

# Accelerated Wound Healing of Pressure Ulcers by Pulsed High Peak Power Electromagnetic Energy (Diapulse)

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## ■ ABSTRACT

*The purpose of this study was to evaluate the effect of pulsed high-frequency, high peak power electromagnetic energy (Diapulse) in the healing of pressure ulcers. Patients with Stage II ulcers unhealed within three to 12 weeks and those with Stage III ulcers unhealed within eight to 168 weeks by conventional methods were included in the study. When Diapulse was added to conventional therapy during the nine-month study, all 22 patients healed as evidenced by photographs and measurements of the ulcers. Stage II ulcers healed in one to six weeks (mean 2.33) and all Stage III ulcers healed in one to 22 weeks (mean 8.85). The decreased healing time can provide significant cost savings and improved patient care.*

The pressure ulcer, a pervasive health problem, is one of several preventable, but sometimes fatal, secondary disabilities. Individual suffering and financial expense to society are enormous (Itoh & Lee, 1990; NPUAP, 1989). Pressure ulcers are highly prevalent among the neurologically impaired, chronically ill, and elderly (Lee & Itoh, 1988; Allman, 1989a, 1989b, 1986). The natural history, particularly causative factors, is well documented, and pressure ulcer epidemiological considerations have been described (Daniel, Priest, & Wheatley, 1981; Kosiak, 1959; Witkowski & Parish,

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1982). In acute care hospitals, the prevalence of pressure ulcers ranges between 3% and 14%, in long-term care settings 15% and 25% (Reed, 1981).

Development of pressure ulcers in a healthcare facility is often difficult to avoid. A shortage of nursing personnel may become a contributory factor for ulcer development if there is not enough time to turn patients. Prognosis of a pressure ulcer is extremely difficult because of many factors which contribute to formation of an ulcer, such as pressure, nutritional status, and severity of health problems.

Under the most ideal situation, Stage II ulcers should heal within one month, while Stage III ulcers may require three months or longer, depending on size (Allman, 1989). When the ideal situation is not attainable, the actual time required for healing an ulcer may double or triple. A chronic pressure ulcer with duration of one year or longer is most unlikely to heal, or healing would require an inordinate period of time.

When a pressure ulcer develops in a given area and remains untreated without eliminating or minimizing the causative factors, the ulcer continues to progress. The progression may be expressed by size and depth and is commonly classified in four stages (NPUAP, 1989). It is universally recognized that the higher the stage, the longer the period required for healing. Frequently, even with meticulous skin treatment and other physical care provided by nursing staff, the ulcer persists and progresses. Conventional treatment with topical medication, vitamin and dietary therapy, specialized beds or support systems, plus modalities such as ultraviolet or iontophoresis have been utilized for treatment of Stage II to IV ulcers with limited success (Allman, 1989a, 1986). The ulcer may eventually heal, providing the causative elements are eliminated and no further complications develop. Slow-healing ulcers require prolonged hospital stay, enormous costs in personnel and materials, and the patient may develop other secondary disabilities which further delay rehabilitation. The average cost

of pressure ulcer treatment is estimated to be approximately \$2,000 to \$30,000 (NPUAP, 1989) and is reported to range as high as \$86,000 per patient (Allman et al., 1986).

### ■ HEALING METHODS

The healing process of pressure ulcers is similar to healing of other wounds. There are many studies available that describe wound healing processes (Brown, Nanney, Griffen, et al., 1989; Eaglestein, & Mertz, 1981; Knighton, Ciresi, Fiegel, Austin, & Butler, 1986).

The use of pulsed high-frequency high peak power electromagnetic energy (Diapulse) has recently been described by the Food and Drug Administration as a segment of "Emerging Electromagnetic Medicine" (O'Connor, 1990). Experimental and clinical applications of this energy are reported in the literature as providing a safe and effective method of aiding soft tissue healing (Goldin, Broadbent, Nancarrow, & Marshall, 1981; Ross, 1990), reduction of edema (Rhodes, 1981), absorption of hematoma (Fenn, 1969) reduction of inflammation (Wilson, 1972), nerve (Raji & Bowden, 1983) and spinal cord regeneration (Kiwinski, Chrostowski, & Weiss, 1980), and peripheral vasculature (Erdman, 1960).

Although the mechanism of action is not well understood, studies have revealed that Diapulse produces certain biological effects which enhance wound healing. Increased blood flow without hyperpyrexia or tissue damage has been observed by application of Diapulse (Erdman, 1960). With the increase of blood flow, there is an increase of oxygen to the previously deprived regions.

