

Report of adverse event with electroacupuncture

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ABSTRACT

Electroacupuncture (EA) is becoming more common as a treatment for chronic musculoskeletal pain. It can be associated with adverse events related to the small electric currents used, in addition to the adverse events related to needle penetration of tissues. This paper reports a case of minor tissue damage following high intensity EA for 30 min with a device delivering a waveform that does not appear to be completely charge-balanced. This case highlights a rare but preventable adverse event. Manufacturers should be encouraged to develop EA stimulators that use charge-balanced waveforms.

INTRODUCTION

This case describes minor tissue damage related to the use of electroacupuncture (EA), when a new device (with a different waveform) was used in a patient who was familiar with using EA at high intensity from a different device that produced a charge-balanced biphasic waveform.

CASE PRESENTATION

The patient was a 35-year-old female accountant, who presented to the British Medical Acupuncture Society's London Teaching Clinic at the Royal London Hospital for Integrated Medicine in January 2007. She was referred by an occupational health physician associated with her employer's health insurance scheme. She described a six month history of lateral elbow pain in her right (dominant) arm, which had first come on after a bout of vigorous physical activity (swimming back crawl)—she was a former competitive swimmer no longer in training. She had had a specialist orthopaedic assessment including MRI of the area. She had been offered a steroid injection. She had seen a physiotherapist and been treated with three sessions of acupuncture. Her pain had improved by 80% but her function (the ability to use a keyboard and mouse) had improved by only about 20%. My physical assessment was consistent with an enthesopathy and associated myofascial pain. The enthesopathy appeared to affect the attachment of

extensor carpi radialis longus (ECRL) just above the lateral epicondyle and extensor carpi radialis brevis (ECRB) at the common extensor origin onto the lateral epicondyle. Myofascial pain that extended from the elbow area down the dorsal aspect of the forearm appeared to derive from trigger points in ECRL and ECRB.

In view of the patient's good symptomatic but limited functional response to manual acupuncture, I initiated a course of EA targeted at the area of enthesopathy and the trigger points. Stretching and eccentric exercise was encouraged, and a graduated return to normal keyboard activities. A workstation ergonomic assessment had already been performed.

Progress was slow but there appeared to be gradual improvement, and during this protracted period of rehabilitation the patient had become accustomed to using EA at the maximum output settings on the Acus 4 (Cefar, Malmö, Sweden)—that is, 12 mA; 80/2 Hz dense dispersed (2 Hz is a burst of 8 biphasic pulses);

180 μ s pulse width. The placement of needles was consistent throughout a protracted course of treatment, and sessions were performed monthly for over 2 years. Needle placement was as follows: a pair of fine needles (Seirin J-type No1) was placed close together into the tender point at the attachment of ECRL just above the common extensor origin at the lateral epicondyle; these needles were 0.16 mm diameter by 30 mm length, and were inserted 15 mm into the tissues—the surface area of each electrode was therefore approximately 15 mm². A further three needles (Seirin L-type No. 5) were used: two placed into persistent myofascial trigger points in ECRL and ECRB around 2–3 cun distal to the lateral epicondyle, and one in LI11; these needles were 0.25 mm diameter by 40 mm length, and were inserted 25 mm into the tissues—the surface area of each electrode was therefore approximately 40 mm². The needles were connected in pairs with the needle in LI11 used as a common electrode for the needles in the myofascial trigger points.

The patient was then introduced to a new EA device that was under evaluation by the author (AS Super 4 digital; schwa-medico GmbH, Ehringshausen, Germany). This device appeared to be similar to the Acus 4, in that it had four outputs with push button digital control of current in steps of 0.1 mA for each output. The parameters used were similar—2/100 Hz dense dispersed; 210 μ s at 2 Hz and 120 μ s at 100 Hz predominantly monophasic pulses. The patient was accustomed to controlling the intensity herself, and on the first occasion she increased the output to around 15 mA over the

