British Journal of Plastic Surgery (1981) 34, 267–270
0007-1226/81/0187-0267 $02.00

The effects of Diapulse on the healing of wounds: a double-blind randomised controlled trial in man

J. H. GOLDIN, N. R. G. BROADBENT, J. D. NANCARROW and T. MARSHALL

Summary—A double-blind trial of the effect of pulsed radio-energy on the healing of donor site wounds was carried out in man.

Approximately twice as many patients were healed in seven days where active treatment was given as opposed to those receiving placebo treatment.

The strictest criteria of clinical and statistical analysis were used and the results were found to be clinically and statistically significant.

Physical energy in the form of heat has been used for many years in the treatment of various ailments, from psychiatric disturbance to fractures. More recently it has been administered as electrical energy using infra-red, ultraviolet, short wave diathermy and ultrasonic techniques.

These latter techniques deliver continuous radio-energy into tissues. Since absorption of these waves produces heat and ultimately leads to a burn, therapeutic radio-energy emitting devices must be modified to produce a low energy output. Despite this limitation the results of therapy were so good that Ginsberg (1940) postulated that an athermic physico-chemical phenomenon might be occurring in the damaged tissues. He developed a device which delivered repeated short pulses of high energy radio-waves, reducing a peak pulse energy of 975 Watts to an average of 38 Watts and which produced no rise in tissue temperature.

The Diapulse Corporation of America has designed and marketed a pulsed electro-magnetic field generator called "Diapulse" with its output in the VHF band suitable for medical use.

Beneficial effects on the peripheral circulation and on the acceleration of healing of damaged tissues have been noted in animal and human trials.

Cameron (1961) in an experimental study in dogs, showed that pulsed radio-energy could increase the number of white cells, histiocytes, and fibroblasts appearing in a wound; accelerate the absorption of oedema fluid and haematomata; stimulate the more rapid orientation of fibrin fibres and the deposition of collagen.

Nadasdi (1960) described a reduction in the severity of chemically induced arthritis and anaphylaxis in rats. Lobell (1962) reported more rapid resolution of pelvic inflammatory disease, and Splitter (1966) described a beneficial effect in sinusitis. In clinical practice pulsed radio-energy was administered direct to the diseased area and also to distant components of the reticulo-endothelial system—the liver and spleen—to stimulate the immune mechanism.

Cameron's work was confirmed in the laboratory by Fenn (1969) and clinically by Wilson (1972 and 1974) and Pasila *et al.* (1978).

King *et al.* (1968) and Bassett (1974) have shown experimentally in dogs that osteogenesis is stimulated and that the repair is more orderly and rapid.

Wilson and Jagadeesh (1975) investigated the effects of pulsed radio-energy on healing in the peripheral and central nervous systems and reported encouraging results.

Aronofsky (1971) showed that in dental practice pain was reduced, the rate of healing increased in intra-oral surgical procedures and that pre-operative local therapy enhanced these results.

Erdman (1960) and Hedenius *et al.* (1966) demonstrated increased blood flow in the legs of normal subjects and claudicants following epigastric administration of Diapulse.

The present study was designed as a randomised double-blind controlled trial to show the clinical response of a standard wound in man to Diapulse, the standard wound being the donor site of a medium-thickness split-skin graft cut with a Braithwaite knife.

Materials and Methods

Patients between the ages of 15 and 65 years of age, were admitted to the trial whenever a medium-thickness split-skin graft was taken from the thigh. The mean graft thickness was 0.22 mm. Patients were specifically excluded from the trial when there was a known history of diabetes, uremia or steroid therapy. Each patient was assigned to one of two groups by a randomised series of coded cards. One group was given treatment by a dummy machine and the other group by a functioning "Diapulse" machine giving a peak output of 975 Watts at a frequency of 400 pulses per second. The average pulse duration was 65 micro-seconds. The mean energy output was 25.3 Watts with a 3 cm depth penetration. The treatment schedule was identical in both groups and was as follows:

One 30 minute treatment was given to the donor site at the time of pre-medication and post-operatively 6 hourly. The treatment was given by the nursing staff and was continued for seven days. The donor site was dressed with a single layer of tulle gras and Melolin held in place by a lightly applied cling bandage or some micropore tape.

The two parameters chosen in assessment were the state of healing of the donor site at seven days and the degree of pain experienced by the patient during the healing phase.