Cameron (1961) conducted a histological study on the effect of pulsed high-frequency radio waves (Diapulse) on accelerating wound healing. Results on acute wounds demonstrated a stimulation of collagen formation, WBC infiltration, phagocytosis, histiocytic activity, fat activity, and hematoma canalization. Hymes (1986) also demonstrated an increase in plasma fibronectin concentration to a wound site.

An enzyme study on burn wounds (Ionescu, 1984) demonstrated that when compared to normal skin, the activities of proteins, LDH, and alkaline phosphatase are considerably and significantly increased after Diapulse therapy. The author noted that the earlier Diapulse is applied to injured tissue, the more rapidly are normal enzymatic activities restored.

Additional laboratory studies (Young, 1984) demonstrate that Diapulse applied to spinal cords shortly after contusion reduces calcium accumulation in the cord adjacent to the injury site. This change in calcium is associated with better recovery of motor and sensory function in severe spinal injury.

Duma-Drzewinska and Buczynski (1978) reported that Diapulse was a positive influence in treatment of superficial and deep pressure ulcers which had failed to heal when treated with conventional therapies.

### ■ MATERIAL AND METHODS

Based on the literature, this clinical trial was designed to assess the effect of Diapulse treatment on healing of Stage II and Stage III pressure ulcers which were demonstrably slow to heal or failed to heal with conventional treatment.

Diapulse technology produces pulsed high-frequency high peak power electromagnetic energy, and operates on an assigned Federal Communication Commission medical frequency of 27.12 MHz. The energy is delivered in 65 micro-second bursts at six settings of 80 to 600 pulses per second with a wattage range from 293 to 975 peak watts in six steps. Energy is induced through a 9 inch diameter drum-shaped treatment head, placed in contact with the area to be treated. Treatment is non-invasive and can be applied through clothing and surgical dressings.

Seven patients (four male, three female) ranging in age from 52 to 86 years (mean 70.1) with nine Stage II pressure ulcers, and 13 patients (five male, eight female) ranging in age from 49 to 93 (mean 69.7) with 13 Stage III pressure ulcers, were stud-



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ied over a nine-month period. All were institutionalized patients.

Ulcers selected for the study had received conventional treatment for eight or more weeks, except for three. The three exceptions were Stage II ulcers which showed a duration of three weeks but their deterioration was so rapid they may have progressed to Stage III and possibly to Stage IV if eight weeks had passed before including them in the study.

All patients had routine blood work to determine RBC, WBC, hematocrit, and hemoglobin, electrolyte levels, and nutritional status within normal limits. Excluded from the study were patients with cardiac pacemakers, malignancy, or metallic implants in the area of the ulcer.

All patients' demographic data and past histories of pressure ulcers were extracted from their medical records. Time elapsed between the earliest documented presence of the ulcer and the date Diapulse treatment commenced was calculated in weeks. The duration of the ulcer for each patient was used as a control.

The ulcers were located on the sacrum (7), buttock (4), heel (5), leg (2), foot (2), right malleolus (1) and knee (1). The primary diagnoses among the patients were cerebrovascular accident (31.8%) with three Stage II and four Stage III pressure ulcers; multiple sclerosis (22.7%) with three Stage II and two Stage III ulcers; organic brain syndrome (18.2%) with two Stage II and two Stage III ulcers; spinal cord tumor (9.1%) two Stage III ulcers; spinal cord injury (4.55%) one Stage III; spinal stenosis (4.55%) one Stage III. (See Table I.)

Conventional treatment prescribed prior to commencement of Diapulse was continued without any modification. The conventional methods included cleansing with H<sub>2</sub>O<sub>2</sub>, sterile normal saline, or povidone iodine. Dressings included Bacitracin ointment, povidone iodine (wet/dry), acetic acid (wet/dry), Vaseline gel, Silvadene, or H<sub>2</sub>O<sub>2</sub> dressing (wet/dry). Granulex spray was administered to two Stage III ulcers. Water mat-

PRIMARY DIAGNOSIS AND STAGE OF PRESURE ULCER

Primary Diagnosis	Stage II	Stage III	Total	%
Cerebrovascular Accident Stage II: FC, FC, HE Stage III: MH, HA, LG, FC	3	4	7	31.8
Multiple Sclerosis Stage II: PC, PC, FA Stage III: SC, FA	3	2	5	22.7
Organic Brain Syndrome Stage II: JS, RC Stage III: FS, ER	2	2	4	18.2
Spinal Cord Tumor Stage II: Stage III: PW, DS	0	2	2	9.1
Diabetes Mellitus Stage II: Stage III: WA	1	1	2	9.1
Spinal Cord Injury Stage II: WA Stage III: IM	0	1	1	4.55
Spinal Stenosis Stage II: Stage III: WC	0	1	1	4.55
Total	9	13	22	100.00

TABLE • I

tresses were provided for one Stage II and three Stage III patients.

