

## Pulsatile Lavage for the Enhancement of Pressure Ulcer Healing: A Randomized Controlled Trial

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**Background.** Pressure ulcer development is a common, serious complication after spinal cord injury (SCI). Although many biophysical agents are available for treatment, few randomized controlled trials of their efficacy have been done.

**Objective.** The study objective was to examine the efficacy of low-pressure pulsatile lavage treatment for stage III and IV pressure ulcers in people with SCI.

**Design.** This study was a randomized controlled trial. Participants and assessors were unaware of intervention assignments.

**Setting.** This study was conducted in an SCI tertiary care center inpatient unit.

**Participants.** Participants were 28 people with SCI and stage III and IV pelvic pressure ulcers; 14 participants each were randomly assigned to treatment and control (sham treatment) groups.

**Intervention.** Daily low-pressure pulsatile lavage treatment with 1 L of normal saline at 11 psi of pressure was applied to the treatment group along with standard dressing changes. The control group received only sham treatment and standard dressing changes.

**Measurements.** Linear and volume measurements of pressure ulcer dimensions were obtained weekly for 3 weeks.

**Results.** Statistical analysis with the *t* test revealed no statistically significant difference in demographics between groups. Random-coefficient models for analysis of linear and volume measurements revealed improvements over time for both groups. Time trend analysis revealed greater measurement decreases for the treatment group. Differences in rates of change (with 95% confidence intervals) for treatment and control groups, respectively, were: depth,  $-0.24$  (0.09 to  $-0.58$ ) cm/wk; width,  $-0.16$  (0.06 to  $-0.39$ ) cm/wk; length,  $-0.47$  (0.18 to  $-1.12$ ) cm/wk; and volume,  $-0.33$  (0.13 to  $-0.80$ ) cm<sup>3</sup>/wk.

**Limitations.** Study limitations were small sample size and inclusion of only one site. Additionally, participants were not queried about their group assignments.

**Conclusions.** Pulsatile lavage enhanced stage III and IV pelvic pressure ulcer healing rates in people with SCI relative to standard pressure ulcer treatment alone.

Recent data from the National Spinal Injuries Model System indicate that pressure ulcers remain among the most prevalent causes of long-term morbidity in people with spinal cord injury (SCI) and are the leading cause of hospitalization for this population.<sup>1</sup>

There are no recent studies on the overall incidence of SCI in the United States, but it has been estimated that approximately 40 new cases per million people occur annually.<sup>2-4</sup> Spinal cord injury predominantly affects young adults. Although life expectancy after the first year of injury is somewhat lower than that of the general population,<sup>5</sup> increasing numbers of people with SCI have long lives.<sup>6</sup> These people remain at elevated risk of pressure ulcer development throughout their lifetime, with a lifetime incidence of 80% to 95%.<sup>7</sup> Charlifue et al<sup>8</sup> reported that US model systems data indicated that the number of pressure ulcers increases significantly with the duration of injury. McKinley et al<sup>9</sup> reported that the incidence rate increases from 15% at 1 year after injury to nearly 30% at 20 years after injury. These data may be attributable to a combined effect of aging and long-term SCI. Aging with SCI has been shown to negatively affect many health factors,<sup>6</sup> including the odds ratio for pressure ulcer development.<sup>10</sup> Data from these large database studies have been confirmed, in part, by a small preliminary study of US veterans with SCI; in that study, veterans with a grade III pressure ulcer were found to have a mean postinjury time of 22 years.<sup>11</sup>

The cost of treatment ranges from \$2,000 to more than \$120,000 per pressure ulcer.<sup>12,13</sup> Nearly 20 years ago, it was estimated that the total costs of pressure ulcer treatment might exceed \$10 billion annually.<sup>14</sup> Although the magnitude of the problem has long been recognized, the

fourth national pressure ulcer prevalence survey (in 1997) found that the prevalence of pressure ulcers was still not decreasing.<sup>15</sup> This finding is of particular relevance to the care of people with SCI because their mobility and independence are significantly reduced. Consequently, there are significant limitations in the ability of people with SCI to participate in normal activities of daily living, an active rehabilitation program, or both.<sup>16</sup> Furthermore, the presence of pressure ulcers can lead to secondary medical complications, such as local tissue infections and more severe systemic problems, such as sepsis or amyloidosis.<sup>17</sup> Total health care costs for people with SCI are higher than those for other groups at risk for pressure ulcer development and are increasing rapidly.<sup>18</sup> The additional cost of treating a veteran who has SCI and a pressure ulcer has been estimated to be more than \$73,000 annually, primarily because of higher costs for inpatient treatment.<sup>19</sup> People who do not have SCI or are not veterans may have

lower health care costs related to pressure ulcer management; however, it has long been recognized that the development of a pressure ulcer increases both hospital costs and length of stay for all patients.<sup>20</sup>

