Effect of electrical stimulation on chronic wound healing: a meta-analysis

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The purpose of this meta-analysis was to quantify the effect of electrical stimulation on chronic wound healing. Fifteen studies, which included 24 electrical stimulation samples and 15 control samples, were analyzed. The average rate of healing per week was calculated for the electrical stimulation and control samples. Ninety-five percentage confidence intervals were also calculated. The samples were then grouped by type of electrical stimulation device and chronic wound and reanalyzed. Rate of healing per week was 22% for electrical stimulation samples and 9% for control samples. The net effect of electrical stimulation was 13% per week, an increase of 144% over the control rate. The 95% confidence intervals of the electrical stimulation (18–26%) and control samples (3.8–14%) did not overlap. Electrical stimulation was most effective on pressure ulcers (net effect = 13%). Findings regarding the relative effectiveness of different types of electrical stimulation device were inconclusive. Although electrical stimulation produces a substantial improvement in the healing of chronic wounds, further research is needed to identify which electrical stimulation devices are most effective and which wounds respond best to this treatment. **(WOUND REP REG 1999;7:495–503)**

Electrical stimulation (ES) is a largely unknown and poorly understood treatment modality for chronic wound healing. Appreciation for the potential contribution of ES in promoting chronic wound healing has been limited by the scientific community's failure to collectively consider the entire body of clinical research in this area. Instead, attention has focused on the limited data available for each specific type of ES device and the unanswered questions regarding the optimal ES dose-response.[1] Examination of ES based on the entire body of evidence, regardless of the ES device or dose parameters, can provide valuable information about the merits of using this adjunctive therapy in practice and the utility of pursuing further research in this area.

ES is believed to restart or accelerate the wound healing process by imitating the natural electrical current that occurs in skin when it is injured.[2–5] This *current of injury* was found to vary in specific ways during the regeneration process with current ceasing to flow as healing is completed or arrested.[6] Electrical current applied to wounded tissue increases the migration of neutrophils and macrophages[7–9] and stimulates fibroblasts,[6,10,11] cells vital to the wound healing process. ES may also play a role in wound healing through improved blood flow.[12,13]

The variety of ES devices examined in clinical trials can be categorized as belonging to one of four basic types: low intensity direct current (LIDC), high voltage pulsed current (HVPC), alternating current

AC	Alternating current
ES	Electrical stimulation
HVPC	High voltage pulsed current
LIDC	low intensity direct current
PHW	Percent healing per week (mean, within sample)
$\overline{PHW}$	Percent healing per week (average, across sample)
RCT	Randomized clinical trial
rhPDGF-BB	Recombinant human platelet-derived growth factor-BB
TENS	Transcutaneous electrical nerve stimulation

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(AC), and transcutaneous electrical nerve stimulation (TENS). LIDC is a continuous, monophasic waveform using 20–200 μA of current at low voltage (< 8 V).[14] HVPC is characterized by a waveform of short, paired pulses with a long interval between pulses. HVPC is typically delivered at 75–200 V and 80–100 pulses per second with a total current of 2.5 μA reaching the tissue when standard-sized electrodes are used.[15] DC and HVPC can be delivered to the wound tissue as either a positive (anode) or negative (cathode) charge. Typically, a cathode electrode is used during the first 3–5 days to decrease bacterial levels in the wound. After the wound is clean, polarity is reversed to anode stimulation until tissue repair is complete.

AC is characterized by symmetrical biphasic pulses using low voltage milliamperage. The amount of charge contained in the two symmetrical phases of each pulse is equal, and therefore, the accumulation of charge in the tissue is zero. TENS represents a type of alternating current. Current is delivered at 15–20 μA with 150 μsec pulse width and 85 Hz (standard low frequency). Unlike LIDC and HVPC current devices, the electrode is placed at the edge of the wound on intact skin.