Diapulse was applied to each ulcer, directly through dressings, at 600 Pulse Frequency and 6 Peak Power for a period of 30 minutes twice daily at approximately eight-hour intervals. Although the application of Diapulse therapy was the responsibility of personnel on the unit where the patient was located, one technician with special training was responsible to check that the personnel administering the treatment were trained in the use of Diapulse and that treatments were carried out correctly on all shifts.

To document and analyze the progress of wound healing, serial visual evaluations (including measurement of the ulcer) and 35mm color photographic observations were made. A professional rehabilitation nurse specialist and physician also conducted assessments at set weekly intervals. Photographs of each site were made

with a centimeter scale in view with the camera kept at a fixed focal distance.

## ■ RESULTS

Tables II and III show healed Stage II and III ulcers after Diapulse was added to conventional treatment. Stage II ulcers ranged in size from 1 cm<sup>2</sup> to 15 cm<sup>2</sup> (mean 5.55 cm<sup>2</sup>) and Stage III from 0.09 cm<sup>2</sup> to 40 cm<sup>2</sup> (mean 8.77 cm<sup>2</sup>). The depths of Stage III ulcers were 0.5 cm to 1.0 cm (except one which was 3 cm). The duration of Stage II pressure ulcers prior to adding Diapulse ranged from three to 12 weeks (mean 8.2) and Stage III ulcers, eight to 168 weeks (mean 34.6). The duration of combined Diapulse and conventional treatment to complete healing (treatment duration) was one to six weeks (mean 2.3) for Stage II ulcers and one to 22 weeks (mean 8.85) for Stage III ulcers.



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HEALED STAGE II PRESSURE ULCER: DIAPULSE AND CONVENTIONAL TREATMENT

Name	M	F	Age	Ulcer Location	CONVENTIONAL TREATMENT Duration (Weeks)	Ulcer Size (cm <sup>2</sup> )	DIAPULSE AND CONVENTIONAL TREATMENT Duration (Weeks)	Status
AW	1	0	79	Sacrum	3	3.00	4	Healed
PC	1	0	56	Sacrum	3	2.25	1	Healed
PC	1	0	56	Buttock	3	15.00	3	Healed
CA	0	1	52	Buttock	8	1.00	1	Healed
JS	0	1	77	Knee	12	1.00	1	Healed
FC	1	0	86	Rt. Mal.	12	7.50	6	Healed
FC	1	0	86	Foot	12	7.50	3	Healed
HE	1	0	60	Leg	12	6.75	1	Healed
RC	0	1	81	Heel	9	6.00	1	Healed
Total	6	3						
Mean			70.33		74	5.56	21	
SD			12.6		8.22	4.18	2.33	
					3.94		1.70	

TABLE • II

HEALED STAGE III PRESSURE ULCER: DIAPULSE AND CONVENTIONAL TREATMENT

Name	M	F	Age	Ulcer Location	CONVENTIONAL TREATMENT Duration (Weeks)	Ulcer Size (cm <sup>2</sup> )	DIAPULSE AND CONVENTIONAL TREATMENT Duration (Weeks)	Status
FS	0	1	82	Sacrum	52	0.15	1	Healed
GL	0	1	49	Sacrum	168	1.00	7	Healed
DS	0	1	56	Sacrum	16	0.09	6	Healed
IM	1	0	57	Sacrum	10	4.50	6	Healed
MH	0	1	61	Sacrum	52	0.25	22	Healed
PM	0	1	93	Heel	14	1.00	3	Healed
AW	0	1	79	Heel	24	17.50	8	Healed
FC	0	1	79	Heel	34	28.00	13	Healed
ER	0	1	91	Heel	12	5.60	6	Healed
WC	1	0	65	Leg	44	40.00	21	Healed
SC	1	0	70	Foot	8	1.00	7	Healed
HA	1	0	72	Buttock	8	9.00	10	Healed
CA	0	1	52	Buttock	8	6.00	5	Healed
Total	5	8			450		115	
MEAN			69.7		34.62	8.78	8.85	
SD			14.0		41.71	11.96	6.09	

TABLE • III

Clinical observation revealed that within 24 to 48 hours of initiating Diapulse treatment, most Stage II ulcers showed an appearance of drying with start of scab formation and proceeded to heal. At 24 to 48 hours the granulation color of Stage III ulcers became bright red. Within seven to 10 days, pale colored epithelialization became visible around the edges and exudate began to decrease.

