Noncontact Ultrasound Therapy for Adjunctive Treatment of Nonhealing Wounds: Retrospective Analysis

Autumn L Bell and Joseph Cavorsi

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Background and Purpose. The optimal adjunctive therapy for wounds that fail to heal despite conventional wound care has not been established. Clinical evidence suggests improved healing in wounds treated with noncontact ultrasound therapy (NCUT). Although existing evidence supports the use of NCUT for enhanced wound healing, the total number of participants studied remains modest. This study was conducted to assess the impact of adjunctive NCUT on the healing of wounds that fail to progress to healing with conventional wound care alone.

Participants and Methods. A retrospective review of charts for 76 patients who had received outpatient wound care at a single center between January 2005 and December 2006 and who were treated with NCUT as an adjunct to conventional wound care was conducted. All wound care interventions used during the study period were assessed. The primary effectiveness endpoint was the percentage of change in wound area from the start of NCUT to the end of NCUT.

Results. Noncontact ultrasound was administered for a mean of 5.1 minutes per session for a mean of 2.3 times per week. The median duration of therapy was 4.3 weeks. The median wound area was reduced by 79% from the start of NCUT to the end of NCUT (from 2.5 to 0.6 cm^2). The proportion of participants with greater than 75% granulation tissue increased from 32% before NCUT to 46% after NCUT.

Discussion and Conclusion. The single-arm, retrospective design did not allow for comparative assessments of the efficacies of noncontact ultrasound and other wound care interventions. The use of adjunctive NCUT appears to improve healing in wounds that fail to heal with conventional wound care alone.

AL Bell, PT, MPT, CLT, is Clinical Director, Center for Advanced Wound Care, St Joseph's Medical Center, PO Box 302, Reading, PA 19601 (USA). Address all correspondence to Ms Bell at: autumncawc@aol.com.

J Cavorsi, MD, is Medical Director, Center for Advanced Wound Care, St Joseph's Medical Center.

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Traditional wound healing interventions (eg, optimized nutritional status; debridement to remove devitalized tissue; moist dressings to maintain a clean, moist bed of granulation tissue; compression; and treatment to resolve infection) often succeed in promoting wound closure in a reasonable time.[1] For wounds that fail to heal despite the administration of conventional wound care, clinicians are challenged to determine the optimal treatment to augment conventional therapy. Even with type-specific care, such as frequent repositioning for pressure ulcers, off-loading of pressure and good glucose control for diabetic ulcers, and compression systems for venous ulcers, some wounds still fail to heal.

Wound healing modalities offer a potential solution for closing nonhealing wounds. Electrical stimulation, pulsed electromagnetic induction, negative-pressure wound therapy, and high-frequency (megahertz) pulsed-current ultrasound have all contributed in healing chronic wounds.[1] Noncontact, low-frequency ultrasound is among the newer modalities available to enhance the healing of chronic wounds. Although high-frequency ultrasound (1–3 MHz) has been used in clinical practice in physical therapy, physical medicine, rehabilitation, and sports medicine for many years, noncontact ultrasound therapy (NCUT) operating at a markedly lower frequency (40 kHz) has been approved for use in the wound care setting for only about 3 years.[2]

In recent years, clinical evidence of improved healing of chronic wounds treated with NCUT has been accumulating. Two prospective randomized studies demonstrated greater wound healing at 12 weeks when conventional therapy was augmented with NCUT. In a randomized study of 70 patients with chronic critical limb ischemia (transcutaneous oximetry value of ≤40 mm Hg), 63% of patients treated with noncontact ultrasound in addition to conventional wound care showed greater than 50% wound healing at 12 weeks, whereas 29% of patients receiving conventional wound care alone (control patients) showed this level of healing ($P<.001$).[3] Ennis et al[4] conducted a double-blind, sham-controlled trial of 55 patients receiving conventional wound care for recalcitrant diabetic foot ulcers. In that study, 41% of patients treated with noncontact ultrasound healed in 12 weeks, whereas 14% of patients treated with a sham procedure healed in that time period ($P=.04$).[4] In addition, 2 prospective nonrandomized studies did not include control groups. For 51 patients with lower-extremity wounds of various etiologies, Kavros and Schenck[5] observed reductions in healing time (9.8 weeks versus 5.5 weeks, $P<.0001$) and percentage of wound volume (37% versus 95%, $P<.0001$) when NCUT was added to conventional wound care. A mean healing time of 7 weeks in 23 patients treated with noncontact ultrasound and conventional wound care was statistically significant compared with a mean healing time of 10 weeks reported for a historical control group treated with conventional wound care alone ($P=.0005$).[6]