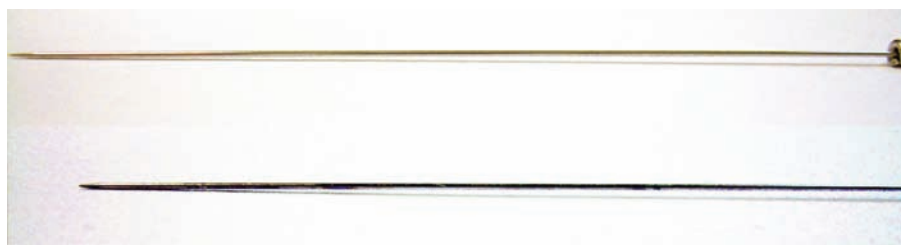


Figure 1 This image shows the discolouration of the needle (foreground) that was sited at the acupuncture point LI11 (this was the common 'anode' for two paired leads). An unused needle of the same gauge and make is shown in the background.

course of the 30 min treatment session. On the second occasion that the patient used the device, she rapidly increased the intensity to the maximum output of 20 mA early in the 30 min session. At the end of the session the needle in LI11 (the common 'anode') seemed to be a little tethered in the tissues, and when removed the needle shaft appeared blackened in places (see figure 1). The needle site was also blackened and appeared to ooze a small bleb of serous fluid (see figures 2 and 3). There was a similar appearance at the 'anode' of the pair of needles placed at the attachment of ECRL.

The tiny blackened and ulcerated areas healed over a 24 h period, and after about 10 days the patient was left with small rounded pink scars (see figure 4). The latter eventually disappeared over the course of the about 6 weeks. The patient continues to have EA treatment and is working a normal schedule, although she has never returned to her preinjury functional ability. She has altered some of her workflow to reduce excessive keyboard use, and still uses a left-handed mouse.

DISCUSSION

EA is increasingly used as a treatment for chronic musculoskeletal pain conditions, as well as in other areas of acupuncture practice,¹ despite some controversy surrounding national guidelines.² Adverse events (or potentially adverse events) related to the use of EA have been reported,³ and these have mostly related to cardiac effects (angina, cardiac arrest, interference with a demand pacemaker). Up to 2004, White found five primary reports (written by clinicians involved in the relevant case) and four secondary reports (written by other authors) of deaths related to needle trauma during EA.³ The author is only aware of one further case report to date, which involved EA across the chest triggering an intracardiac defibrillator to discharge unnecessarily.⁴

This case report describes visible tissue damage at the site of one

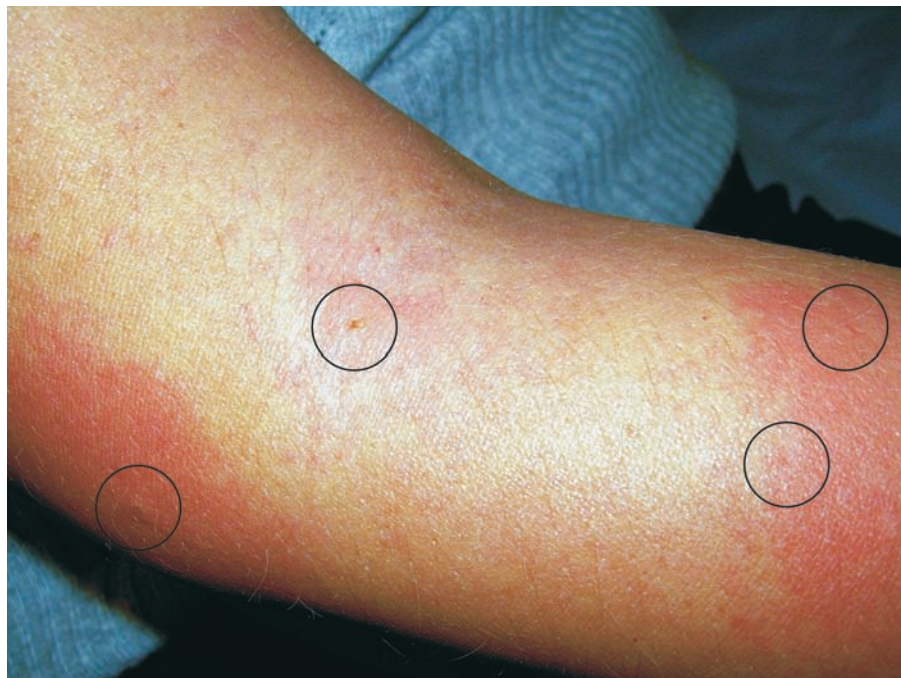


Figure 2 This image shows the patient's right elbow from the dorsolateral aspect immediately after treatment. The image has been marked with circles at the sites of needle insertion. A normal red flare is visible at all four sites, but tissue damage is only visible at the proximal two (the left hand side of the image).