Daily assessments were made by the medical staff who were unaware of which machine had been used. Subjective assessments of pain were made for each patient on an arbitrary scale ("present" or "absent"). A record was made of the analgesics required by each patient. The choice of medication and its mode of administration did not deviate from normal ward routine.

On the seventh post-operative day the dressing was gently peeled or soaked off and an assessment made of the percentage area of healing.

The extent of wound healing was expressed as a percentage, the maximum being 100% for complete healing. For this analysis we have divided the assessments at a healing rate of 90% or above, or less than 90%.

Results

The results of these assessments are indicated in Figure 1. Using the "active" machine 17 out of 29 patients had donor site wounds that were 90% or more healed at seven days compared with only 11 out of 38 patients using the "dummy" machine. Healing rates can thus be expressed crudely as 59 % and 29 %. This gives a χ^2 value of 4.79 with a probability level of between 0.05 and 0.25. If the null hypothesis were true (no association between treatment and outcome) a result like this should be expected to occur on between 1:20 and 1:40 occasions.

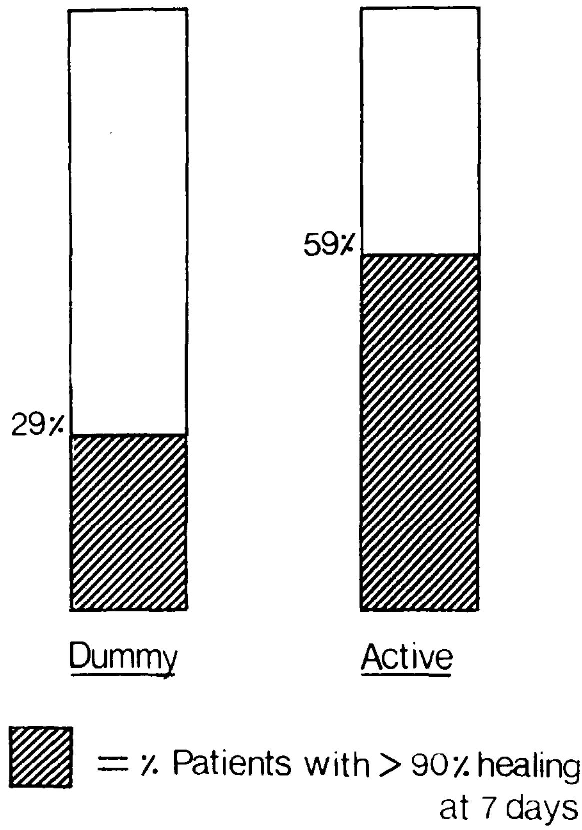

Fig. 1 Graphic representation of the results of the pulsed radio-energy trial showing percentages in the test and control groups which had achieved greater than 90% healing in seven days.

This does not indicate the probability of any one individual benefitting or failing to benefit from the administration of the active treatment. This would be most usefully assessed by a quantity called "therapeutic value" which is an exact counterpart of "protective value" used in considering the efficacy of immunisation programmes (Fig. 2). The logic of this index is based on the premise that if the active treatment is to be of benefit, it must be so to those patients who would not otherwise have achieved 90% or greater healing at seven days (i.e., the 27 out of 38 (71%) patients in the control group).

The index assesses the proportion of that 71% whom the active treatment appears to have benefitted. In this instance, the therapeutic value is

$$\frac{71.5-41.38}{71.05}=0.42$$

in other words, 42% of the patients who did not achieve 90% or more healing at seven days, would have done so if Diapulse had been used.

The results of the wound healing subjected to the x test show a value of 4.79 with a probability level of between 0.05 and 0.025 which is statistically significant.

THERAPEUTIC VALUE (T.V) OF PULSED R.E.

$$TV=\frac{\left[\begin{array}{l}\%\text{ not healing}\\ \text{under dummy}\\ \text{treatment}\end{array}\right]-\left[\begin{array}{l}\%\text{ not healing}\\ \text{under active}\\ \text{treatment}\end{array}\right]}{\left[\begin{array}{c}\%\text{ not healing under}\\ \text{dummy treatment}\end{array}\right]}$$

Fig. 2 Formula used in the calculation of therapeutic value of pulsed radio energy.