The prompt and effective treatment of pressure ulcers in people with SCI is therefore of paramount importance. There are many treatment options for pressure ulcers, but the Agency for Health Care Policy and Research (AHCPR) clinical guidelines only recommended the use of 2 specialized treatment modalities to enhance wound healing; hydrotherapy was one of the modalities.<sup>21</sup>

Generally, there are 2 types of commercially available hydrotherapy for wound treatment: whirlpool therapy and pulsatile lavage therapy.<sup>22</sup> Whirlpool therapy has commonly been used for wound treatment. However, the immersion of large body surface areas into a whirlpool tank used by multiple patients may lead to complications, such as cross-

## The Bottom Line

### What do we already know about this topic?

Clinical guidelines for pressure ulcer treatment recommend the use of hydrotherapy. Pulsatile lavage delivers localized hydrotherapy directly to the wound via a pulsating pressurized stream of normal saline. A single-patient-use device with a disposable tip is used for each treatment.

### What new information does this study offer?

Pulsatile lavage enhances the healing of stage III and stage IV pelvic pressure ulcers in people with spinal cord injuries compared with standard pressure ulcer treatment alone.

### If you're a patient, what might these findings mean for you?

Pulsatile lavage therapy combines the clinical advantages of whirlpool therapy with an easier bedside mode of application, which also reduces the risk of cross-contamination. Pulsatile lavage therapy was well tolerated by the patients in this study.

contamination for both the patients and the operator<sup>23,24</sup> and even burn injuries.<sup>25</sup> Furthermore, transfer of patients with mobility impairments into the whirlpool tank and decontamination of the whirlpool tank after each use<sup>26</sup> can be labor-intensive processes. The limited mobility and sensory impairment of people with SCI may make the use of whirlpool therapy for pressure ulcer management a challenging and risky process. In addition, the equipment needed for whirlpool therapy is large, expensive, and not portable, and the pressure applied is variable.

On the other hand, pulsatile lavage therapy provides direct, localized hydrotherapy to pressure ulcers via a pulsatile pressurized stream of normal saline. The treatment is delivered through a single-patient-use device, with a disposable tip for each treatment, so that cross-contamination is unlikely. The equipment is simple and economical to use and portable (allowing bedside treatment), and operation of the device is not labor-intensive. In addition, the pressure applied is known. Therefore, pulsatile lavage therapy may encompass the therapeutic benefits of whirlpool therapy without its potential adverse effects. This technique is widely accepted in the orthopedic field for joint cleansing during surgery.<sup>27</sup> Despite its clinical use by physical therapists and nurses for wound care, the efficacy of pulsatile lavage therapy for pressure ulcer treatment has not been studied.

Most of the work on the use of whirlpool therapy and pulsatile lavage therapy has focused on the debridement properties of the treatments. The direct effects on the healing of pressure ulcers have not been measured. The expectation has been that with improved debridement, the healing of pressure ulcers would be improved. To date, only

one randomized controlled study has addressed this issue with the use of whirlpool treatment.<sup>28</sup> The innovative aspect of that study was that ulcers that did not require debridement (clinically clean ulcers) were assessed, rather than pressure ulcers that required mechanical debridement. The authors demonstrated that whirlpool therapy and regular dressings improved the healing of stage III and IV pressure ulcers compared with regular dressings alone.<sup>28</sup> These positive outcomes supported the clinical use of whirlpool therapy to enhance the healing of pressure ulcers.

The clinical efficacy of whirlpool therapy for pressure ulcer healing and the potentially easier application of and lower complication rate with pulsatile lavage therapy in people with SCI motivated us to evaluate the effects of pulsatile lavage therapy. The specific aim of this study was to investigate the efficacy of low-pressure pulsatile lavage treatment of stage III and IV pressure ulcers in people with SCI. The study hypothesis was that the use of pulsatile lavage treatment and standard care for nonnecrotic, stage III and IV pressure ulcers would increase their healing rate relative to that achieved with standard care alone.

## Method

### Design Overview

The study objective was to examine the efficacy of low-pressure pulsatile lavage treatment for stage III and IV pressure ulcers in people with SCI. A randomized controlled trial was carried out. Participants and assessors were unaware of intervention assignments.

