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Pulsed, Non-Thermal, High Frequency Electromagnetic Energy (Diapulse®) in the Treatment of Grade I and Grade II Ankle Sprains

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Acutely sprained ankles represent a frequent and common injury among active duty troops in training, and are a significant source of morbidity with respect to days lost to training. Swelling in the form of periarticular edema limits motion, causes pain, prevents wearing of normal foot gear, and slows the healing process. Reduction of edema was attempted in acutely sprained ankles by the use of pulsed electromagnetic energy (Diapulse). In a randomized, prospective, double blind study of 50 grade I and II (no gross instability) sprained ankles, a statistically significant ($p < 0.01$) decrease in edema was noted following one treatment with Diapulse. The application of this modality in acutely sprained ankles could result in significant decreases in time lost to military training.

Non-thermal, pulsed, high-peak power, electromagnetic energy, Diapulse, has been in use for many years. In the early 1950s, Diapulse received approval from the Federal Communications Commission, which set forth strict regulations on short wave equipment used for medical purposes. Numerous animal and human experiments have been done to corroborate the safety and efficacy of Diapulse. Laboratory rats exposed for 6 to 7 hours of Diapulse therapy demonstrated no functional or morphological damages.[1]

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The exact mechanism of action of Diapulse is not known, but several interesting biological responses have been observed. Increased collagen formation at 3 days and increased capillary budding at 5 days were noted in canine studies.[2] These dogs underwent incisor extraction, and evaluation of the wound healing was done histologically. The acceleration of wound healing was also studied using a canine model, in which microscopic evaluation of surgically induced thigh wounds was performed sequentially for 10 days.[3] A marked increase in leukocyte (WBC) infiltrate and phagocytosis was seen in wounds treated by Diapulse. Collagen formation and the presence of fibroblasts were seen at day 6 in the treatment group. This same response was not seen until after day 10 in the untreated group.

Experimental hematomas were produced in rabbit ears and then treated with Diapulse.[4] Resolution of the hematomas was found to be accelerated in the treated group compared to the control rabbits. Additional studies reveal that Diapulse has been shown to be helpful in the healing of many different types of surgical procedures and acute injuries.[5–12]

Injuries to the ligaments of the ankle are very common, especially with athletic endeavors. Approximately 250 to 300 sprains are treated by the Brooke Army Medical Center Emergency Room and Physical Therapy Department each year. Ankle sprains can be divided into two large groups, medial and lateral.[13] Rarely does a sprain involve the medial deltoid ligament; almost always it involves the lateral complex. This is due to the anatomical configuration of the mortise joint, which has a fibula (lateral malleolus) that extends more distally than the tibia (medial malleolus). Lateral sprains are commonly divided into grades I, II, and III.[14] Grade I sprains are minor, with no ligamentous laxity. Grade II sprains involve partial tears with some instability and are usually accompanied by swelling. Grade III sprains involve complete tears of the ligamentous complex on the lateral aspect of the ankle causing gross instability.

Treatment for sprained ankles varies from the use of an ace wrap, the application of a cast, and from early ambulation to surgery.[13] Obviously, the treatment depends on the degree of injury. In our patient population, the majority of ankle sprains fall into grades I and II. Swelling and pain seem to be the greatest complaint of most patients with these sprains, and stability is usually maintained. Diapulse therapy has been used in the treatment of sprained ankles. Treated patients in other studies demonstrated a 75% improvement based on pain, swelling, and disability after 3 days of treatment.[15,16]

Since swelling is such a major part of sprained ankles irrespective of the grade, it often prevents placing the foot in a military boot. The goal of this study was to administer Diapulse and evaluate whether it decreases edema, thus decreasing tissue congestion and disability time of sprained ankles.