Discussion

The mechanism of the increased rate of healing is speculative at present but certain facts are known. Blood flow is increased; the incidence of oedema is reduced; reparative cells are stimulated; and the healing wound becomes ordered by polarisation of the cells. Pulsed radio-energy is thought to be able to repolarise the depolarised cell membranes of damaged cells, reversing the "injury potential" and the electrical field will give the tissue a directional polarity. The reversal of damage to the cells will aid in reduction of oedema and dispersal of haematoma, which in this trial could have led to the more rapid epithelialisation of the donor sites. Whether the tissue polarity influences the rate of migration of epithelial cells or whether the rate of cell division is increased is not known.

However, in spite of the uncertainty of the mechanism of action of pulsed radio-energy in the healing of tissues, this trial indicates that reparative processes are clearly accelerated by pulsed radio-energy therapy.

Acknowledgement

Thanks are given to the Diapulse Corporation of America for the loan of their equipment for the trial.

References

Aronofsky, D. H. (1971). Reduction of dental post-surgical symptoms using non-thermal pulsed high-peak-power electro-magnetic energy. *Oral Surgery, Oral Medicine and Oral Pathology*, **32**, 688.

Bassett, A. (1974). Augmentation of bone repair by inductively coupled electro-magnetic fields. *Science*, **184**, 575.

Cameron, B. M. (1961). Experimental acceleration of wound healing. *American Journal of Orthopaedics*, **3**, 336.

Erdman, W. J. (1960). Peripheral blood flow measurements during application of pulsed high frequency currents. *American Journal of Orthopaedics*, **2**, 196.

Fenn, J. (1969). Effect of pulsed electro-magnetic energy (Diapulse) on experimental haematomas. *Canadian Medical Association Journal*, **100**, 251.

Ginsberg, A. (1940). A description of my athermic shortwave apparatus with clinical application. Exhibited and demonstrated at the "Fortnight on Infection", New York Academy of Medicine, New York. October 1940.

Hedenius, P., Odeblad, E. and Wahlmstrong, L. (1966). Some preliminary investigations on the therapeutic effect of pulsed short waves in intermittent claudication. *Current Therapeutic Research*, **8**, 317.

King, D. R., Hataways, J. and Reynolds, D. C. (1968). The effect of pulsed short waves on alveolar healing. *Journal of the District of Columbia Dental Society*, **42**, 1.

Lobell, M. J. (1962). Pulsed high frequency and routine hospital antibiotic therapy in the management of pelvic inflammatory disease. *Clinical Medicine*, **69**, 8.

Nadasdi, M. (1960). Inhibitors of experimental arthritis by athermic pulsating short waves in rats. *American Journal of Orthopaedics*, **2**, 105.

Pasila, M., Visuri, T. and Sundholm, A. (1978). Pulsating short wave diathermy—value in treatment of recent ankle and foot sprains. *Archives of Physical Medicine and Rehabilitation*, **59**, 383.

Splitter, S. R. (1966). New approach to the management of subacute sinusitis. *Delaware Medical Journal*, **38**, 83.

Wilson, D. H. (1972). Treatment of soft tissue injuries by pulsed electrical energy. *British Medical Journal*, **12**, 269.

Wilson, D. H. (1974). Comparison of short wave diathermy and pulsed electro-magnetic energy in treatment of soft tissue injuries. *Physiotherapy*, **60**, 309.

Wilson, D. H. and Jagadeesh, P. (1975). Experimental regeneration of peripheral nerves and the spinal cord in laboratory animals exposed to a pulsed magnetic field. *Paraplegia*, **14**, 12.

The Authors

J. H. Goldin, MB, ChB, BS, FRCS, Consultant Plastic Surgeon, West Midlands Regional Plastic and Jaw Surgery Unit.

N. R. G. Broadbent, MB, ChB, FRCS, Registrar in Plastic Surgery.

J. D. Nancarrow, BSc, MB, BS, FRCS, Senior Registrar in Plastic Surgery.

T. Marshall, MSc, Lecturer in Social Medicine, The Medical School, Birmingham.

Requests for reprints to: J. D. Nancarrow, BSc, MB, BS, FRCS, Senior Registrar in Plastic Surgery, West Midlands Regional Plastic and Jaw Surgery Unit, Wordsley Hospital, Wordsley, Stourbridge, West Midlands DY8 5QX.