### Setting and Participants

A prospective, randomized controlled study of inpatients who had SCI and were receiving standard wound care for stage III and IV pelvic pressure ulcers at the Spinal Cord

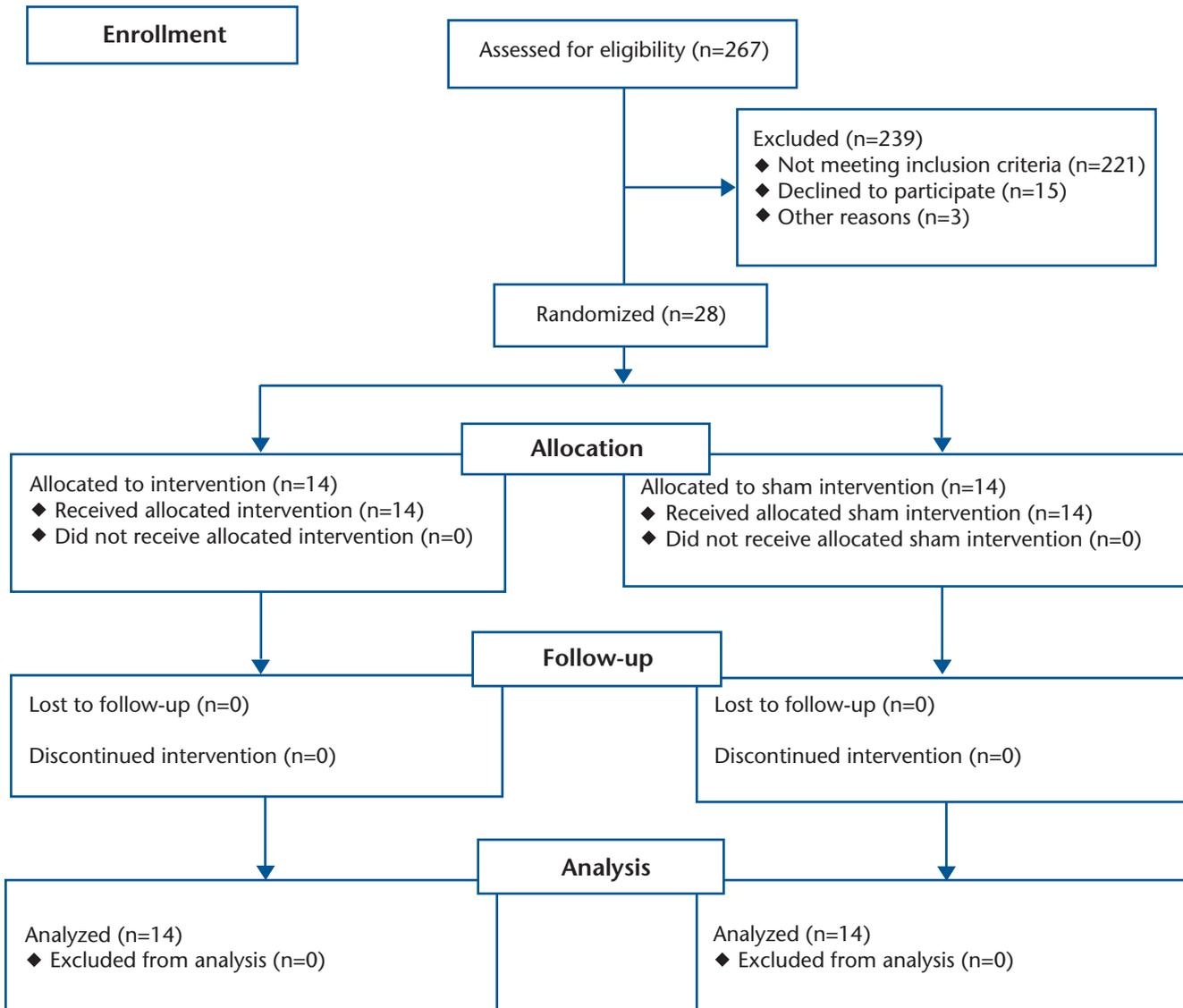
Injury Unit of the Louis Stokes Cleveland Department of Veterans Affairs Medical Center was carried out. An *a priori* power analysis based on previous work comparing whirlpool treatment with standard treatment<sup>28</sup> indicated that a total sample size of 60 participants, with 30 per group, was required.

Standard care was provided in accordance with the recommendations made in *Pressure Ulcer Prevention and Treatment Following Spinal Cord Injury: A Clinical Practice Guideline for Health-Care Professionals* by the Consortium for Spinal Cord Medicine, Paralyzed Veterans of America.<sup>29</sup> This protocol included routine dressing changes and cleansing as appropriate, together with regular turning and use of pressure relief support systems, such as a low-air-loss mattress.

