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Similar diagnostic criteria are used for pelvic stress fractures and musculoskeletal pelvic pain. Differential diagnosis is made with a three phase bone scan. Of fifty-four sequential female soldiers having the symptoms of pelvic area stress fractures, seven had positive bone scans. Subjects were stratified by stress fracture or musculoskeletal pain then randomized into placebo or real treatment groups. Treatment was exposure to pulsing electromagnetic fields five days per week until resolution of the problem according to pain ratings, bone scans, and return to duty. Only twelve subjects accepted treatment because it was impossible for most to do their jobs and come to the hospital every weekday for months. Seven subjects dropped out for the same reason. Thus, although both patients with stress fractures receiving a significant number of treatments improved and the three who only received a few treatments did not, the randomized portion of the study never completed a meaningful number of subjects. None of the subjects with musculoskeletal pain nor those receiving placebo treatment improved. The results indicate that pelvic stress fractures are being over-diagnosed. It is recommended that bone scans be given to soldiers meeting the diagnostic criteria early in the diagnostic / treatment process to avoid lengthy treatments for the wrong problem.

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19 April, 1996

Principal Investigator

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1. INTRODUCTION:

a. **Objectives**:

1. To determine the percentage of female soldiers who show the complex of symptoms indicative of pelvic area stress fractures who have conformation of these fractures by bone scan.

2. To determine whether application of Pulsing Electromagnetic Fields (PEMFs) over the stress fracture site or the site of maximal musculoskeletal pain, used in conjunction with standard therapeutic approaches, (a) increases the rate of healing of the stress fractures as determined by changes in bone scans or reduces pain while increasing range of motion among subjects with musculoskeletal pain and (b) reduces the time to return to full duty in relation to those receiving the standard treatments and placebo PEMFs.

b. **Hypotheses**:

1. That application of PEMFs over the stress fracture site, used in conjunction with standard therapeutic approaches, (a) increases the rate of healing of pelvic stress fractures and (b) reduces the time to return to full duty in relation to those receiving the standard treatments and placebo PEMFs.

2. That application of PEMFs over the site of maximum pain among female soldiers with musculoskeletal pelvic pain, used in conjunction with standard therapeutic approaches, (a) increases range of motion, (b) decreases pressure induced pain, and (c) reduces the time to return to full duty in relation to those receiving the standard treatments and placebo PEMFs.

3. That very few of the women who meet the current clinical criteria for pelvic area stress fractures actually have this problem.

c. **Medical and military applications**: Reduction in the number of days of training and work time lost before return to full duty and a decrease in the number of female soldiers who have to be boarded out due to pelvic stress fractures and musculoskeletal pelvic pain are important to the system. Our pilot data indicate that a minimum of a ten day decrease in the time to return to full duty is likely to accrue. A large minority of patients require many months of inactivity to heal and, even then, never return to full levels of activity. It is possible that this treatment will help these relatively slow healers return to full duty more quickly.

d. **Status**:

1. Pelvic stress fractures: Meurman (1980) found that about six percent of stress fractures (39 out of 600) occurring among Finnish military recruits were in the pubic arch. It took an average of thirty days (range of 1 - 83) to make an accurate diagnosis of their problem. However he reports that Morris and Blickenstaff (1967) found only four cases out of 700 stress fractures among soldiers. Matheson et al (1987) found that 1.6 percent of their series of 320 stress fractures occurring among athletes were in the pelvic area. They reported that the average time between occurrence of symptoms and diagnosis was 13.4 weeks (range of 1 to 78) with the average time to recover being 12.8 weeks. Meurman (1980) states that pain was most often reported in the sacral, inguinal, perineal, or gluteal regions, became worse with exercise, and improved with rest.

Moran (1988) discussed pubic stress fractures during the later stages of pregnancy and related their occurrence to increased physical activity among pregnant women. Thorne and Datz (1986) reviewed information on pelvic stress fractures in female runners and found that their usual complaint was groin pain. Both Matheson et al (1987) and Pavlov et al (1982) found that the preponderance of pelvic area stress fractures occurred among very active young females (a ratio of 9 to 2).

