

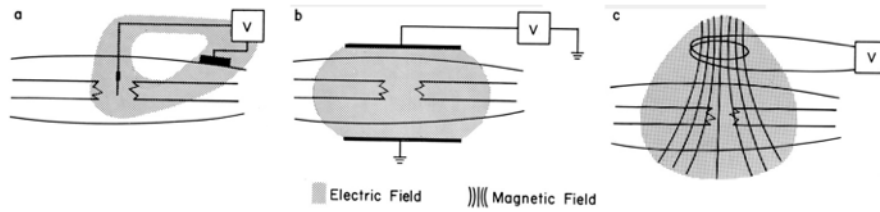
Systemic Effects of Electromagnetic Energy

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The efficacy and risks of the use of electromagnetic energy to stimulate bone growth have been studied in animal models. In most cases the focus of the studies has been to assess the effect of the energy on a healing system, typically a surgically-induced bone fracture. Commonly, the energy is applied systemically in the sense that an electric or magnetic field is applied to the whole animal, not only to the local injury site. Today, I offer evidence indicating that the energy has systemic effects that are independent of the effects on the rate of local healing. I am going to conclude that because the systemic and local effects are confounded, the use of animal models involving systemic exposure is problematical and a serious question is presented concerning the relevance of the studies to the clinical evaluation of the modality for applying the energy.

Types of commercial devices for growing bone



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Clinically, the energy is always applied locally, either by indwelling electrodes which permit the direct passage of current, metal plates placed outside the target region to permit capacitive application of the energy, or by means of the use of coils that generate a fluctuating magnetic field which delivers the energy to a healing site.

Whole-body exposure Biological effect produced using capacitive coupling

Investigator	Animal	Biological Effect	Electric Field (v/cm)	Frequency (hertz)	Exposure Duration
Lott	Rats	EEG	0.4	640	90 minutes
Marino	Mice	Body weight & mortality	150	60	100 days
Noval	Rats	Neurohormones & body weight	0.5	45	1 month
Hamer	Humans	Reaction time	0.04	2-12	Several minutes
Wever	Humans	Circadian rhythms	0.02	10	8 weeks

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This slide summarizes the published results of five studies in which capacitive energy was applied systemically. With the exception of the Hamer study, the energy was applied to the entire body of the subject (capacitor plates larger than the dimensions of the subject's body). In the Hamer study, the plates were larger than the subject's head which was directly exposed to the energy. The studies show that capacitively-induced energy causes biological effects unrelated to bone growth.

Whole-body exposure Biological effect produced using capacitive coupling

Investigator	Animal	Biological Effect	Electric Field (v/cm)	Frequency (hertz)	Exposure Duration
Friedman	Humans	Reaction time	3	0.2	Several minutes
Goodman	Slime mould	Mitotic rate	2	45	Several days
Beischer	Humans	Triglycerides	1	45	1 day
Grissett	Monkeys	Body weight	1	72	Several minutes
Gibson	Humans	Psychological tests	1	45	Several minutes

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This slide presents the results of five additional studies. Particularly in the case of primates, the data shows that the whole-body effect can occur after even only brief exposure durations.

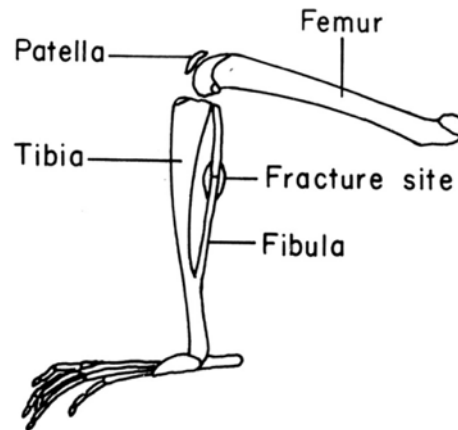
Whole-body exposure Biological effect produced using capacitive coupling

Investigator	Animal	Biological Effect	Electric Field (v/cm)	Exposure Duration
Mose	Mice	Immune response	0.4	15 days
Brown	Planaria	Behavior	2	Several hours
Mitchell	Tumor cells (mouse)	Chromosomal abnormalities	80	10 weeks
Sidaway	Plants	Germination rate	360	1 day
Jones	Humans	Behavior	12	Several hours

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This slide presents data from five additional studies and emphasizes the phenomenon of systemic effects occurs across a range of living systems: on plants to worms, mice, and humans.

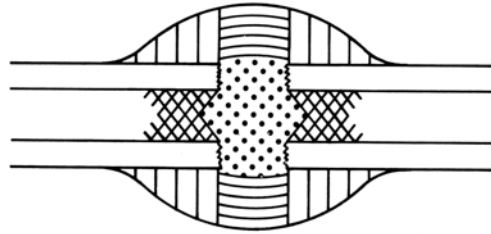
Animal model used to study effect of electric field on fracture healing







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I will present results from our laboratory in a rat fracture model where capacitively-coupled energy was applied systemically in the presence or absence (controls) of the energy. We created a surgically-induced fracture in the fibula, which was used to obviate the necessity of applying a cast, because the fracture site was inherently stable.