Although the evidence supporting NCUT appears to be fairly positive, the total number of participants studied remains modest. An evaluation of more participants is needed to firmly establish the benefit of this novel therapy. The present study was undertaken at the Center for Advanced Wound Care, St Joseph's Medical Center, Reading, Pennsylvania, to assess the impact of adjunctive NCUT on the healing of wounds that fail to progress to healing with conventional wound care.

Method

Study Population

We conducted a retrospective review of charts for patients who had received outpatient wound care at our center from January 2005 to December 2006 and who were treated with NCUT as an adjunct to conventional wound care.

All participants who were treated with noncontact ultrasound during the study period and who met the entrance criteria were considered for this analysis. Eligible participants were aged 18 years or older, had a nonhealing wound of any etiology, and received NCUT of the wound at least 2 times per week during the study period. Nonhealing wounds were those that had failed to progress to at least 15% closure in the prior 2 weeks of therapy. Clinicians trained in the use of NCUT selected wounds on the basis of the need for cleansing and debridement. At the time of treatment, the clinicians were not aware that these data would be collected for a retrospective study.

Participants were excluded from this analysis if therapy was provided fewer than 2 times per week, their life expectancy was less than 6 months, or NCUT was contraindicated. Noncontact ultrasound therapy is contraindicated when an electronic implant or prosthesis is located near the treatment site (eg, near or over the heart or thoracic area in a participant with a cardiac pacemaker) or the treatment site is on the lower back during pregnancy, over the uterus during pregnancy, or over an area of malignancy.[7]

Before the start of this study, participants included in this analysis signed a general consent form authorizing review of their medical records for research purposes. An additional consent form for this analysis was not required. Investigative

site personnel confirmed the presence of a signed general research consent form for all participants included in this study.

Study Treatments

Data on all wound care interventions used during the study period, including conventional wound care and NCUT, were assessed. Conventional wound care at our center consists of moist wound dressings, selective debridement of devitalized tissue, pneumatic sequential compression and compressive wrapping for edema reduction, and other biophysical technologies indicated for the wound characteristics or associated symptoms.

For NCUT, treatment time per session is dependent on the total ulcer area. In general, treatment time increases as total ulcer area increases. The manufacturer's treatment algorithm for the NCUT system covers ulcer areas from less than 10 cm^2 to 180 cm^2, with treatment times ranging from 3 to 20 minutes.[7] The noncontact ultrasound device delivers low-frequency (40-kHz) ultrasound to the ulcer bed through a fine, sterile saline mist without direct contact of the ultrasound transducer with the body.[2] The mist generated by the system is of relatively uniform particle size and acts as a conduit for transmitting ultrasound energy. The US Food and Drug Administration has identified the device as a low-energy ultrasound wound cleaner that "produces a low-energy ultrasound-generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates and bacteria."[8]

Data Collection

The following baseline parameters were collected: medical history (including comorbidities), physical examination (height, weight, and vital signs), appropriate laboratory and imaging studies (including the ankle-brachial index), history and etiology of the treated wound, wound measurements and characteristics, and participant-reported pain rating with a numeric rating scale, if available. All treatments used during the study period were recorded. For NCUT, data collection included time, frequency, and duration of treatments (eg, 5-minute treatments 3 times per week for 6 weeks); total number of treatments; and adverse events related to devices, therapy, or both. Data on wound sizes, wound characteristics, and numeric pain ratings at the completion of NCUT were collected.