Purulent exudate was eliminated without any systemic or local use of antibiotics.

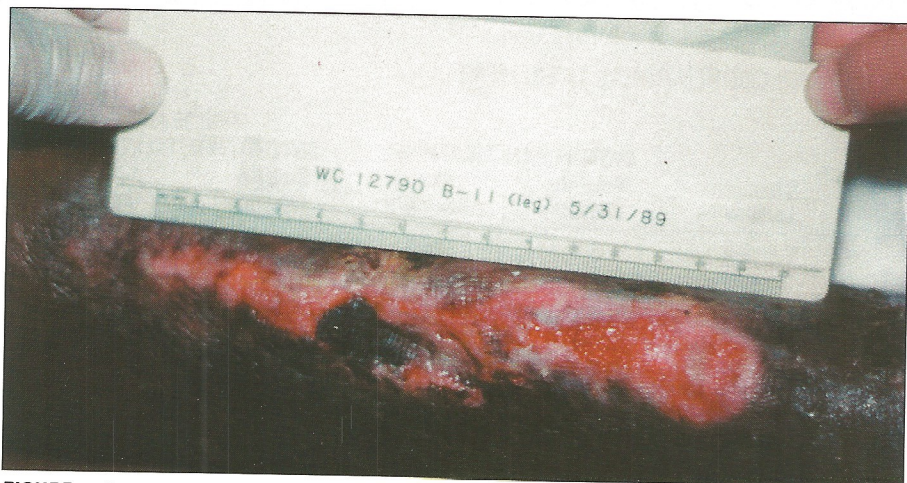
In one Stage III ulcer (Table III, Case WC), a necrotic area of dermis with an approximate size of 2 x 3 cm was observed at the center of a 4 x 10 cm ulcer on the leg before start of Diapulse treatment (Figure I). A conventional treatment approach for this necrotic dermis is surgical debridement.

After one week of Diapulse treatment, the necrotic tissue was eliminated (Figure II). The ulcer subsequently healed (Figure III).

After beneficial results of Diapulse treatment were demonstrated, one additional patient was added to the study. The patient's Stage III ulcer had failed to heal with conventional treatment over a period of 168 weeks. After seven weeks of combined Diapulse and

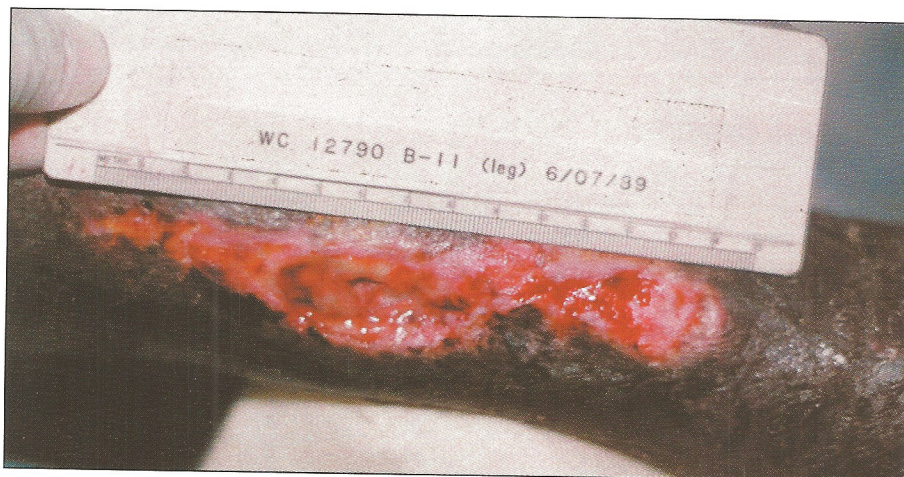


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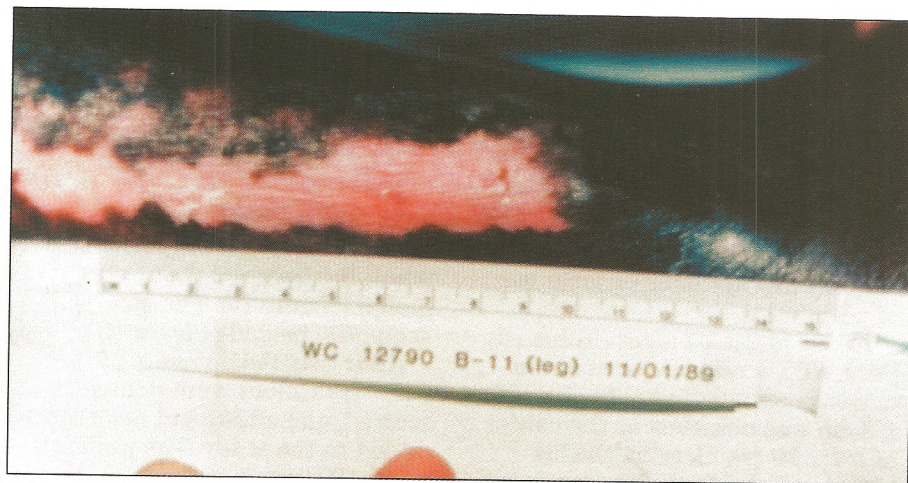
**FIGURE • I**