### Randomization and Interventions

Participants were randomly assigned to a treatment group or a control (sham treatment) group after enrollment using a computer-generated randomization table. Only the research nurse administering the intervention was aware of the group assignments. Participants and assessors were unaware of the intervention assignments. Written informed consent was obtained from all of the participants. To minimize the presence of confounding factors that might affect the outcomes of the study, we established the following strict inclusion criteria:

- Age older than 18 years
- No preserved sensory function in the area of the pressure ulcers
- Stage III and IV pelvic (coccygeal, ischial, or trochanteric region) pressure ulcers
- Clinically clean wound area (ie, no necrotic tissue, no odor, and no exudate or minimal serosanguinous exudate only)



**Figure 1.**  
CONSORT flow diagram.

- No surrounding erythema or other evidence of cellulitis
- No tunneling, no actual or possible connection to body cavities, and no fistula
- No malignancy or vascular disease associated with the area of tissue breakdown
- No significant active systemic disease, such as heart disease, renal failure, diabetes, or end-stage cancer
- Pressure ulcers with maximum diameters of 3 to 15 cm at recruitment into the study

- No antibiotic therapy for 7 days before recruitment into the study

A total of 267 inpatients with SCI and stage III and IV pelvic pressure ulcers were screened for the study (Fig. 1). Twenty-eight inpatients met the strict study inclusion criteria and agreed to participate in the study. Eleven participants had sacrococcygeal pressure ulcers, 15 participants had ischial pressure ulcers, and 2 participants had buttock area pressure ulcers. Participants were randomized to group A (treatment

group,  $n=14$ ) and group B (control [sham treatment] group,  $n=14$ ). Seven group A participants had sacrococcygeal ulcers (50%), and 7 had ischial pressure ulcers (50%). Eight group B participants had ischial ulcers (57%), 4 had sacrococcygeal ulcers (29%), and 2 had buttock area pressure ulcers (14%). Unfortunately, data entry regarding the location of the buttock area ulcers was incomplete, and because of data masking, it was not possible to retrospectively determine whether they were actually ischial or

did not appear to be over a bony prominence.

The following demographic data were collected: location of the pressure ulcer being studied, age, sex, weight, height, baseline serum albumin level, baseline total protein level, and baseline lymphocyte count. Men and women of all races and ethnicities were potentially eligible for the study.

### Low-Pressure Pulsatile Lavage Protocol

As part of their routine wound care regimen, each study participant received standard wound care and bed rest with regular turning. Standard wound care was defined as conservative management with regular dressing changes to provide the optimal moist healing environment. The dressing order was given by each participant's attending physician and was compliant with AHCPR guidelines.

The pelvic pressure ulcers of participants in the treatment group were treated with pulsatile lavage in addition to the standard wound care protocol of dressing changes and pressure relief with the use of a low-air-loss mattress and turning every 2 hours. Participants in the control group received sham treatment (see below) and the standard wound care protocol. Because of the absence of regional sensory function and ulcer location, participants were unaware of their group assignments.

A Stryker Interpulse System (Stryker Instruments, Kalamazoo, Michigan), which is designed for single patient use only, was used. This battery-powered system consists of a portable handheld pump that produces pulsed jets of fluid. Unlike the high-pressure lavage devices that are commonly used in orthopedic indications, this device delivers a low pressure—less than 15 psi—and thus

is compliant with the irrigation pressure (4–15 psi) recommended by the AHCPR<sup>21</sup> for wound irrigation. A 1-L bag of sterile normal saline at room temperature was used as the source of the fluid, and the device was attached to it during the lavage procedure. Protective garments and goggles were worn by study personnel during both the intervention treatment and the sham treatment to avoid splash injury. Saline was delivered to the pressure ulcer through a soft, detachable fan shower spray. Concurrently, suction at the tip of the fan removed lavage fluid. The shape of the fan spray and the concurrent suction prevented accidental splashing of the lavage fluid during the procedure. The contaminated lavage fluid was immediately taken up by the concurrent suction and collected in a disposable canister. For the prevention of cross-contamination, the canister was changed after every application, and a new lavage tip was used for each treatment.

A research nurse who was aware of the group assignments applied all of the pulsatile lavage and sham treatments at the participant's bedside on a daily basis for the 3-week period of study participation. Dressings were removed before the commencement of treatment. Participants in the intervention treatment group received the lavage treatment directly over the pressure ulcer. For participants in the sham treatment group, the lavage flow was directed into a washbasin positioned adjacent to the wound and not visible to the participants, although they could hear the operation of the device. None of the participants could feel the treatments because of the absence of sacral sensation. The delivery of 1 L of normal saline at room temperature with the Stryker Interpulse System took 10 to 20 minutes for both the intervention treatment and the sham treat-

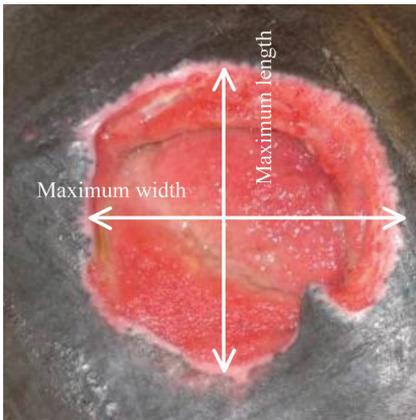
ment. Dressings were replaced at the completion of treatment. When weekly wound measurements were scheduled (see below), they were obtained before dressings were replaced.