Study Assessments

The primary effectiveness endpoint was the percentage of change in wound area from the start of NCUT to the end of NCUT. Wound area was measured as the greatest length times the greatest width perpendicular to the length or by use of a head-to-toe anatomical orientation measuring the length from 12 o'clock to 6 o'clock and the perpendicular width from 3 o'clock to 9 o'clock. The percentage change in wound area from the beginning of NCUT to the end of NCUT was calculated as follows: $[(\text{beginning area} - \text{end area})/(\text{beginning area})] \times 100$. The primary safety endpoint was the proportion of participants experiencing treatment-related adverse events during the study period. Secondary endpoints included changes in amounts of exudate and devitalized tissue from the beginning of NCUT to the end of NCUT.

Data Analysis

This retrospective study population consisted of participants treated with adjunctive NCUT between January 2005 and December 2006. Up to 100 participants could be reviewed against the entrance criteria to determine eligibility. Formal power calculations to determine sample size were not performed. The primary endpoint was the percentage of change in wound area. Four normality tests (Shapiro-Wilks test, $P<.0001$; Kolmogorov-Smirnov test, $P<.0100$; Cramer-von Mises test, $P<.0050$; and Anderson-Darling test, $P<.0050$) indicated significant departure from the normality assumption. Additionally, a visual inspection of the histogram of values for the percentage of reduction in wound area and a normal quantile plot of the values confirmed a significant skewed distribution. Therefore, the Wilcoxon signed rank test was used to determine significance.

Other statistical comparisons were performed to assess corroboration with the primary endpoint. Descriptive statistics were used to describe the participants and their wounds at the start of NCUT and the end of NCUT. Paired comparisons of data at baseline and at the end of treatment were made with the Wilcoxon signed rank test for continuous variables and the McNemar test for categorical variables. Statistical analyses were performed with SAS, version 9.1.3.*

Role of the Funding Source

Statistical and writing support was funded by Celleration Inc. The authors report no financial interest in Celleration Inc and received no funding or compensation for the study or their time spent writing the article.

Results

Participant Characteristics

Between January 2005 and December 2006, 76 participants meeting the study eligibility criteria were treated with NCUT in addition to conventional wound care. As shown in Table 1, participants in this study were predominantly white, with a

* SAS Institute Inc, PO Box 8000, Cary, NC 27511.

Table 1.
Demographic Characteristics of 76 Participants at the Start of Noncontact Ultrasound Therapy

Characteristic	Value[a]
Male	55 (42)
Mean age, y (range)	62 (23–96)
Race	
Black/African American	7 (5)
White	91 (69)
Hispanic/Latino	3 (2)
Smoking (current)	20 (15)
Cardiovascular or vascular disorder	91 (68)
Hematologic disorder	42 (32)
Neurological or psychological disorder	20 (15)
Pulmonary disease	24 (18)
Diabetes	42 (32)
Gastrointestinal disorder	16 (12)
Musculoskeletal disorder	60 (45)
Integumentary disorder	75 (57)
Cancer	23 (17)

[a] Reported as percentage (number) of participants, unless otherwise indicated.

mean age of 62 years and a slightly higher proportion of men than of women. As is often the case in chronic wound care, comorbid medical conditions were the rule rather than the exception. By far, the most common comorbid condition was cardiovascular or vascular disorder (91% of participants). Disorders of the integumentary and musculoskeletal systems also were present in most of the participants. Forty-two percent of participants had diabetes mellitus.

Wound Characteristics

Wound characteristics at the start of this study are shown in Table 2. Most of the wounds were located on the lower extremities. Approximately one third of the wounds resulted from venous insufficiency. The origins of the remaining two thirds of the wounds were related to pressure, surgery, and trauma. Infection was not present in any wounds in this study. Wounds in this study had been present for a median of 8 weeks, although the range was broad, spanning from 2 to 332 weeks.