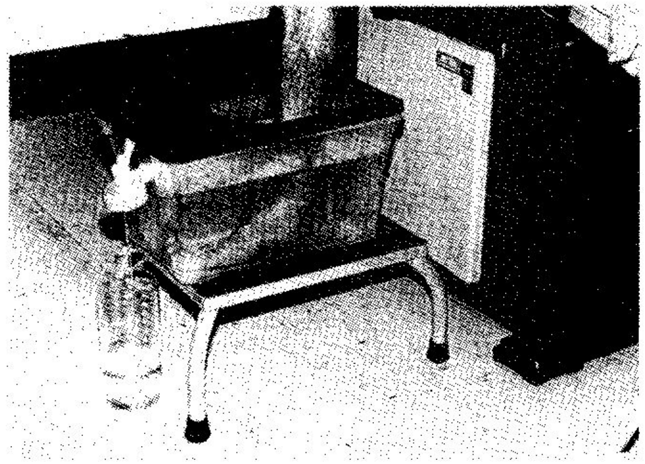

Fig. 1. Photograph of the foot tank with run-off valve to measure water displaced to nearest cc.

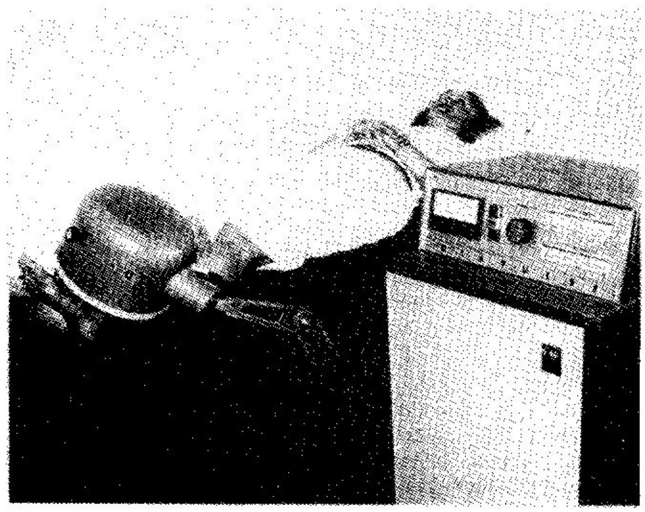

Fig. 2. Photograph of patient in supine position receiving Diapulse therapy.

Materials and Methods

Using a double-blind, prospective, randomized study, 50 patients with acutely sprained grade I and II injuries were seen within the first 72 hours following their initial injury. These patients were referred by the Emergency Medicine Clinic at Brooke Army Medical Center and Troop Medical Clinic at Ft. Sam Houston on a 72-hour consult. All patients were evaluated by the orthopedic surgery service and radiographs were obtained. Patients were excluded from the study if they had any evidence of the following:

- a fracture on radiograph of the ankle;
- a history of chronic ankle sprain to the same extremity;
- a history of previous surgery to the same extremity;
- sprains of greater than 72 hours since injury;
- pregnancy;
- pacemakers.

Since there are no experimental data existing as to whether or not harm might be done to pregnant women or patients with pacemakers, these patients were excluded from our study.

Fifty randomly selected patients were assigned a number from 1 to 50 on arrival. Twenty-five randomly selected numbers were assigned to the treatment or the placebo groups. During the study, neither the patient nor the attending physician were aware of the group to which the patient was assigned.

Clinical Ratings

After explaining the treatment and obtaining informed consent, a clinical evaluation and diagnosis of the injury was made. The time from injury was noted, and patients were categorized into three main groups: (a) 1 to 24 hours post-injury; (b) 25 to 48 hours post-injury; and (c) 49 to 72 hours post-injury. This was done in an effort to analyze the time elapsed from injury on the effect of treatment.

Each patient was asked to rate his pain pre-treatment as to severity on a scale of 1 to 10, with 10 being intolerable and 1 being absence of pain.

Patients were evaluated to determine if they could bear weight on the affected ankle, and the approximate percentage of weight borne. These were classified as full-weight bearing, moderate-weight bearing with aid of cane or crutches, touch-weight bearing only, and non-weight bearing.

Active range of motion was noted for dorsi flexion and plantar flexion only, because subtalar motion was difficult to measure in the swollen acute ankle. The ankle also was taken through varus and valgus, and anterior posterior stressing to verify that there were no grade III sprains included in the study.