Despite the type of ES device employed, most clinical trials of ES found that it is an effective adjunctive therapy for healing chronic wounds. Comprehensive narrative reviews of ES[16,17] reinforce these conclusions. Nonetheless, attention to differences among ES devices has caused many to ignore this body of evidence. Unlike a traditional narrative review, a meta-analytic review is able to quantify the magnitude of the treatment effect.

Meta-analysis, which quantitatively averages the findings across multiple studies, is increasingly being used to better estimate the magnitude of a treatment effect than can be derived from a single study.[18] The purpose of this meta-analysis was to quantify the effect of ES as an adjunctive therapy for chronic wound healing and to explore the influence that the type of ES and type of wound may have on the effectiveness of ES. Specifically, this meta-analysis estimated the rate of healing of chronic wounds treated with ES and compared this rate with controls using the findings of multiple studies with human subjects. The analysis also estimated and compared the rate of healing of chronic wounds treated with different types of ES devices. Lastly, the rate of healing of different types of chronic wounds treated with ES were estimated and compared.

METHODS

Published studies of ES and chronic wound healing were identified from searches of computerized and printed bioengineering, health, and medical indices using the keywords, electrical stimulation and wound healing. The reference list of each study was searched for additional studies. Unpublished studies of ES and chronic wound healing were searched using the index, Dissertation Abstracts, and by personal contacts with known ES researchers.

Among ES studies, percentage healing per week was the most common measure of rate of healing that was either reported or that could be calculated from study data. Percent healing was defined as the percentage reduction in wound size from baseline measurements.

To be included in this review, an ES study had to examine ulcer or periulcer electrical stimulation, include human subjects, include chronic wounds, defined as pressure ulcers, venous ulcers, arterial ulcers or neuropathic ulcers, and report quantitative data of baseline and post-treatment wound size, or report percent healing per week. Studies on electromagnetic fields and epidural stimulation were excluded.

Twenty-eight studies were reviewed for inclusion; 15 met the inclusion criteria and are listed in Table 1.[14,19–32] Of those that did not meet inclusion criteria, most were case reports. The studies meeting the inclusion criteria employed a variety of research designs including blinded, placebo-controlled randomized clinical trials (RCTs) (n = 8 studies), non-placebo-controlled, randomized clinical trials (n = 1 study), nonrandomized trials (n = 5 studies), and descriptive designs (n = 1 study). Some clinical trials also contained a descriptive study (n = 2 studies) or crossed the control group over to ES (n = 4 studies) (Table 1). Therefore, the 15 studies contained 24 ES samples and 15 control samples. Twelve of the studies assigned treatments to subjects; three trials assigned treatment to ulcers. That is, multiple ulcers on the same subject were assigned to treatment or control conditions.

Wound treatments

Although the topical treatments in the study samples varied, the local wound treatment administered to 10 of the control samples appeared to be standardized to the ES treatment group. Various types of moist dressings were used on 13 of the control samples, although four samples were treated with antiseptics. Whirlpool treatments were used on some ulcers in