### Outcomes and Follow-up

A research nurse who was unaware of the group assignments measured all of the outcomes, and the measurements then were evaluated by the investigators and a statistician (who were unaware of the group assignments). The primary outcome measure of the study was the pressure ulcer healing rate over the 3-week study period. Several parameters were assessed to evaluate the primary outcome measure, and no secondary outcome measure was considered. Baseline measurements of the pressure ulcers were obtained at the beginning of the study, and outcome measurements were obtained at weekly intervals over the study period. Therefore, 4 sets of outcome measurements were obtained for each participant.

Monitoring changes in wound size is critical to evaluation of the healing rate. Several approaches for wound measurement have been described in the literature,<sup>30–32</sup> and many novel techniques are being developed<sup>33</sup>; however, no standardized method has been adopted clinically. Techniques commonly used in current clinical practice include linear measurement with a paper ruler and volume measurement with saline. In the present study, changes in linear and volume measurements obtained with standard clinical techniques were therefore used to describe the primary outcome measure (wound healing rate).

Linear measurements included the length, width, and depth of the pressure ulcer, as measured with a Decubitus Disposable Measuring Guide (Hill-Rom, Batesville, Indiana). We



**Figure 2.**  
Linear pressure ulcer measurement.

defined pressure ulcer length as the maximum measurement from head to toe, the width as the maximum measurement perpendicular to the length, and the depth as the measurement at the deepest part of the wound (Fig. 2). All measurements were obtained at weekly intervals by the same research nurse.

The volume measurement was obtained with a saline injection method. The pressure ulcer was covered and sealed with an occlusive dressing (Tegaderm; 3M, St Paul, Minnesota). Normal saline was injected into the wound through the occlusive dressing with a syringe and needle until the wound was filled. The volume of normal saline needed to fill the wound was noted. The same research nurse collected the volume data at weekly intervals.

### Data Analysis

The Student *t* test was applied to examine differences in demographic data between the intervention treatment and sham treatment groups. The healing rate was determined by studying the linear (length, width, and depth) and volume measurements as described above. Data were obtained longitudinally; that is, the pressure ulcers being studied were measured at weekly intervals over

the 3-week study period. The longitudinal data were correlated over time. Therefore, it was not appropriate to fit a conventional linear regression model, which assumes independent, identical distributed random errors for the data.<sup>34</sup> Random-coefficient models are regression models that are particularly suitable for data analysis when repeated measurements of multiple parameters have been obtained from a group or sample drawn from a larger population. Random-coefficient models have a nested covariance structure that accounts for random variations both within and between groups. In the present study, 2 sources of variation were recognized: (1) random variation among participants due to, for instance, biological variation and (2) random variation within participants due to the process of obtaining a measurement for a particular participant at a particular time or location. Random-coefficient models, therefore, were applied to the correlated data,<sup>35</sup> allowing the introduction of 2 sources of variation: random variation among participants and random variation within participants.

This approach enabled all parameters to be evaluated to study time trend differences between group A and group B to determine the primary outcome measure (pressure ulcer healing rate) over the study period. Maximum-likelihood methods were applied to fit the random-coefficient models to the repeated linear and volume measurements. For each group, the following model equation was applied:  $y = \text{intercept} + (\text{slope} \times \text{time}) + \text{error}$ . With the random-coefficient models, both the intercept and the slope allowed random noise for each participant. After fitting of the models, the fixed effects for the intercept and the slope could be compared and tested. In the present study, analysis-of-variance *F*-type tests were con-

structed on the basis of the models to test treatment effects and time trends at a significance level of .05.<sup>36</sup>

### Role of the Funding Source

This study was supported by the Department of Veterans Affairs Rehabilitation Research and Development Service.

### Results

All participants in this study were men. The Student *t* test was performed to test for demographic differences between the participant groups, specifically, age, height, weight, hemoglobin level, serum albumin level, total protein level, and lymphocyte count. No statistically significant difference was found between group A and group B for all parameters (Tab. 1), indicating that the 2 groups were equivalent.

For determination of the efficacy of low-pressure pulsatile lavage treatment of stage III and IV pressure ulcers in the study population, linear (length, width, and depth) and volume measurements were obtained at baseline (initial values) and weekly over a 3-week period. For all wound measurements, the initial values were comparable (not significantly different) between the groups (Tab. 2). The slopes indicating changes over time were different between the groups. The slope for group A was more negative than the slope for group B, indicating that wound measurements were reduced more in the treatment group (group A) than in the control group (group B) (Fig. 3). Statistically significant differences ( $P < .001$ ) in changes over time (healing rate) between the treatment group (group A) and the control group (group B) were seen for all wound healing parameters of interest (Tab. 3).