Finally, an objective volume measurement of the ankle was done using water displacement to determine the exact volume of the foot and ankle. A tank with a simple run-off spout was constructed (Fig. 1). Both the normal and the swollen ankles were individually measured prior to treatment, and the values recorded in cubic centimeters of water displaced.

Diapulse was administered to the supine patient for 30 minutes with the treatment drum applied to the medial side of the ankle (Fig. 2), for 30 minutes with the drum applied to the lateral side of the ankle, and for 10 minutes with the drum centered over the epigastrium. Treatment to the epigastrium has been shown to increase blood flow to the lower extremities,

TABLE I

MEAN ANKLE VOLUME (CC OF WATER): EFFECT OF PLACEBO TREATMENT AND DIAPULSE TREATMENT ON ANKLE EDEMA RESULTING FROM GRADE I OR GRADE II SPRAINS AS MEASURED IN CC OF WATER DISPLACED

Group	Before	After	Difference
Placebo treatment	1,152 ± 216	1,141 ± 213	11
Diapulse treatment	1,295 ± 255	1,251 ± 255	44

which may contribute to the healing process.[17,18] Following treatment, the injured ankle was submerged with the foot resting flat on the bottom of the overflow tank so the displaced water could be measured and recorded constantly.

Prior to leaving the office, each patient rated pain on the scale of 1–10 previously used. Any increased ability to bear weight by standing and attempting to walk was recorded. All data were recorded on coded sheets and analyzed independently by a co-investigator. Results are reported as the mean ± standard deviation unless otherwise noted. Comparisons between groups were made using the Student's *t* test (one-tail).

Results

As this was a randomized, prospective, double-blind study, neither the patients nor the examiner were able to distinguish who were in the treatment or control groups. Because Diapulse causes no change in tissue temperature or skin sensation, patients were unable to determine if they were receiving active treatment or placebo care. For this study, no efforts were made to restrict the age, weight, or sex of subjects. Consequently, there was a wide range in ankle volumes. Table I lists the mean values ± SD of ankle volumes for control and experimental groups. The large standard deviations reflect the heterogeneity of the two groups. To determine if there was a difference in the magnitude of change between the control and experimental groups, the absolute difference and the percent changes in ankle volume after treatment were calculated. When comparing the absolute mean size change of the group that was given active treatment to the group that received placebo, the former demonstrated an average decrease of 44 cc compared to an average decrease of 11 cc for the latter. This was significant, with a p value of < 0.01 (Fig. 3). The percent decrease in ankle volume was also calculated and found to be 4.7% for the active treatment group vs. only 0.95% for the patients receiving placebo care. This was statistically significant, with a p value of < 0.01 (Fig. 4).

Differences between control and experimental groups were also noted in the responses of individuals to treatment. Twelve subjects in the control group demonstrated a percent change in ankle volume of 1.0% or less; three subjects actually experienced an increase in ankle swelling following placebo treatment. In the active treatment group, only three subjects demonstrated a reduction of 1.0% or less, and no subjects manifested an increase in swelling.

Elemental analysis of data based upon the elapsed time from injury to treatment was not done because of insufficient numbers of subjects. However, within the experimental group, the data suggest that the effectiveness of Diapulse therapy was

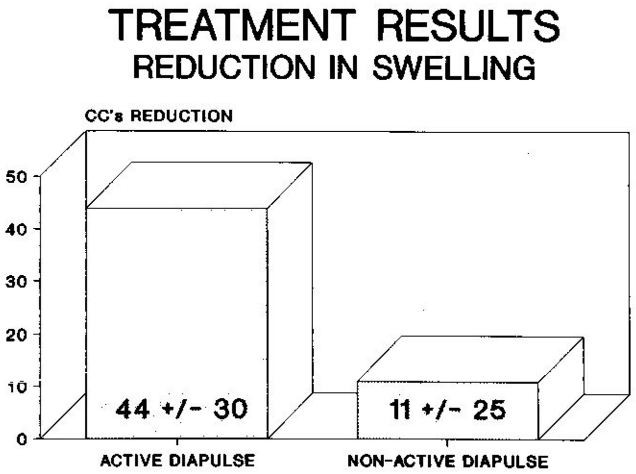

Fig. 3. The reduction in cc of water displaced ± SD measured between experimental and control groups.