The marked difference between the mean (8.2 cm^2) and the median (2.5 cm^2) values for wound area reflects a distribution skewed by a few large wounds. In such a population, median values provide the more representative picture of wound size over time. Wound volume in our study population could not be calculated because of the inability to assess wound depth for both necrotic wounds (for which depth measurements cannot be obtained) and partial-thickness wounds (routinely classified at our center as <0.1 cm and interpreted as 0 in database analysis).

Treatment Characteristics

On average, participants received NCUT for a mean of 5.1 (range=3.0–10.4) minutes per session for a mean of 2.3 (range=1.5–4.0) times per week. The median duration of NCUT over the course of the study period was 4.3 weeks, although the range of treatment durations was broad (0.9–21.7 weeks). For the 13 wounds (18%) that closed completely during the study period (Tab. 3), the median time to closure was 3.6 weeks. The relatively short duration of NCUT, given that only 18% of wounds healed completely, reflects the use of this modality for a cleansing and debridement indication (ie, until slough is removed and the development of healthy granulation tissue is evident).

Wound Healing Outcomes

Wound area data were available for all 76 participants at both the start and the end of NCUT. As shown in the Figure, median wound area was reduced by 79% from the start of NCUT to the end of NCUT ($P<.0001$).

Several changes in wound tissue characteristics and drainage suggested a clinical benefit of NCUT (Table 3). First, the proportion of participants with greater than 75% healthy granulation tissue rose significantly, from 32% before NCUT to 46% after NCUT ($P<.0001$). Second, the proportion of skin around the wound rated as normal increased from 20% before NCUT to greater than 75% after NCUT ($P<.0001$). Third, the proportion of participants with no fibrin slough increased from 27% to 55% ($P=.0116$). Fourth, the amount of exudate was reduced significantly. Most of the wounds (88%) had either moderate or scant drainage at the start of NCUT, whereas by the end of treatment, most of the wounds (73%) were classified as having either scant or no drainage ($P=.0002$).

The type of exudate (primarily serous) did not change substantially during the study period. Pretreatment eschar was present only in 2 wounds and was not present after

the course of treatment with noncontact ultrasound. Undermining, tunneling, odor, and maceration were uncommon, although any amount present before ultrasound treatment was eliminated after the course of treatment.

Subgroup Analyses

The largest wound type subgroups were venous insufficiency leg wounds (n=28) and combined traumatic and surgical wounds (n=25). Median treatment durations (3.8 and 4.4 weeks, respectively), mean treatment frequency (2.3 times per week), and mean treatment times (5.2 and 5.1 minutes, respectively) were similar to those reported for the study population as a whole. Median wound duration before NCUT, however, was slightly longer for venous insufficiency wounds (12 weeks, range=2–156) and traumatic or surgical wounds (8 weeks, range=2–332). As shown in the Figure, wound area reductions for venous insufficiency wounds (80%, $P<.0001$) and traumatic or surgical wounds (76%, $P=.0002$) were comparable to those observed for the study population as a whole. However, traumatic or surgical wounds tended to be larger both before and after NCUT.

Adverse Events

The only adverse event reported in this study, a rash, was classified as a nonserious adverse event and was determined to be unrelated to the study treatments. The rash was assessed by the medical director of our center and was determined to be a reaction to the primary dressing. Symptoms were alleviated through the use of a different dressing.

Pain Ratings

Because there have been reports of reduced wound pain in participants receiving NCUT,[8] we analyzed the change in pain ratings after the start of NCUT in this study. Numeric pain ratings were available for 56 participants (74%) at the initiation of ultrasound treatment and 32 participants (42%) at the end of the course of ultrasound treatment. In paired analyses of the 26 participants for whom numeric pain ratings were available at both the start and the end of ultrasound treatment, the mean pain rating was reduced by 1.8 points ($P=.0010$).