Table 1. Extracted data from studies included in the meta-analysis

Study	Study design	Age (yr)	Time of follow up, weeks	No. of subjects	No. of Ulcers	Type ES or control	Type of ulcers	PHW
Baker et al.[19]	*RCT	34.0	4.9	20	67	Pulsed	Mixed-chronic-other	36.40
		40.0	6.0	21	58	Pulsed	Mixed-chronic-other	29.70
		36.0	5.5	20	42	TENS	Mixed-chronic-other	23.30
	Placebo	33.0	2.9	19	25	Control	Mixed-chronic-other	32.70
	Crossover	NR§	NR§	11	11	Pulsed	Mixed-chronic-other	43.30
Barron et al., 1985[20]	Descriptive	80.5	3.0	6	6	TENS	Pressure	34.50
Carley & Wainapel, 1985[21]	‡RCT	70.3	5.0	15	15	Direct	Mixed-chronic	17.90
	No placebo	73.6	5.0	15	15	Control	Mixed-chronic	8.98
Feedar & Kloth, 1985[22]	Nonrandom clinical trial	NR§	7.3	5	5	Pulsed	Pressure	25.30
	Placebo	NR§	10.6	3	3	Control	Pressure	-13.80
Feedar et al., 1991[23]	*RCT	66.6	4.0	NR§	26	Pulsed	Mixed-chronic-other	14.00
	Placebo	60.7	4.0	NR§	24	Control	Mixed-chronic-other	8.25
	Crossover	NR§	4.0	NR§	14	Pulsed	Mixed-chronic-other	12.80
Prantz, unpublished[24]	*RCT	75.2	8.0	20	20	TENS	Pressure	8.62
	Placebo	73.5	8.0	17	17	Control	Pressure	0.45
Gault & Gatens, 1976[25]	Nonrandom clinical trial	NR§	4.0	6	6	Direct	Mixed-chronic	30.00
	No placebo	NR§	4.0	6	6	Control	Mixed-chronic	14.70
	Descriptive	NR§	4.7	76	100	Direct	Mixed-chronic	28.40
Gentzkow et al. 1991[26]	*RCT	63.3	4.0	NR§	21	Pulsed	Pressure	12.50
	Placebo	62.2	4.0	NR§	19	Control	Pressure	5.80
	Crossover	NR§	4.0	NR§	15	Pulsed	Pressure	12.00
Gogia et al., 1992[27]	Nonrandom clinical trial	52.5	2.9	6	6	Pulsed	Mixed-chronic	11.98
	No placebo	63.0	2.9	6	6	Control	Mixed-chronic	9.37
Griffin et al., 1991[28]	*RCT	32.5	2.9	8	8	Pulsed	Pressure	27.59
	Placebo	26.0	2.9	9	9	Control	Pressure	17.93
Katelaris et al., 1987[29]	Nonrandom clinical trial	74.2	12.0	4	4	Direct	Venous	8.30
	No placebo	71.5	7.0	11	11	Control	Venous	14.29
		77.0	6.6	5	5	Direct	Venous	15.25
	No placebo	68.3	6.6	4	4	Control	Venous	15.19
Kloth & Feedar, 1988[30]	†RCT	70.1	7.3	9	9	Pulsed	Pressure	44.80
	Placebo	65.6	7.4	7	7	Control	Pressure	-11.59
	Crossover	74.3	8.3	3	3	Pulsed	Pressure	38.09
Lundeberg et al., 1992[31]	*RCT	67.5	12.0	24	24	Alternating	Venous	5.08
	Placebo	66.0	12.0	27	27	Control	Venous	3.42
Wolcott et al., 1969[15]	Nonrandom clinical trial	25.9	10.1	8	8	Direct	Mixed-chronic	27.00
	No placebo	25.9	10.1	8	8	Control	Mixed-chronic	5.03
	Descriptive	42.0	7.7	67	75	Direct	Mixed-chronic	13.40
Wood et al., 1993[32]	*RCT	75.6	8.0	41	43	Pulsed	Pressure	11.04
	Placebo	74.9	8.0	30	31	Control	Pressure	4.10

*RCT, Randomized clinical trial, double blind with placebo control group.
†RCT, Randomized clinical trial, single blind with placebo control group.
‡RCT, Randomized clinical trial, unknown blind, no placebo control.
§NR, Not reported
PHW, Mean percent healing per week.

four control samples. Nine of the control samples (8 from RCTs and 1 from a nonrandomized trial) were treated with an ES placebo.

Calculation of the healing rates

The mean percentage healing per week (PHW) was coded or calculated for each ES and control sample independently by two of the authors, SG and RF (Table 1). Agreement between coders was 85%, with disagreements resolved through consultation. The following decision rules were used in coding or calculating mean percent healing per week for each sample:

- Reported values of PHW were always used when available (n = 21 samples).
- If reported values were not available, PHW was calculated for each subject and then averaged for the entire sample when subject level data was available (n = 5 samples).
- If neither reported values or subject level data were available, PHW was calculated from mean sample data (n = 11 samples) or median sample data (n = 2 samples).
- When PHW was calculated from sample or subject data, baseline wound sizes were compared to post-treatment wound sizes. The last post-treatment measurement reported for the sample or the subject was used when more than one post-treatment measurement was done. Interim measurements were not used in the calculations.