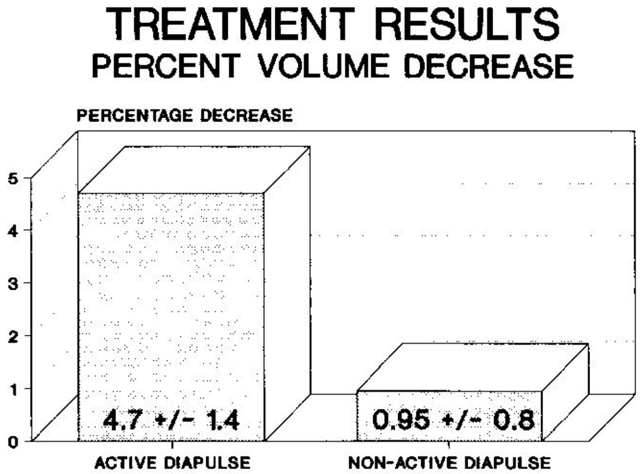

Fig. 4. The percent change in ankle volume ± SD between experimental and control groups.

independent of elapsed time: i.e., patients responded to treatment up to 72 hours after injury.

When asked to evaluate changes in pain or discomfort, 8 of 24 patients in the control group (one response incomplete) indicated that their pain was reduced after treatment; whereas 16 of 25 patients in the experimental group indicated a reduction in pain (Fig. 5). No patients in either group reported feeling worse after treatment.

Conclusion

In this study, the reduction in swelling effected by Diapulse was 4-fold greater than that effected by placebo treatment. In the subjective area of measuring pain, Wilson[15,16] reported that Diapulse significantly reduced the pain associated with walking on a sprained ankle. In our study, twice as many subjects in the treatment group (16/25) reported a decrease in the pain experienced with standing on a sprained ankle as compared with the control group (8/25), suggesting that treatment in-

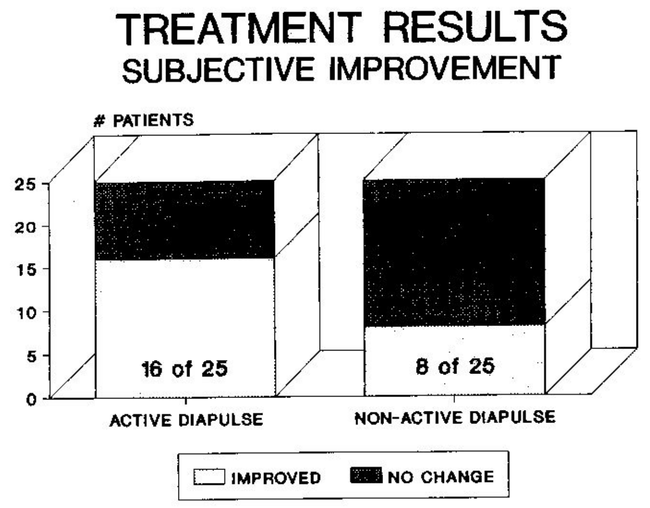

Fig. 5. Twice as many patients in experimental group had subjective improvement compared to the control group.

duced some analgesic effect. However, it cannot be stated that there is a direct correlation between pain and swelling. We observed some patients having a large decrease in swelling but only a small or no change in pain, while other patients had a small change in swelling but substantial improvement in pain.

We conclude that non-thermal, pulsed, electromagnetic energy as delivered by Diapulse can be used to decrease swelling and pain in the acutely sprained ankle. This can be important in a population which is required to wear restrictive footwear and is expected to return to continued active training as rapidly as possible.

This modality has several advantages in the treatment of acutely sprained ankles. It applies no heat, eliminating the possibility of burns which can occur with hot or cold packs. Pressure, as in application of a pneumatic compression device to decrease swelling, can be avoided as well.

This study was not designed to determine if ankle sprains with a decrease in swelling heal faster. Future functional studies would be indicated in this area.

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