Table 2.
Wound Characteristics at the Start of Noncontact Ultrasound Therapy for 76 Participants

Wound Characteristic	Value
Duration, wk	
Mean/median	20.9/8.0
SD	44.8
Range	2–332
Area, cm^2	
Mean/median	8.2/2.5
SD	14.8
Range	0.1–96.0
Location, % (no.)	
Sacrum	1 (1)
Leg	68 (52)
Heel	3 (2)
Foot[a]	20 (15)
Other[b]	8 (6)
Etiology, % (no.)	
Pressure	4 (3)
Venous insufficiency	37 (28)
Arterial insufficiency	4 (3)
Surgery	13 (10)
Trauma	20 (15)
Other[c]	22 (17)

[a] Includes 6 diabetic foot ulcers.
[b] Other locations: amputation below the knee (4), abdomen (1), and back (1).
[c] Other etiologies: diabetic foot ulcers (6), burns (2), spider bites (3), vasculitis (2), bullous pemphigus (1), warfarin necrosis (1), edema (1), and necrobiosis lipoidica (1).

Discussion

In this retrospective analysis, wound area decreased by 79% with the addition of a median of 4.3 weeks of NCUT to conventional wound care at our center. This reduction in wound size was accompanied by concomitant increases in the amounts of healthy granulation tissue and normal skin around the wound. Furthermore, the amounts of exudate and fibrin slough—characteristics associated with delayed wound healing—decreased significantly during the course of NCUT.

Although retrospective in nature, this analysis contributes data for a comparatively large number of participants treated with noncontact ultrasound to the published body of smaller, prospective studies supporting the utility of NCUT in the treatment of nonhealing wounds. Four prospective studies demonstrated either faster healing times or greater proportions of wounds healed with NCUT than with conventional

Table 3.
Wound Characteristics at the Start of Noncontact Ultrasound Therapy (NCUT) vs the End of NCUT

Characteristic	% (no.) at:		*P*[a]
	Baseline	End of Treatment	
Skin around wound			<.0001[b]
Normal	20 (15)	76 (58)	
Irritated	3 (2)	4 (3)	
Erythematous	21 (16)	3 (2)	
Edematous	41 (31)	4 (3)	
Calloused	8 (6)	4 (3)	
Other	26 (20)[c]	9 (7)[d]	
Undermining	1 (1)	0 (0)	.3173
Tunneling	0 (0)	0 (0)	NA[e]
Odor	1 (1)	0 (0)	.3173
Maceration			.0082
None	91 (67)	100 (76)	
Minimal	8 (6)	0 (0)	
Moderate	1 (1)	0 (0)	
Maximum	0 (0)	0 (0)	
Amount of exudate			.0002
None	3 (2)	34 (24)	
Scant	35 (26)	39 (28)	
Moderate	53 (39)	21 (15)	
Maximum	9 (7)	6 (4)	
Type of exudate			.7127
Sanguineous	13 (9)	17 (8)	
Serous	76 (54)	79 (37)	
Serosanguineous	4 (3)	4 (2)	
Purulent	7 (5)	0 (0)	
Amount of healthy granulation tissue			.0001[f]
Complete closure	0 (0)	18 (13)	
76%–99%	32 (24)	46 (34)	
51%–75%	7 (5)	4 (3)	
26%–50%	28 (21)	15 (11)	
1%–25%	22 (17)	11 (8)	
None	12 (9)	7 (5)	
Amount of eschar			.1573
None	97 (73)	100 (75)	
<50%	3 (2)	0 (0)	
Amount of fibrin slough			.0116
None	27 (19)	55 (41)	
<50%	18 (13)	13 (10)	
≥50%	55 (39)	32 (24)	

[a] As determined with the McNemar test.
[b] *P* value for comparison of percentage of normal skin around wound at start of treatment vs end of treatment.
[c] Other=indurated (11), inflamed (3), cyanotic (2), bruised (1), ecchymotic (1), excoriated (1), and hyperpigmented (1).
[d] Other=indurated (6) and hyperpigmented (1).
[e] NA=not applicable.
[f] *P* value for comparison of start logos75% granulation tissue at start of treatment vs end of treatment.