Subject level and sample data were reported in a variety of ways. Some studies only reported mean time to complete healing (n = 4 samples), which was then taken as the last time point for the entire sample. Other studies reported total percentage reduction in wound size by sample (n = 7 samples). When this was the case, this value was divided by the study period (in weeks) to arrive at PHW. Other studies reported baseline wound sizes and post-treatment wound sizes (n = 7 samples). For these samples, percent healed was calculated from baseline to the last post-treatment measurement and PHW was arrived at by dividing by study period. All but three PHW estimates were based on surface area measurements (length × width). The other three PHW estimates were based on volume measurements (length × width × depth). Positive PHW values represent healing or a decrease in ulcer size. Negative values represent deterioration of the ulcers.

Supplemental information

Six additional items of information were extracted from the primary studies: type of ES device, type of chronic wound, sample size (number of subjects and number of ulcers), mean age of the subjects in each sample, length of follow-up for each sample, and mean baseline size of the wounds in each sample (Table 1). Type of ES device was categorized as continuous direct, pulsed direct, alternating, or TENS. Study samples were coded as pressure ulcers, venous ulcers, mixed-chronic-ulcers (more than one type of chronic wound), or mixed-chronic-and-other wounds (chronic wounds and acute wounds). There were no studies that contained only neuropathic or arterial ulcers, although these ulcers were among some of the mixed samples. The mean age of each subject sample was coded when available along with the mean length of the follow-up and mean baseline wound size.

Meta-analysis procedures

Meta-analytic procedures often include the calculation and averaging of effect sizes across clinical trials, studies with a treatment and control group. Of the 14 ES studies that were clinical trials (9 RCTs and 5 nonrandomized trials), only 4 (3 RCTs and 1 nonrandomized trial) contained enough information to calculate the variance associated with rate of healing. Therefore, an effect size could not be calculated for the remaining trials. Excluding these studies from the meta-analysis would have dismissed most of the available clinical data. To retain the maximum amount of available clinical data, this meta-analytic review averaged PHW across ES samples and across control samples for comparison.

The principles of meta-analysis advocated by Hunter and Schmidt[18] guided the procedures of this study. Although Hunter and Schmidt have developed procedures to correct for the artifact of sampling error in meta-analytic reviews, these procedures could not be applied in this study because ratio level data (percentage healing per week) does not lend itself to correction for sampling error. Confidence interval estimates were constructed in order to exhibit the influence of random sampling error since correction for this artifact could not be accomplished.

Data available for each sample included PHW and sample size (n_j). The overall average percentage healing per week $\overline{PHW}$ across ES samples and across control samples was weighted by sample size and computed as:

$$\overline{PHW} = \Sigma n_j PHW_j / \Sigma n_j$$

where j represents one sample.

The overall average rate of the control samples was subtracted from the overall $\overline{PHW}$ of the ES samples in order to estimate "net" difference in rate of healing using ES as an adjunctive therapy.

The observed variance of the mean PHW was also weighted by sample size and computed as:

$S^2_{PHW} = \Sigma n_j (PHW_j - \overline{PHW})^2 / \Sigma n_j$

The 95% confidence interval was then computed as

95% C.I. = $\overline{PHW} \pm SE \times (1.96)$.

The confidence intervals of the ES and control samples were compared for width and overlap.

Estimates of the overall $\overline{PHW}$ and confidence intervals were initially done using only blinded, placebo-controlled RCTs. These RCTs contained 10 ES samples and 8 control samples. $\overline{PHW}$ estimates were then recalculated adding the ES and control samples from other RCTs, nonrandomized clinical trials and descriptive studies. Crossover control groups from RCTs and nonrandomized trials were also included in these recalculations (see Table 1).

