Rohde, C., et al. 2009. Effect of Pulsed Electromagnetic Fields on Post Operative Pain: A Double-Blind Randomized Pilot Study in Breast Reduction Patients. Bioelectomagnetic Society Meetings June, Davos, Switzerland.

Introduction: Post-surgical pain increases patient morbidity and slows healing, particularly if narcotics are employed for pain management. Therefore the surgeon is continually looking for other means to control post-operative pain. There is a growing body of clinical evidence that pulsed electromagnetic field (PEMF) therapy can have physiologically significant effects on tissue repair. Certainly PEMF therapy has been extensively employed for the treatment of recalcitrant bone fractures and is reported as successful as the first bone graft [1]. Recent advances in knowledge of the mechanism of PEMF effects on pain and tissue repair have allowed signals to be developed which can target the anti-inflammatory cascade involving the calmodulin (CaM) dependent nitric oxide (NO) pathway. The present study was designed to clinically assess the effect of a PEMF signal designed to modulate Ca2+ binding to calmodulin (CaM) [2], as a first step in the body's response to injury or trauma. Tuning the drug-free PEMF signal for the NO cascade provides an immediate stimulus independent of pharmacokinetics since the time-varying magnetic field appears instantaneously in all compartments of the target tissue. This pilot study was designed to determine if PEMF treatment, given in addition to standard of care, could reduce postoperative discomfort and morbidity after breast reduction surgery.

Materials And Methods: Twenty healthy women, aged 27 to 59 years, who were candidates for breast reduction for medical reasons, were admitted to this double-blind, placebo-controlled randomized study. Breast reduction was performed by the same surgeon using the standard Wise or vertical incision techniques with superomedial pedicles. Patients were equally divided into active and sham groups. A disposable dual coil PEMF device (Ivivi Health Sciences, Inc., Montvale, NJ), placed in the post surgical support bra normally used for all patients, was activated on transfer to the recovery stretcher. The PEMF signal, configured, a priori, to modulate Ca2+ binding to CaM, consisted of a 2 msec burst of 27.12 MHz sinusoidal waves repeating at 2 bursts/sec. Peak magnetic field was 0.05G which induced an average electric field of 32 ± 6 mV/cm in each breast. An active PEMF device automatically provided a 20 minute treatment every 4 hours for the typical treatment period of seven days post-op. Sham devices were activated in exactly the same manner as the active devices, but produced no electromagnetic field in tissue. The primary outcome measure in this study was the effect of a PEMF signal on the rate of post surgical pain reduction. Pain data was obtained using a Visual Analog Scale (VAS) which patients self-recorded throughout the overnight hospital stay and for seven days thereafter. Post operative pain medication was also monitored for each patient.

Results: A total of 19 patients were available for analysis. VAS scores were excluded for one patient who became unblinded. Mean VAS scores over the critical first 24 hour post surgical period were compared using the ratio of the score at 24 hours to the initial post-op score. The results show mean VAS

decreased to 48 ± 12 % of initial value in the active group, while mean VAS increased to 129 ± 35% of initial value in the sham group. This difference was significant to P = 0.013 and represents a PEMF effect of approximately 2.7X faster pain reduction within the first 24 hours. Use of narcotic pain medication over the first 24 hours was assessed by comparing pill count for each patient. The results show mean pill count in the active group was 2.6 ± 0.7 vs 5.2 ± 0.6 in the sham group. This difference represents a concomitant PEMF effect on narcotic use of approximately 2X which was significant to P = 0.021. No adverse effects from PEMF treatment were noted in this study.

Conclusions: This randomized study suggests PEMF therapy can have a significant impact on post operative pain management. The PEMF effects reported here are similar to those reported in a randomized study on post operative pain in breast augmentation patients [3]. The mechanism of action of PEMF signals on tissue repair is not completely elucidated. However, it is intriguing to consider that the known effects of PEMF on NO release via effects on Ca2+ binding to CaM which, in turn, activates the constitutive nitric oxide synthases (cNOS) may be applicable here. NO is a short-lived signaling molecule which is known to be involved in anti-inflammatory cascades. Thus, the observed accelerated pain relief may occur through PEMF increases in the normal anti-inflammatory process of vasodilatation. Of potentially greater importance is that increased NO production leads to increased cGMP production which cascades to the appropriate growth factor release dependent upon the stage of healing. It is thus intriguing to speculate the use of PEMF to control post surgical pain may also lead to enhanced healing. This would impact all surgical procedures and may well lead to a reduction in the cost of health care.