### Discussion

To our knowledge, this is the first randomized controlled trial of the

## Pulsatile Lavage for Pressure Ulcer Healing

**Table 1.**  
Demographic Characteristics of Study Groups<sup>a</sup>

Parameter	Group	$\bar{X}$	SD	Minimum	Maximum	t Test Value for Group A vs Group B	P Value for Group A vs Group B
Age (y)	A	57.00	13.07	38.00	74.00	0.42	.68
	B	55.50	5.16	43.00	63.00		
Weight (kg)	A	72.13	12.08	56.70	92.00	-1.23	.23
	B	80.45	22.28	48.26	133.36		
Height (cm)	A	176.00	10.57	149.86	187.96	-0.11	.91
	B	176.00	28.40	83.82	203.20		
Hemoglobin (g/dL)	A	11.55	1.76	8.5	11.4	-1.35	.19
	B	11.54	2.2	8.3	14.8		
Serum albumin (g/dL)	A	3.03	0.31	2.6	3.7	-0.89	.38
	B	3.16	0.44	2.5	3.9		
Total protein (g/dL)	A	6.75	0.7	5.4	7.7	-1.87	.07
	B	7.19	0.52	6.2	8.4		
Lymphocytes (%)	A	25.36	5.79	18	37	-0.014	.89
	B	25.79	9.85	12	42		
Absolute lymphocytes (10 <sup>3</sup> )	A	2.29	0.73	2	4	0.27	.79
	B	2.21	0.7	1	3		

<sup>a</sup> Group A=treatment group (n=14), group B=control (sham treatment) group (n=14).

**Table 2.**  
Baseline and Final Wound Dimensions<sup>a</sup>

Group	Measurement Time	Depth (cm)		Width (cm)		Length (cm)		Volume (cm <sup>3</sup> )	
		$\bar{X}$	95% CI	$\bar{X}$	95% CI	$\bar{X}$	95% CI	$\bar{X}$	95% CI
A	Baseline	2.4	1.67 to 3.19	4.2	3.15 to 5.15	5.0	3.92 to 6.02	10.7	6.54 to 14.83
	Final	1.4	0.59 to 2.20	2.9	1.92 to 3.78	3.5	2.47 to 4.54	5.8	2.79 to 8.79
B	Baseline	3.0	2.16 to 3.84	4.5	2.83 to 6.17	5.1	3.68 to 6.47	16.1	10.56 to 21.69
	Final	2.5	1.81 to 3.16	3.0	1.30 to 4.65	4.9	3.53 to 6.32	12.4	8.39 to 16.38

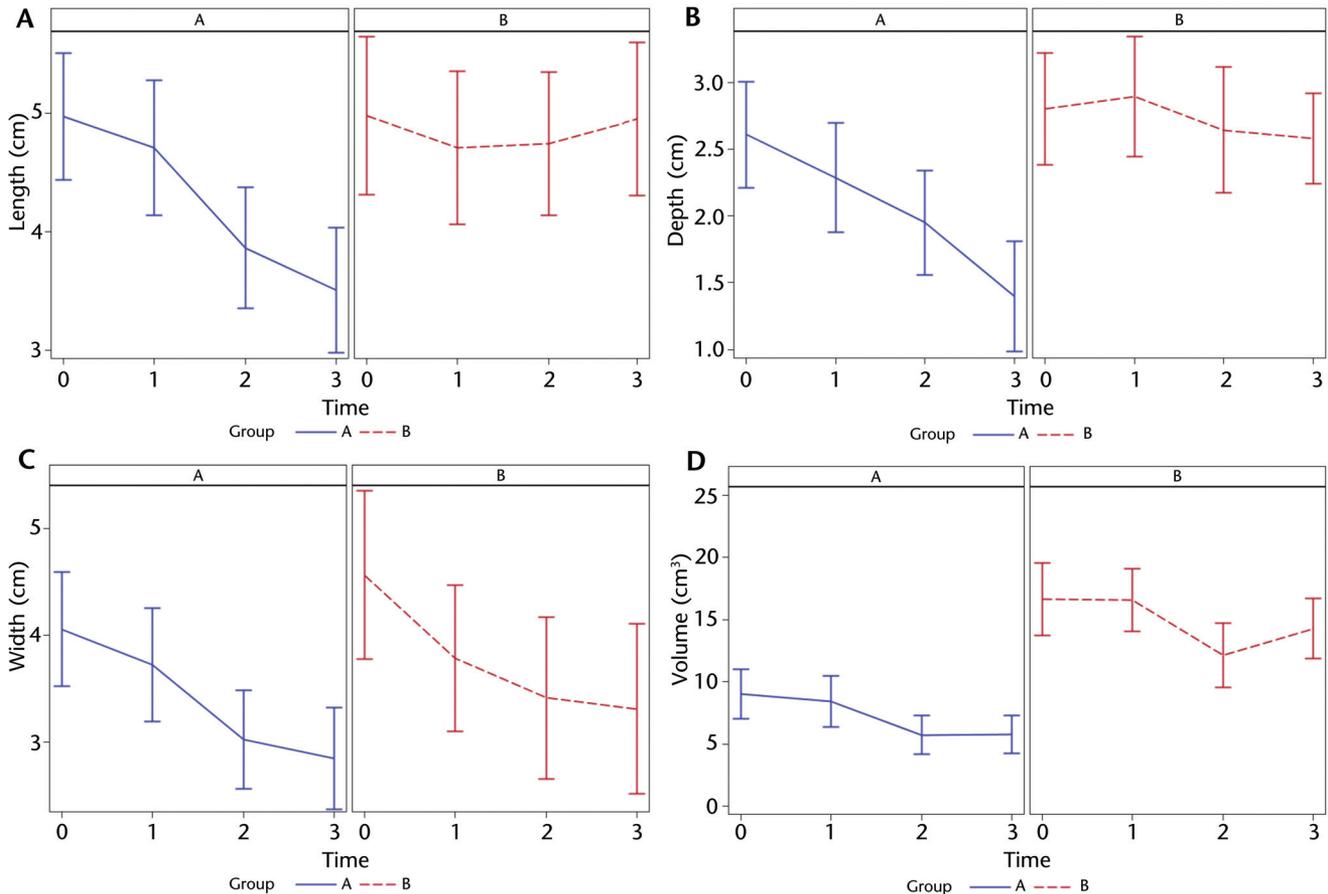
<sup>a</sup> Group A=treatment group (n=14), group B=control (sham treatment) group (n=14), CI=confidence interval.