The ES samples were then grouped and meta-analyzed according to type of ES. All studies were included in these analyses because the ES samples of blinded, placebo-controlled RCTs were too homogenous (7 pulsed direct samples, 2 TENS sample, and 1 alternating current sample). Limiting the analysis to these studies, only pulsed direct and TENS samples could have been meta-analyzed. Using all the studies, a meta-analysis was conducted on those categories with two or more samples, which included continuous direct, pulsed direct, and TENS. AC could not be analyzed as there was only one study in this category. The net effect of each type of ES was calculated by subtracting the overall control $\overline{PHW}$ from each ES device $\overline{PHW}$.

The ES and control samples from all the studies were then grouped according to the type of chronic wound. All studies were used because the control samples from blinded, placebo-controlled RCTs were again too homogenous (5 pressure ulcer samples, 1 venous ulcer sample, and 2 mixed-chronic-other samples). Limiting the analysis to these studies, only pressure ulcers and mixed-chronic-other ulcers could have been meta-analyzed. Using all the studies, a meta-analysis was conducted on those categories with two or more samples, which included pressure ulcers, venous ulcers, mixed-chronic ulcers, and mixed chronic-other ulcers. The average ES and control $\overline{PHW}$ was calculated for each type of chronic wound category. The net effect of ES for each type of wound was calculated by subtracting the control $\overline{PHW}$ from the corresponding ES $\overline{PHW}$.

RESULTS

Based on all of the studies meeting the inclusion criteria, there were a total of 591 ulcers in the ES samples and 212 in the control samples (see Table 2). The mean age of the subjects in the ES and control samples was 58.8 (SD = 18.5; n = 18) and 58.8 (SD = 18.0; n = 13), respectively. Age was not reported for 6 of the ES samples and 2 of the control samples. The mean post-treatment follow-up period was 6.2 weeks (SD = 2.7; n = 24) for the ES samples and 6.4 weeks (SD = 3.0; n = 15) for the control samples. The mean baseline wound size for the ES samples was 8.8 cm^2 (SD = 6.8; n = 15) as compared to 9.2 cm^2 (SD = 6.4; n = 11) for the control samples. Three studies that used volume measures and six studies that did not report baseline measures of wound size were excluded from this comparison.

Overall rates of healing

The estimates of $\overline{PHW}$ provide a basis for quantitating the effectiveness of electrical stimulation as an adjunctive therapy for chronic wounds. The estimates of $\overline{PHW}$ were calculated using only blinded, placebo-controlled RCTs and using all studies (see Table 2). Comparison of the results from these two procedures reveals minimal differences, which indicates that the rates of healing of nonblinded, uncontrolled ES samples were not inflated due to a "placebo-effect." The "net" effect of ES was 13% per week, which represents a 144% increase over the control rate of healing (13% increase/9% control rate × 100 = 144% increase).

Table 2. Meta-analyses of ES and control samples by study design

	Blinded, placebo-controlled RCTs			All study designs		
	ES samples	Control samples	Net effect	ES samples	Control samples	Net effect
Number of samples	10	8		24	15	
Number of ulcers	318	159		591	212	
$\overline{PHW}$*	22.51	9.01	13.50	22.22	9.10	13.12
Standard Deviation	11.41	11.43		10.32	10.44	
SE of mean	3.61	4.04		2.11	2.70	
95 % confidence interval	15.44–29.58	1.09–16.93		18.08–26.35	3.82–14.38	

*Average percent healing per week.

The standard deviation across samples indicates that the amount of variability was similar for both the ES and control samples. The RCT-only estimates reveal an ES confidence interval approximately 15 points wide and a control confidence interval approximately 16 points wide. Comparison of these intervals reveals a slight overlap of 1.5 points.

When all studies were included, the ES confidence interval was 8 points wide and the control confidence interval was approximately 10 points wide. These more narrow intervals reflect the larger number of studies included in these analyses. Comparison of the ES and control intervals using all studies reveals no overlap. Based on these interval estimates, there is a 90% probability that the net effect of ES is 3.7% per week or more, which represents an increase of 40% or more over the control rate.