Date: 5/31/89. Prior to commencement of DIAPULSE treatment necrotic dermis observed in pressure ulcer.



**FIGURE • II**

Date: 6/7/89. First week assessment. Necrotic tissue no longer in evidence.



**FIGURE • III**

Date: 11/1/89. Pressure ulcer healed.

conventional treatment, the ulcer completely healed.

The epidermis of a newly healed pressure ulcer after Diapulse treatment is fragile, and friction between the new epidermis and protective dressing can cause excoriation. An additional seven to 10 days of Diapulse treatment to the area was effective in preventing such occurrence.

### ■ DISCUSSION

**P**atient selection for the study was limited to chronic ulcers without any sign of healing, or ulcers of short duration that were deteriorating rapidly with conventional treatment. The conventional treatment in use was continued during the study and, to limit variables, the only new element introduced to the treatment regimen was Diapulse. This method of evaluation demonstrated that it was the addition of Diapulse that aided the healing of the pressure ulcers.

A distinct advantage of the Diapulse treatment was the simplicity of application. Once the patient is comfortable and the Diapulse treatment head is placed over the pressure ulcer, it is necessary only to ascertain that Diapulse head and patient remain in position.

### ■ COST FACTOR

**C**ost of pressure ulcer treatment is a significant factor contributing to the financial burden of patients, families, institutions, and healthcare payment systems. Costs include personnel and support services; materials such as pressure relieving devices; pharmaceutical and nonpharmaceutical supplies; laboratory tests; and physical therapy.

At this institution in 1990, conventional treatment cost of a Stage III ulcer in the buttock or sacral area (including the costs of personnel and dressing material) was approximately \$8.94 to \$10.93 per treatment depending upon the personnel involved. With change of dressing performed three times



per day, the cost of ulcer treatment varies between \$187.74 and \$229.53 per week. One 30-minute Diapulse treatment administered twice daily by a medical surgical technician costs \$7.23 (including the use of the Diapulse unit) with a weekly cost of \$101.22.

Nine Stage II pressure ulcers received conventional treatment for a mean average of 8.22 weeks. The cost per ulcer of conventional treatment was \$229.53 per week, with a total cost of \$1,886.74 per ulcer. None of these ulcers demonstrated evidence of healing during the entire course of treatment. The ulcers were then treated with a combination of Diapulse and conventional treatment for a mean average of 2.33 weeks. The mean cost of treatment per ulcer was \$331.03 per week, with a total cost of \$771.30 per ulcer. All Stage II ulcers completely healed.

Thirteen Stage III pressure ulcers received conventional treatment for a mean average of 34.62 weeks. The mean cost of conventional treatment per ulcer was \$229.53 per week with a total cost of \$7,946.33. These ulcers demonstrated no evidence of healing during the entire course of treatment.

The ulcers were then treated with Diapulse and conventional treatment for a mean average of 8.85 weeks. The cost of treatment per ulcer was \$331.03 per week with a total cost of \$2,929.62 per ulcer. All Stage III ulcers completely healed.

A cost differential between conventional treatment and Diapulse-and-conventional treatment of Stage II ulcers, showed a mean average of \$1,115.44 per ulcer. Treatment of the nine ulcers with combination therapy produced a total savings of \$10,038.96.

The same comparison was made for the Stage III ulcers. The cost differential between conventional treatment and Diapulse and conventional treatment of Stage III ulcers showed a mean average of \$5,016.71 per ulcer. Treatment of the 13 ulcers with combination therapy indicated a total savings of \$65,217.23.

## ■ SUMMARY

After a thorough review of the literature, we found that under current hospital conditions there was no evidence of complete healing of Stage II ulcers in a mean average of 2.33 weeks and Stage III ulcers in a mean average of 8.85 weeks.

Based on historical and clinical experience, any improvement in rate and degree of healing of the ulcer was attributable to Diapulse technology. More importantly, all 22 pressure ulcers in this study healed after Diapulse had been added to the conventional regimen of treatment.

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