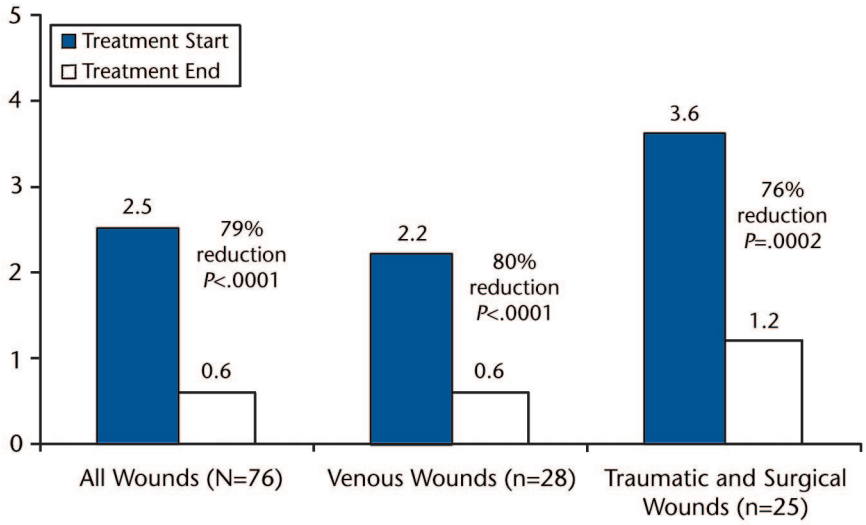

Figure.
Changes in median wound area from the start of noncontact ultrasound therapy (NCUT) to the end of NCUT. *P* values from Wilcoxon signed rank test.

wound care. Comparing NCUT with a baseline period of conventional wound care for 51 participants, Kavros and Schenck[5] reported a statistically significant 44% reduction in treatment time associated with NCUT. Ennis et al[6] observed a statistically significant 30% reduction in mean healing time for chronic lower-extremity wounds of various etiologies treated with noncontact ultrasound in a comparison with a historical control group treated with conventional wound care. In a sham-controlled study of 55 patients with diabetic foot ulcers, 40% more wounds treated with noncontact ultrasound healed completely by 12 weeks.[4] In a randomized study of 70 patients with chronic critical limb ischemia, 54% more wounds treated with noncontact ultrasound showed greater than 50% closure in 12 weeks.[3] In the present study, the benefit of 75% to 80% wound area reduction was reported for the overall study population and for the subgroups of participants with venous insufficiency leg wounds (n=28) and wounds of traumatic or surgical origin (n=25).

Although anecdotal reports of pain relief associated with noncontact ultrasound are numerous, this is only the second study to document decreased wound pain after the initiation of noncontact ultrasound for painful wounds. Gehling and Samies[9] retrospectively analyzed the records of 15 consecutive patients who had lower-extremity wounds and received NCUT for 2 to 4 weeks. They noted a statistically significant 80% reduction in patient-reported visual analog scale pain scores.[9] Although small, our study population was treated at a facility at which numeric pain ratings are routinely collected at the start of every visit for wound care. Despite the absence of consistent numeric pain ratings in our analysis, we did find a statistically significant pain reduction of 1.8 points in the 26 participants with numeric pain ratings at both the start and the end of NCUT. The potential for a palliative benefit of NCUT for painful wounds appears to warrant prospective investigation. Perhaps such a benefit could be achieved by using noncontact ultrasound as a painless alternative to other debridement therapies known to exacerbate wound pain (ie, pulsed lavage or sharp debridement).

