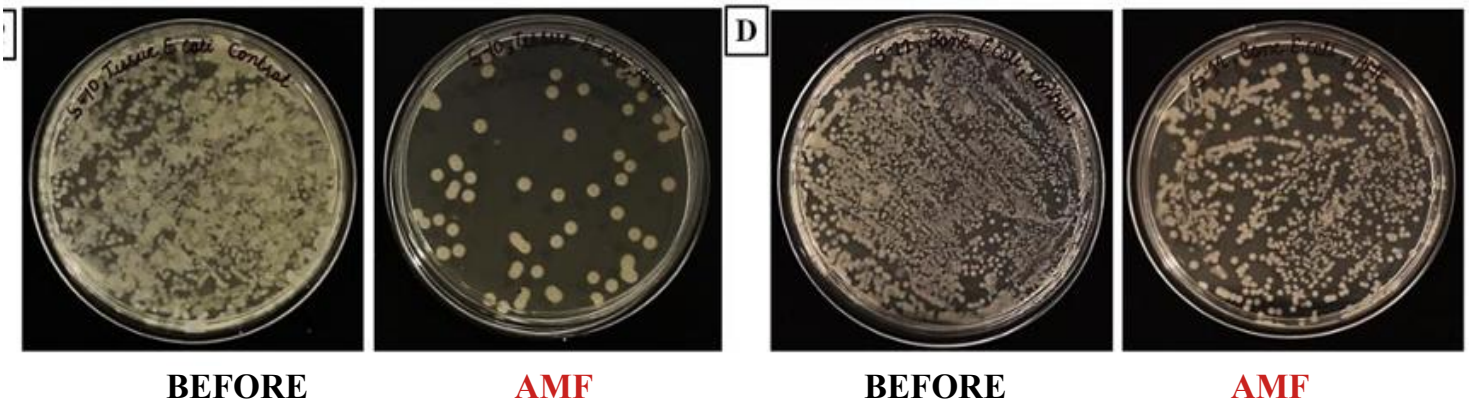
- 1) **AMF Treatment** can over-heat the bacteria membrane internally by heating the iron nanoparticles residing in it.
- 2) **The Cell Membrane** denatures and can no longer function.
- 3) Regardless of diabetic patient's **Peripheral Vascular Disease** that restricts antibiotics from reaching the infection, the magnetic field heats and kills the bacteria directly.
- 4) The **Magnetic Field** is uninhibited by both tissue and bone mass. The magnetic heating easily penetrates the bone to kill the bacterial infection inside the bone.
- 5) Magnetic Heating is a **Quasi-Drug Treatment** that uses the bacteria's own iron to over-heat the cell membrane, resulting in cell death.
- 6) **Magnetic Heating** is not a conventional drug and does not cause the bacteria to mutate and develop a resistance to the treatment or another pathogen.
- 7) **NIH Heating Control:** The introduction of the MSI Automation Computer technology allows the heating to be controlled and limited to the level specified by the NIH:  $H \times f = 9.46$

### LIVE HUMAN TISSUE

#### E-Coli Infection

### LIVE HUMAN BONE

#### E-Coli Infection



Tissue samples taken from live patients whose infections spread despite antibiotic treatment. (C) E. Coli infected muscle sample. (D) E. Coli infected bone sample. Both treatments were exposed to magnetic hyperthermia heating (AMF) for 5-15 minutes. Longer exposure results in higher death rate for the bacteria. Scanning electron microscope images revealed the destruction of the bacterial cell wall. AMF treatment also resulted in excess reactive oxygen species formation, which might contribute to bacteria cell death. As required by the FDA: A lengthy safety study of 25 female rats showed an overall lack of significant edematous response to AMF. (*Journal of the Royal Society of Chemistry 2022: NanoScale,14. 1713...*)

**Upon exposure of the bacteria for 5-15 minutes with AMF (360 kHz / 400 Oe), we observed a hyperthermia response with 3-5 log reduction in live bacterial load. The hyperthermia anti-bacterial treatment was confirmed using multiple patient specimens with different pathogens. “This validates the clear potential of the drug-free strategy to address the infection.”** (Dr. Deepa Ghosh)

\*Dr. Deepa Ghosh of The *Institute of Nano Science and Technology* / (Mohali, India). Aug 7, 2022 **Nanoscale DOI: 10.1039/d1nr07435k (pp 1713-1722)**

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# **Study of Impact on Living Tissue using Magnetic Hyperthermia**

(Dec. 2022 – Dec. 2024) / *Institute of NanoScience and Technology*

***Exploratory Study to evaluate the efficacy of alternate magnetic field (AMF) to reduce bacterial loading human subjects with bacterial infections in the limbs.***

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**Study type:** Academic clinical trial. PI's: Dr. Sanjay P.I.: Bhadada (Dept. Endocrinology), Dr. Sameer PI: **Dr. Deepa Ghosh**, INST, Mohali, INDIA

To confirm the safety of continuous/pulsed AMF, we exposed cohorts of female SD rats to AMF of **225 kHz, 325 Oe /  $5.3 \cdot 10^9$ \*** and **375 kHz, 320 Oe /  $9.3 \cdot 10^9$ \***, respectively. A total of 25 female rats, inclusive of one acting as the control, underwent diverse AMF treatments.

The **Pulsed Treatment** involved subjecting 4 rats AMF treatment in precise intervals of 5 minutes of treatment, 5 minutes of rest, followed by an additional 5 minutes of treatment. Subsequently, two rats were sacrificed on the same day, while the remaining two underwent sacrifice the following day.

Similarly, 4 rats were analyzed after **Continuous Treatment of 10 minutes**. Furthermore, two separate cohorts, each comprising four rats, underwent repeated continuous treatments at **7-day** intervals, culminating in their sacrifice after an aggregate period of 21 days.

Analysis of the exposed skin to AMF, showed no significant changes on visualization after treatment (Fig 6). The absence of observable signs of paw swelling or edema across the experimental conditions implied an overall lack of significant edematous responses to AMF (Fig.7). This was confirmed with the consistent measurements of paw size that suggested an absence of inflammation in the paws on exposure to AMF (Fig. 8).

**Histological Examinations** of skin and muscle tissues from rats exposed to AMF showcased no notable changes in comparison to control groups. Microscopic analyses revealed **(1)** intact tissue architecture, **(2)** the absence of necrotic foci, **(3)** inflammatory responses, or **(4)** other discernible alterations in both skin (Fig. 9) and muscle sections (Fig. 10). These findings suggest a lack of substantial tissue damage or inflammatory reactions elicited by the applied AMF.

This data proves that AMF heating is safe. The **MSI Magnetic Hyperthermia System** is safe. It uses a supervisory algorithm to control the heating power to within the guidelines set by the NIH.

**\*Proposal of New Safety Limits for In Vivo Experiments of Magnetic Hyperthermia Antitumor Therapy: Cancers 2022, 14(13), 3084; <https://doi.org/10.3390/cancers14133084>**