Histological divisions of healing callus used to score extent of healing



Anchoring Callus  Uniting Callus 
Bridging Callus  Sealing Callus 

We analyzed the results using a histological grading system that measured the extent of healing that occurred in the four distinct regions of the healing callus.

Comparison of histological gradings of experimental and control animals

Criterion	Experiment 1		Experiment 2	
	Control (n=17)	Experimental (n=18)	Control (n=20)	Experimental (n=20)
Union	5.3 ± 0.9	4.2 ± 1.0	5.4 ± 0.8	4.4 ± 0.8
Alignment	1.9 ± 0.3	1.4 ± 0.7	1.6 ± 0.7	1.4 ± 0.8
Callus size	2.9 ± 0.8	1.9 ± 0.8	3.0 ± 1.0	2.0 ± 0.9
Cartilage—Anchoring	3.9 ± 1.6	2.1 ± 1.4	4.1 ± 1.0	1.8 ± 1.6
Cartilage—Bridging	3.8 ± 1.4	2.3 ± 1.2	3.6 ± 0.9	2.4 ± 0.9
Cartilage—Uniting	3.9 ± 1.4	2.0 ± 1.3	3.4 ± 0.7	2.4 ± 0.9
Cartilage—Sealing	3.8 ± 1.6	2.1 ± 1.4	3.3 ± 0.7	2.1 ± 1.4
Bone—Anchoring	4.2 ± 0.6	3.2 ± 0.5	4.0 ± 0.8	2.8 ± 0.9
Bone—Bridging	2.9 ± 0.9	1.7 ± 0.9	3.0 ± 1.0	1.4 ± 0.8
Bone—Uniting	3.1 ± 1.2	1.8 ± 1.1	2.2 ± 0.8	1.2 ± 0.4
Bone—Sealing	3.5 ± 0.8	2.5 ± 0.9	3.5 ± 0.6	2.0 ± 0.8
Healing Index	39.3 ± 7.7	25.2 ± 3.5	37.2 ± 6.1	24.0 ± 3.2

The means in each category in both experiments are significantly different ($p < 0.01$), except for Alignment.

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This slide shows the results of two independent controlled experiments. The data clearly showed the retardation in healing in every criterion used to assess the effect of the energy.

Risks of electrically-induced osteogenesis

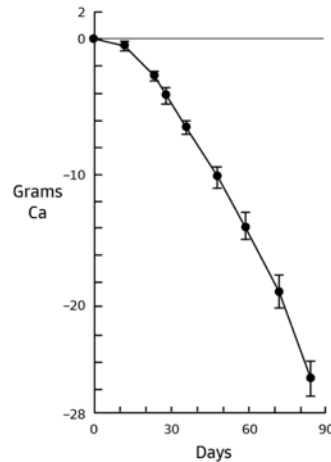
1. Short-term*
2. Long-term

*period comparable to the duration of application of the energy

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The results of our study, and indeed all the other studies I mentioned, involved short-term biological effects. I will describe what I believe is a long-term effect from what was actually an unintended human study of the effects of electromagnetic energy on bone metabolism.

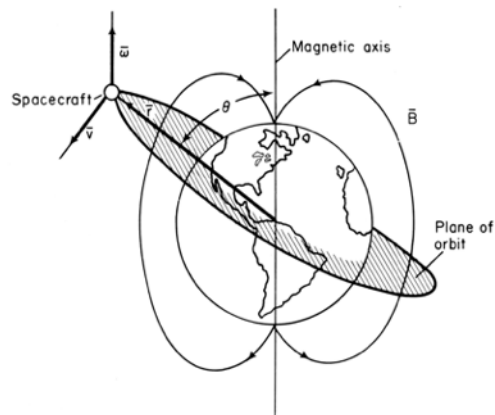
Average cumulative calcium loss during Skylab flights



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This slide shows data from NASA regarding the loss of bone calcium in astronauts on the Skylab flights. You can see that the loss of calcium increased continuously with time, never leveling off. By about 85 days, the astronauts had lost, on average, almost 26 grams of calcium. We published a paper in *Aerospace Medicine* that provided calculations of the electromagnetic energy deposited in the bodies of the astronauts due to the motion of the spacecraft through the earth's magnetic field. We suggest the possibility that the calcium loss might have resulted from similar physiological processes that occurred in the rats we studied and resulted in retarded healing.

Mechanism by which electrical signals are induced in the body of an astronaut



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We have presented considerable evidence indicating that electromagnetic energy is a stressor, and is capable of activating the neuroendocrine system in exposed subjects. Stress, therefore, could be the underlying physiological mechanism in both the animal studies and the bone loss that occurred in the astronauts. The salient aspect of the NASA observations is that the bone loss experienced by the astronauts was not recovered after they returned to earth, and thus constitutes a long-term effect.

Summary: Origins of risk

- Electromagnetic fields are stressors
- Notion of dose not developed
- Adverse effects in bone exist
- No long-term studies

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It seems prudent to evaluate questions of dose and long-term consequences before accepting electromagnetic energy as a healing modality in orthopedics. Further, obvious questions regarding the confounding of healing and stress responses in animal systems intended to model human clinical exposure should be reevaluated.