2. Use of pulsing electromagnetic fields to speed recovery: This technology has been in use since the 1950s. It has recently been used very successfully by the Army in a study on treatment

of grade I and II ankle sprains (Pennington et al 1993). Pennington's article reviews the safety of the technique and its usefulness for speeding recovery and reducing swelling. Kaplan & Weinstock (1968) performed a double blind study with 100 foot-surgery patients and found that pulsed fields significantly reduced swelling and pain. The technique has been successfully used to prevent initial development of edema and pain in burn patients (Ionescu et al 1982). It has also been successfully used to reduce swelling and control pain among 250 patients with non-operative hand injuries participating in a controlled study (Barclay et al 1983). Pulsed fields also sped the healing of donor site wounds in patients in a double blind trial (Goldin et al 1981).

3. Use of pulsing magnetic fields for helping delayed union and nonunion fractures heal: Uncontrolled clinical trials have reported the use of low frequency pulsing electromagnetic fields to speed and promote the healing of delayed union and nonunion fractures in clinical trials since the 1970s (e.g. Sharrard 1989). At least 14 of the papers report the technique's use for these problems in the tibia. Taken together, they represent trials with 1,275 patients of whom an average of 81% healed after a significant pause in progress (Technology Evaluation, 1989). More recently, double blind studies indicating the technique's effectiveness on a wide variety of bones. have been published. For example, Sharrard (1989) performed a double blind study of 45 fractures of the tibial shaft in which 20 received active coils and 25 received dummy units. Orthopedic examination indicated that nine of the subjects in the active group showed healing relative to three in the control group. Objective radiological evaluation indicated union of five fractures and progress toward union in another five fractures in the active group compared with union in one fracture and progress toward union in one fracture in the control group. Thus, the technique has been shown to be effective in helping nonunion and delayed union fractures of the tibia.

We are only aware of one study in which magnetic fields were used with delayed union stress fractures. The study was done with fractures of the tibia. The authors found that of 8 subjects with confirmed delayed unions, 7 healed with a combination of rest and magnetic fields.

The mechanisms through which PEMFs produce their effects are not known. However, it has been demonstrated that they do not significantly heat exposed tissues so they do not work by heating the effected areas. It has also been demonstrated that PEMFs cause a significant increase in blood flow to exposed tissues. They also have an effect on movement of charged ions in bone and across membranes so may produce their effect on bone healing by directly increasing calcium deposition and/or increasing blood flow in the bones and surrounding tissues. This work has been reviewed in O'Connor et al's book on Emerging Electromagnetic Medicine.

The instruments used to produce and apply the field generally consist of a charger, a combined control and generator unit, and a field coil. The unit is mounted on a rolling cart and the extendable head is positioned over the patient. A typical unit is illustrated in Figure One on the next page.

4. Effect of PEMFs on stress fractures among Army trainees: This team conducted a double blind, placebo controlled pilot study in which the time to return to work, number of hours per day able to stand, and pain patterns were recorded from people with lower limb and metatarsal stress fractures related to Army basic training. Eleven patients with radiologically confirmed tibial and metatarsal stress fractures who received the standard treatment in addition to being exposed to PEMFs five times per week for one hour per day were compared with thirteen similar patients who received the standard treatment and placebo PEMFs. In order to be returned to full activity, participants had to demonstrate: the ability to run for two miles without pain or difficulty, no pain on palpation of the fracture site, no vibratory sensitivity, no edema or erythema at the fracture site, and no pain with weight bearing with increased activity. All had positive X-rays prior to treatment and negative X-rays upon return to full activity. All pre and post X-rays were evaluated (blindly) by the Chief of Orthopedics. The subjects exposed to PEMFs returned to their normal levels of activity without pain in an average of 31.7 days (Standard Deviation = 6.8) while the placebo subjects returned in 38.2 (12.5) days. An independent "t" test between the PEMF and placebo groups did not indicate that the mean difference of 6.5 days was statistically significant ($t = 1.39$ with 19 DF, one tail probability = 0.09). However, a week of time off work is important.