The wound area reduction observed after a median of 4.3 weeks of NCUT must be considered in the context of the inherent limitations of the present study. Because of the single-arm, retrospective design, we were not able to directly compare the efficacies of noncontact ultrasound and other wound care interventions. Furthermore, the observation that only 18% of wounds in the present study had healed completely by the end of NCUT raises questions about the optimal treatment duration for this therapy. It is clear that noncontact ultrasound was discontinued before wound closure was achieved. Given its indications for wound healing and maintenance debridement, noncontact ultrasound may well be needed only until slough has been removed and healthy granulation tissue predominates in the wound bed.

Conclusion

Taken together with the prospective evidence of improved healing with noncontact ultrasound, the present study provides additional support for the clinical utility of adjunctive NCUT in promoting the healing of nonhealing wounds of various etiologies.

Ms Bell and Dr Cavorsi provided writing, participants, and facilities/equipment.

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The study protocol was approved by the St Joseph's Hospital Institutional Review Board.

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References

1 Kloth LC, McCulloch JM. *Wound Healing: Alternatives in Management*. Philadelphia, PA: FA Davis Co; 2002.

2 Unger PG. Low-frequency, noncontact, nonthermal ultrasound therapy: a review of the literature. *Ostomy Wound Manage.* 2008;54:57–60.

3 Kavros SJ, Miller JL, Hanna SW. Treatment of ischemic wounds with noncontact, low-frequency ultrasound: the Mayo Clinic experience, 2004–2006. *Adv Skin Wound Care.* 2007;20:221–226.

4 Ennis WJ, Foremann P, Mozen N, et al. Ultrasound therapy for recalcitrant diabetic foot ulcers: results of a randomized, double-blind, controlled, multicenter study. *Ostomy Wound Manage.* 2005;51:24–39.

5 Kavros SJ, Schenck EC. Use of noncontact low-frequency ultrasound in the treatment of chronic foot and leg ulcerations: a 51-patient analysis. *J Am Podiatr Med Assoc.* 2007;97:95–101.

6 Ennis WJ, Valdes W, Gainer M, Meneses P. Evaluation of clinical effectiveness of MIST ultrasound therapy for the healing of chronic wounds. *Adv Skin Wound Care.* 2006;19:437–446.

7 Celleration, Inc. *MIST Therapy System Instructions for Use.*Eden Prairie, MN: Celleration Inc; 2006.

8 US Food and Drug Administration. Mist Therapy System 510(k) premarket notification. Available at: http://www.fda.gov/cdrh/pdf5/K050129.pdf. Accessed August 12, 2008.

9 Gehling ML, Samies JH. The effect of noncontact, low-intensity, low-frequency therapeutic ultrasound on lower-extremity chronic wound pain: a retrospective chart review. *Ostomy Wound Manage.* 2007;53:44–50.

Invited Commentary

Val J Robertson

White swans had an important role in European philosophy. Different versions of the following sentences were used to illustrate logical arguments and refutations:

Premise 1: All swans are white.

Premise 2: This bird is a swan.

Conclusion: Therefore, this bird is white.

The finding of black swans in Australia in the late 18th century put this to rest and added a new set of variants to these sentences.

How do swans and the present article[1] relate? There are 2 connections: the first concerns an obvious epistemological flaw, and the second concerns evidence of knowledge changing over time. Prior to exploring these connections, I commend the authors on analyzing patient records from a 2-year period. Mining existing patient records can be invaluable and should be attempted more often.

Back to the first connection with swans: the present article implies that knowledge of the outcomes for more patients would increase our conviction of the value of this therapy. The danger of this is obvious: with white swans, centuries of repeated instances of them always being white convinced observers that the first premise was true. One black swan changed this! Likewise, with studies of ultrasound, more observations should not necessarily increase our certainty.

Staying with certainty, the more times we see the sun rise, the more likely we are to believe it will do so again tomorrow. With the sun, the underpinning science does justify our high level of certainty about its rising again tomorrow. This is not so for the effects of many patient interventions. At best, sophisticated statistical analyses tell us the probability of particular outcomes following an intervention under specified conditions.