Rates of healing by ES device

Table 3 provides a basis for comparing the relative effectiveness of different types of ES. Subtracting the overall control $\overline{PHW}$ of 9.10% from the ES $\overline{PHW}$ associated with each type of ES device, the net increase in rate of healing was 10.87% for TENS, 12.59% for continuous direct current, and 15.50% for pulsed current. A great deal of overlap is apparent among the 95% confidence intervals for the three different types of ES devices.

Rates of Healing by Chronic Wound Category

Table 4 provides a basis for comparing the effectiveness of ES on various types of chronic wounds. The highest net difference occurred in the pressure ulcer samples with a net increase of 13.30% per week for ulcers treated with ES, a 403% increase over the control rate. The control $\overline{PHW}$ for pressure ulcers (3.30%) was substantially lower than the overall control $\overline{PHW}$ (9.10%). Therefore, even though the $\overline{PHW}$ for the ES pressure ulcers was only 16.63% (as compared to a $\overline{PHW}$ of 28.26% for the ES mixed-chronic-and-other ulcers), the net difference was higher in the pressure ulcer group. The 95% confidence intervals for pressure ulcers treated with and without ES do not overlap.

The mixed-chronic ulcer subgroup most closely approximated the results from the overall meta-analysis of ES and control samples with a net difference of 12.70% per week and non-overlapping confidence intervals. This is not surprising given that the composition of this subgroup was similar to all samples combined.

The lowest net difference occurred among the venous ulcer group at –0.38% per week. Note, however, that the number of venous ulcer samples in the ES and control group (three in each) is very small and the confidence intervals of the ES and control samples overlap extensively.

The net difference between ES mixed-chronic-and-other wounds and control mixed-chronic-other wounds was 7.50% per week. This subgroup had the highest control $\overline{PHW}$ (20.73%). Because this subgroup contained some acute wounds, the control $\overline{PHW}$ was expected to be higher than those samples consisting only of chronic wounds. The mixed-chronic-and-other confidence intervals overlap completely.

DISCUSSION

This meta-analysis represents the first attempt to quantify the effect of ES on chronic wound healing across the collective body of clinical evidence. The findings support ES as an effective adjunctive therapy for chronic wound healing. Based on overall average rates of healing, ES increases the rate of chronic wound healing 144%. The non-overlapping confidence intervals observed when all studies were included support the inference that ES has a positive effect on chronic wound healing despite the influence of sampling error on average estimates.

The relative effectiveness of specific ES devices remains unsettled. The overlap of confidence intervals for rates of healing by type of ES device indicate that observed differences in average rates may be a function of sampling error. In addition, the rates of healing associated with a specific ES device may have been influenced by the type of wounds contained in the device sample. The control rates of healing by chronic wound

Table 3. Meta-analyses of ES samples by type of ES device

Type of ES	No. of Samples	Total Sample	$\overline{PHW}$*	Standard Deviation	SE of mean	95% confidence interval
Continuous direct current	7	213	21.69	7.33	2.77	16.26-27.11
Pulsed direct current	13	286	24.60	11.55	3.20	18.32-30.88
TENS	3	68	19.97	7.96	4.60	10.96-28.97

*Average percent healing per week.

Table 4. Meta-analyses by type of wound

Type of wound	No. of samples	Total sample	PHW*	Standard deviation	SE of mean	95% confidence interval
Pressure ulcer						
ES	9	130	16.63	10.77	3.59	9.59–23.67
Control	6	86	3.30	7.34	2.99	−2.57–9.17
Net effect			13.30			
Venous ulcer						
ES	3	33	7.01	3.63	2.10	2.90–11.12
Control	3	42	7.39	5.33	3.08	1.36–13.42
Net Effect			−0.38			
Mixed chronic wounds						
ES	6	210	21.82	7.26	2.97	16.01–27.63
Control	4	35	9.12	3.03	1.52	6.15–12.09
Net Effect			12.70			
Mixed chronic & other wounds						
ES	6	218	28.26	8.76	3.58	21.25–35.27
Control	2	49	20.73	12.22	8.64	3.79–37.67
Net Effect			7.53			

* Average percent healing per week.

type indicate that pressure ulcers heal more slowly than other chronic wound categories. As shown in Table 1, the TENS samples were predominantly pressure ulcers. Therefore, the rate of healing estimated for TENS may be suppressed due to the lower rate of healing associated with the wounds that comprised the TENS samples.