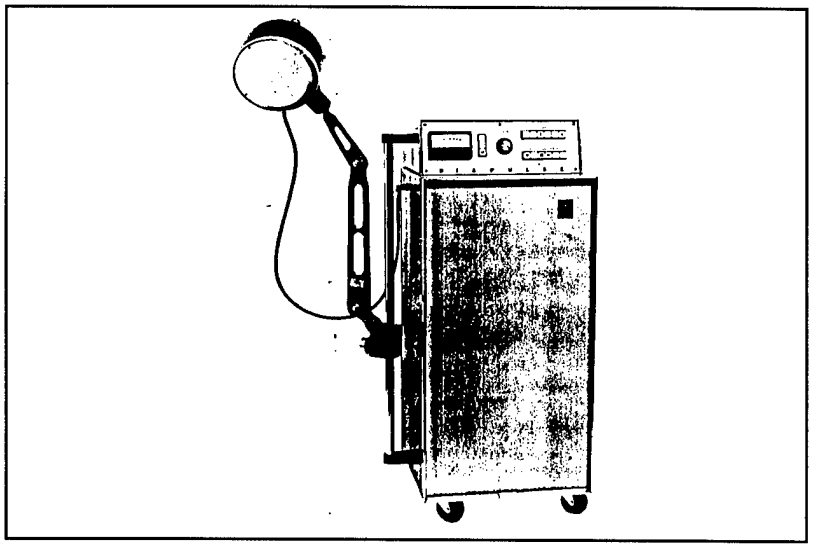
5. Use of pulsed magnetic fields to speed healing of normally healing fractures: We are not aware of any studies showing the techniques' usefulness (or lack there of) for speeding the healing of normally healing fractures. However, we are aware that it has been tried clinically and has a mixed reputation for success. The problem is that fractures heal at very different rates due to many known and probably more unknown and idiopathic factors so a very large group of people of similar ages and physical conditions having similar fractures of similar severities who would all get the same treatment would have to be gathered together in one place at about one

time in order to evaluate the technique's effect. Another complicating set of factors involves the interference of fracture treatment methodologies such as plates, screws, and etc. with operation of the fields and the fact that each appliance has to be placed differently depending on the needs of the patient. Differences in movement around the fracture also complicate the situation.

Figure One

TYPICAL PULSING ELECTROMAGNETIC FIELD GENERATOR*

The unit is about one meter tall and is designed so that the heat can be positioned over a bed or chair. The head is placed within a few millimeters of the site to be exposed. The field extends about 12 cm from the head.



*Diapulse generator model D103
photo courtesy of Diapulse Corporation of America
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Great Neck, NY 11023-2420

2. BODY (METHODS):

a. **Overview of design**:

The literature indicates that the overwhelming incidence of pelvic area stress fractures is among women engaged in strenuous activities. The diagnostic criteria were frequently negative findings on a gynecological examination, no history of trauma, no x-ray evidence of broken bones, and pain reported in the sacral, inguinal, perineal, groin, or gluteal regions which became worse with

exercise and improved with rest. These are the diagnostic criteria for both stress fractures and musculoskeletal pelvic pain. Differential diagnosis is made with a three phase bone scan.

Women identified as having the symptom complex indicative of pelvic area musculoskeletal pain were given a bone scan to determine whether they had pelvic area stress fractures. Subjects agreeable to coming for the daily treatments were stratified depending on whether or not they had radiologically diagnosed pelvic area stress fractures and received one hour of PEMF or placebo PEMF therapy five days per week in addition to the standard treatment (sharply reduced activity and minimized walking) from the time the diagnosis was made until return to full duty. Subjects were randomly assigned to groups and evaluated as described below.

The device was described in the status section and illustrated in Figure One. Patients laid on an exam table with the head of the PEMF generator positioned several millimeters above the stress fracture / most painful site. The patients were exposed to the fields for 15 minutes while on their backs and an additional 15 minutes while on their fronts. This was necessary because the field can not penetrate the entire width of the body. Thus, each subject had a total of 30 minutes of exposure to the field every day until they returned to duty. The machine made the same humming sound regardless of whether or not it was generating a field and subjects could not feel the field. Thus, subjects were not aware of whether they were in the exposure or placebo group. The technician who turns on the device will know which group the subject is in so the machine can be set for either actual or placebo functioning but the technician and physicians doing the evaluations had no idea which group the patients were in.

b. **Subjects**:

(1) Inclusion and exclusion criteria: Subjects had to be between the ages of 18 and 45. They needed to be healthy other than having the symptom complex indicative of a pelvic area musculoskeletal pain or stress fracture. The fracture had to be confirmed by bone scan for subjects to enter the fracture group.