use of low-pressure pulsatile lavage for pressure ulcer management. There was no difference in demographics between the study groups. Our results showed that low-pressure pulsatile lavage and standard wound care enhanced the wound healing rate in people with SCI and stage III and IV pelvic pressure ulcers relative to standard wound care alone. By focusing on the rate of healing rather than absolute changes in size, we demonstrated that pulsatile lavage therapy

can produce a relative change in dimensions for wounds of any initial size.

In the present study, all of the participants had clean wounds that did not require debridement. Therefore, the enhancement of the healing rate in the intervention treatment group could not be attributed to the mechanical debridement effect. Our results indicated that pulsatile lavage enhanced the healing rate through other mechanisms.

Potential mechanisms for the increased healing rate with pulsatile lavage include mechanical stimulation, an increase in wound bed vascularity, negative pressure from the lavage device with concurrent suction, and a decrease in the bacterial load in the wound. Although there is a paucity of research evidence to support these potential mechanisms, there is strong evidence that wound irrigation decreases the bacterial load in the wound bed and that pulsatile irrigation is more effective.



**Figure 3.** Changes in wounds over time in treatment group (group A) and control (sham treatment) group (group B). (A) Change in wound length over time. Difference over time between groups was significant at  $P<.0001$ . (B) Change in wound depth over time. Difference over time between groups was significant at  $P<.001$ . (C) Change in wound width over time. Difference over time between groups was significant at  $P<.0001$ . (D) Change in wound volume over time. Difference over time between groups was significant at  $P<.001$ .

**Table 3.** Differences Between Changes in Wound Parameters Over Time<sup>a</sup>

Parameter	Δ Means	95% CI	P
Linear			
Depth (cm/wk)	-0.24	0.09 to -0.58	<.001
Width (cm/wk)	-0.16	0.06 to -0.39	<.0001
Length (cm/wk)	-0.47	0.18 to -1.12	<.0001
Volume (cm <sup>3</sup> /wk)	-0.33	0.13 to -0.80	<.001

<sup>a</sup> Δ means=difference between sample means (group A-group B). Group A=treatment group (n=14), group B=control (sham treatment) group (n=14), CI=confidence interval.

tive than continuous irrigation for decreasing the bacterial load within a wound.<sup>37,38</sup> It is well known that a large bacterial load in a wound may negatively affect its healing rate.<sup>39</sup>

Therefore, it is possible that a decrease in the bacterial load after pulsatile lavage of a wound is the primary mechanism through which it enhances the wound healing rate.

It is important to recall that low-pressure pulsatile lavage was used in the present study. High-pressure pulsatile lavage was previously found to have potential adverse effects, such as causing deeper penetration of bacteria into a wound and greater retention of bacteria within a wound than low-pressure pulsatile lavage.<sup>40</sup>

The clinical experience at the Spinal Cord Injury Unit of the Louis Stokes Cleveland Department of Veterans Affairs Medical Center showed that pulsatile lavage for pressure ulcer management was well tolerated by our participants and also was easily administered by the nursing staff. It is a modality commonly used by

physical therapists<sup>41</sup> and home care staff<sup>42</sup> for wound management. The results of the present study provide, for the first time, scientific evidence from a randomized, controlled trial to support the use of low-pressure pulsatile lavage therapy for pressure ulcer management in people with SCI.