The findings of this study indicate that ES may be more effective for healing pressure ulcers. Unfortunately, conclusions regarding which wounds respond best to ES are hampered due to the lack of homogenous wound samples from which to make comparisons.

Limitations

A basic assumption of this meta-analysis was that there were no systematic differences between the ES samples and the control samples with respect to moderating variables that influence healing. Although numerous moderating variables impact healing, unfortunately, the studies did not provide data regarding some of the more important ones, such as nutritional status, tissue perfusion, and bacterial burden, from which to make comparisons between the ES and control samples.

Data were available for other moderating variables that could impact rate of healing, including length of follow-up period, baseline wound size, and age of subjects. Based on the data coded for each sample, the correlation coefficient between length of follow-up period and rate of healing (PHW) was −0.35. However, differences in the mean length of follow-up were minimal between the ES and control samples, as reported in the results. Similarly, differences in mean baseline size between the ES and control sample ulcers were minimal (see Results). Finally, although the correlation coefficient between age and rate of healing was −0.28, the ES and control samples were similar in age (see Results).

One study characteristic that may moderate the effectiveness of ES is dose. Although this has never been studied systematically, it may be that different doses of ES produce different results. Unfortunately, many ES trials did not report sufficient parameter information to allow examination of the influence of dose on PHW.

Additional primary research is needed to examine the optimal-dose response and the relative effectiveness of different ES devices. In addition, more primary studies are needed in order to delineate which patients' wounds respond best to ES. Future studies need to improve on the consistency with which study information, such as measurement and variance data, is reported. These improvements would permit a meta-analysis of effect sizes with correction for sampling error. Thus, the true effect of ES could be more precisely estimated and the influence of moderator variables more thoroughly examined.

Implications

Evidence of effectiveness is an appropriate standard from which to base reimbursement policies. Both the effect and the cost of ES compares favorably with a new adjunctive therapy recently approved by the FDA for lower extremity diabetic ulcers (recombinant human platelet-derived growth factor, [rhPDGF-BB]). Based on published clinical trial data,[33] ulcers treated

with rhPDGF-BB for 8 weeks healed at a rate of 8.75% per week, while the controls in the trial averaged 6.25% per week. The net effect (2.50% per week) of rhPDGF-BB is lower than the effect produced by ES, yet the cost may be the same or greater. While both rhPDGF-BB and ES can be administered by the patient in the home, the cost of rhPDGF-BB is approximately $30/day and is a consumable product. In contrast, ES employs a reusable device that can be amortized over multiple patients, and thus, may be more economical.

In the absence of the findings of this meta-analysis, the Health Care Financing Administration has taken action to deny reimbursement of ES for wound healing. This decision has been met with opposition from providers and patients who have observed the clinical improvement of chronic wounds treated with ES.[34] The findings of this meta-analysis support the merits of ES for treating chronic wounds and should be used to enlighten policy decisions regarding ES reimbursement. Without reimbursement, patients will be unable to access an efficacious wound healing treatment, and studies needed to ascertain cost-effective utilization of ES will be abandoned.

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Note added in proof

On September 15, 1999, HCFA released a Veritus Medicare Services bulletin advising its intermediaries and carriers to disregard Section 35–98 of the Medicare Coverage Issues Manual, which withdrew coverage of electrostimulation for the treatment of wounds. Claims for the treatment of wounds with electrostimulation will be reviewed and a payment determination will be made based on supporting documentation.

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