(2) Assignment to groups: Random by picking a numbered card sealed in an envelope from a basket. The study technician stratified and then randomized the subjects and provided the treatment so nobody who evaluated the patients knew which group they were in.

(3) Number of subjects: Fifty-four subjects meeting the diagnostic criteria were identified during the course of the study.

(4) Source of subjects: Subjects were drawn from the pool of patients referred to Orthopedic Surgery and OB-GYN at Madigan AMC.

(5) Subject identification: Each subject's data was given a sequential group code when stored outside of her medical record. Clinical records were kept in the usual way. Additional information recorded for study purposes was kept in a locked file until patient identification was removed and coding substituted.

c. **Evaluations during the study**: Subjects were questioned prior to treatment every day about use of medications for pain, swelling, etc.; and pain. Pain was assessed before each session. Subjects rated their pain on a scale of zero to ten using a visual analog scale. Differences in amount of pain medications required was also recorded. *The bone scan and the clinical examinations were given regardless of participation in the study so were not part of it.* However, the clinical data and results of the bone scans were recorded. For patients with stress fractures, progress was determined by changes in bone scans and duty status. Patients with musculoskeletal pelvic area pain were evaluated by time to return to full duty and change in pain.

This was a double blind study because the subject did not know whether the device was working and the people evaluating the data and performing the measurements did not know which group the subjects are in.

3. RESULTS

Of the fifty - four female soldiers at Ft. Lewis identified as having the clinical symptoms of pelvic area stress fractures during the study period, seven had positive bone scans. Subjects with

negative bone scans but meeting all other criteria were placed into the musculoskeletal pelvic pain group. Patients were stratified by presence or absence of a fracture and then randomized into actual PEMF and placebo PEMF groups. They were treated for one hour per day, five days per week until they returned to duty. Changes in the bone scans were used to determine differences between the fracture groups while differences in pain and return to duty were used to determine differences between the musculoskeletal groups.

Of the fifty-four soldiers offered treatment, only twelve accepted. Of those actually available for treatment, most did not accept because it was simply impossible to do their jobs and come to the hospital every weekday for months. Of the twelve who began treatment, seven eventually dropped out for the same reason. Thus, the randomized portion of the study never completed a meaningful number of subjects.

Both patients with stress fractures receiving a significant number of treatments improved while the three who only received a few treatments did not improve, the randomized portion of the study never completed a meaningful number of subjects. None of the subjects with musculoskeletal pain nor those receiving placebo treatment improved. The results are tabulated in table one.

Table 1

Results of the treatment portion of the study

DIAGNOSIS	REAL TREATMENT		PLACEBO TREATMENT	
# OF CONFIRMED STRESS FRACTURE PARTICIPANTS	5	Improved 2 (35, 65 Rxs)	2	Improved 0
		No Change 3 (5, 5, 10 Rxs)		No Change 2 (5, 50 Rxs)
# OF MUSCULOSKELETAL PAIN PARTICIPANTS	2	Improved 0	3	Improved 0
		No Change 2 (5, 40 Rxs)		No Change 1 (5, 5, 5 Rxs)

4. CONCLUSIONS:

The vast majority of female soldiers currently being diagnosed as having pelvic stress fractures usually do not have stress fractures which can be confirmed by bone scan. Rather, they have musculoskeletal pelvic pain which is likely to require different treatments.

It is strongly recommended that all women meeting the usual criteria for pelvic area stress fractures have three phase bone scans early in the evaluation process so they receive treatments designed to ameliorate musculoskeletal problems instead of relatively rare stress fractures.

Treatments, such as the pulsing electromagnetic fields used in this study, which require months of daily treatment in a clinic setting are not compatible with the normal activities soldiers have to perform. Thus, equivalent devices have to be developed which can be used at night in the barracks or worn in field conditions.

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