### Limitations

Our study had several limitations. The major limitation was the small sample size recruited because of our strict inclusion criteria. Our original goal was to recruit 60 participants, with 30 per group. The strict criteria significantly reduced the recruitment rate; however, they also increased the homogeneity of our participant population and reduced type II errors (false-negative results). At an interim analysis, we found that despite the homogeneity of our participant population, there were uniformly statistically significant differences between the groups for all of the parameters studied. In a review of reasons for screening failure, we found that 90% of the people screened did not meet the inclusion criteria. For eligible people, the primary reason for not participating was that they did not wish to participate in a research study (6%); recent antibiotic therapy and planned surgery were additional reasons (1% combined). In the clinical implementation of pulsatile lavage as wound therapy, these factors would not need to be exclusion criteria. Additionally, a cost-effectiveness study with model data revealed that pulsatile lavage was a low-cost treatment and was cost-effective compared with conservative inpatient treatment.<sup>43</sup> Although not universally generalizable—for example, for pressure ulcers that connect to body cavities—the use of pulsatile lavage would appear to be feasible for many people with chronic pressure ulcers. A larger clinical trial is needed to establish the efficacy of

pulsatile lavage in a broader sample of people with SCI. The use of pulsatile lavage may be generalizable to other populations with pressure ulcers. In the present study, all of the participants had no sensory function in the region of the pressure ulcer. Factors such as sensation or pain associated with a pressure ulcer need to be evaluated in people with sensory function.

Linear measurement of wound size is widely used in clinical practice because it is easy to learn and apply and does not require high-cost, specialized equipment. However, the use of linear measurement as a component of our primary outcome assessment method may have had limitations. Wound dimensions are determined from maximum orthogonal dimensions. This factor leads to a primary source of error in calculation because most chronic wounds are irregularly shaped. Rogers et al<sup>44</sup> found that linear measurements overestimated wound size by approximately 40% compared with digital planimetry.

Theoretically, volume measurements with saline can more accurately determine actual wound size because the use of a fluid enables filling of the 3-dimensional cavity of a pressure ulcer. Volume assessment with saline has been used for the quantitative measurement of wound size for several years<sup>45</sup> and has been considered to be a clinical “gold standard.”

The practicalities of carrying out volume measurements tend to limit accuracy because of the gravitational effects of positioning. Wound location and patient positioning are critically important in determining whether saline volume measurements are even feasible. For example, the radius of curvature of many wounds may be such that the area cannot be covered and filled accu-

rately. In addition to the effects of gravity and geometry, there is a tendency for observers to overfill wounds so that the surface of the covering sheet is not in the same place as the intact skin surface would be, thus leading to an overestimation of wound size. The presence of exudate in a wound can also affect accuracy. Furthermore, it is not known how much saline is absorbed by the wound bed. Many of the practical difficulties inherent in using a liquid to measure wound volume can be overcome by using rapidly setting gel materials. Gel volume measurement has been less widely used than saline volume measurement because it has been considered more demanding for observer time and expertise, with little accompanying increase in accuracy. Schubert and Zander<sup>46</sup> found that volume measurement using gel to fill the wound cavity was as reliable as planimetry. In future clinical trials, digital imaging and analysis techniques may provide more accurate wound dimension characterization.<sup>33,47</sup>

The present study was performed only with people who had SCI. As a result of this approach, study participants were unaware of their intervention assignment because they did not have sensation in the wound region. However, we did not explicitly query the participants to determine whether they knew their group assignments. This factor could represent a limitation of the study design.

### Conclusions

To our knowledge, this is the first randomized controlled trial showing that the use of daily low-pressure pulsatile lavage in addition to standard wound care resulted in an enhanced healing rate for stage III and IV pressure ulcers in people with SCI. This study revealed an association between the use of low-pressure pulsatile lavage and an enhanced healing rate. However,

no exact mechanism for the association between pulsatile lavage and faster pressure ulcer healing was identified. Further studies are needed to determine the exact mechanisms through which pulsatile lavage enhances the healing rate for pressure ulcers.

Dr Ho and Dr Bogie provided concept/idea/research design, data collection, project management, fund procurement, facilities/equipment, and consultation (including review of manuscript before submission). All authors provided writing. Dr Bensitel, Dr Wang, and Dr Bogie provided data analysis. Dr Ho provided participants.

The Louis Stokes Cleveland VA Medical Center Institutional Review Board approved this study.

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