Research methods can help increase our certainty, particularly if patients are randomly allocated to either a treatment group or a nontreatment group. All treatments then should be provided in a double-blinded context: patients not knowing whether they are in an active or placebo treatment arm, administering therapists not knowing either, and assessors blinded to the group assignment of participating patients. If a treated group has a particularly different outcome, we can ascribe this to the intervention if the procedures were implemented as planned, appropriate assessment methods used, and so on. We still prefer more extensive testing in multiple centers with different researchers to be convinced that the outcomes were not due to contiguous events.

Moving on from Epistemology 101: a cursory review of the present article raises important questions that should affect our confidence in its findings. The critical reason, common in retrospective studies, concerns the lack of procedural detail and rationale for treatments. Starting at the beginning, no rationale was provided for the exclusion criteria. Why were patients' data excluded if they were treated less than twice a week? Why not 3 times a week? Was this a convenience, related to the data set, or a decision based on an unspecified rationale or institutional treatment protocols? The descrip-

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Corrections

Marcus RL, Smith S, Morrell G, et al. "Comparison of combined aerobic and high-force eccentric resistance exercise..." *Phys Ther.* 2008;88:1345–1354.

Table 3 contains incorrect footnote symbols for within-group differences for thigh lean tissue and body mass index (BMI) in both the AE/RE and AE groups. The 95% confidence interval for thigh intramuscular fat (IMF) in the AE group also is incorrect. The corrected table is shown below. The Journal regrets the errors.

Table 3.
Outcomes for Glucose Control, Muscle Structure, Physical Performance, Muscle Damage, and Body Mass Index[a]

Variable	AE/RE Group (n=7)			AE Group (n=8)		
	Pretraining $\bar{X}$ (SD)	Posttraining $\bar{X}$ (SD)	Within-Group Difference (95% CI)	Pretraining $\bar{X}$ (SD)	Posttraining $\bar{X}$ (SD)	Within-Group Difference (95% CI)
HbA_{1c} (%)	7.1 (1.2)	6.5 (1.3)	−0.59 (−1.5 to 0.28)[b]	6.3 (1.2)	6.0 (1.1)	−0.31 (−0.60 to −0.03)[b]
Thigh lean tissue (cm^2)	142.9 (33.2)	158.0 (35.2)	15.1 (7.6 to 22.5)[b,c]	138.1 (39.3)	132.7 (41.4)	−5.6 (−10.4 to 0.76)[b,c]
Thigh IMF (cm^2)	32.7 (8.4)	31.6 (7.1)	−1.2 (−2.6 to 0.26)[b]	32.3 (8.7)	30.2 (9.2)	−2.2 (−3.5 to −0.85)[b]
6MWT distance (m)	554.5 (59.3)	600.0 (51.9)	45.5 (7.5 to 83.6)[b]	520.3 (33.0)	550.2 (55.9)	29.9 (−7.7 to 67.5)[b]
BMI (kg/m^2)	35.0 (6.0)	33.2 (5.8)	−1.9 (−3.2 to −0.56)[b,c]	29.8 (4.4)	30.0 (4.2)	0.10 (−0.55 to 0.75)[b,c]
CK (U/L)	160.0 (173.3)	145.1 (120.5)	−14.9 (−80.1 to 50.4)	92.5 (46.9)	108.5 (57.1)	15.7 (−14.1 to 45.5)
Thigh pain VAS score	2.0 (2.3)	0.0 (0.0)	−2.0 (−4.13 to 0.13)	Data not collected		

[a] AE/RE group=subjects who participated in a combined aerobic and eccentric resistance exercise program, AE group=subjects who participated in a program of aerobic exercise only, HbA_{1c}=glycosylated hemoglobin, IMF=intramuscular fat, 6MWT=Six-Minute Walk Test, BMI=body mass index, CK=creatine kinase, VAS=visual analog scale.
[b] Significant ($P<.05$) time effect.
[c] Significant ($P<.05$) interaction (group × time) effect.

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The text of the "f" footnote of Table 3 should read:

P value for comparison of >75% granulation tissue at start of treatment vs end of treatment.

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