Figure 3 This image is a closer view of the needle insertion sites where tissue damage was apparent. These occurred at the 'anode' of the electrode pairs. The black circle surrounds the common 'anode' site at LI11, where a weal is seen with ulceration and blackening at the puncture site. The white circle surrounds an area where a pair of needles was inserted into the tender point at the attachment of extensor carpi radialis longus. These needles were about 5 mm apart at the skin surface, and the discolouration occurred at the 'anode' of the pair.

needle electrode ('anode'—the needle electrode with a positive charge due to a predominantly monophasic

waveform) of each pair following a session of EA using a device that produced a predominantly monopolar

waveform, that is, electrical stimulation with a waveform that was not charge-balanced. The patient was experienced using EA, having had many prior sessions of treatment with the same needle placement. She had become accustomed to using the maximum output of one particular device (12 mA; 80/2 Hz; 180 μ s square wave biphasic). A new device under evaluation by the author was introduced to her for her opinion. She was happy with the sensation produced, and on the second session applied the maximum output for nearly 30 min (20 mA; 2/100 Hz; 210 μ s at 2 Hz and 120 μ s at 100 Hz square wave predominantly monophasic). Tissue damage was noted on the second session at the 'anodes'—the needle electrodes with a predominantly positive charge.

According to Low and Reed's textbook on electrotherapy,⁵ direct current (DC) applied to human tissues in vivo results in chemical changes at the sites of contact with the electrodes. Negative charge at the cathode results in an alkaline environment

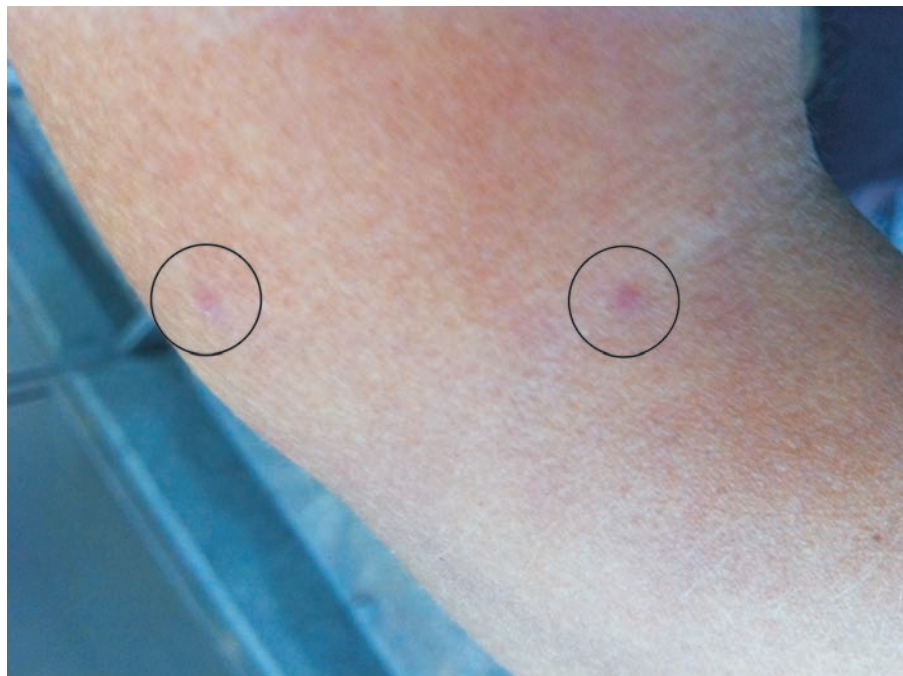


Figure 4 This image was taken by the patient using her own mobile phone 10 days after the treatment session. The black circles indicate the areas of needle insertion where small rounded pink scars can be seen. These disappeared after about 6 weeks.

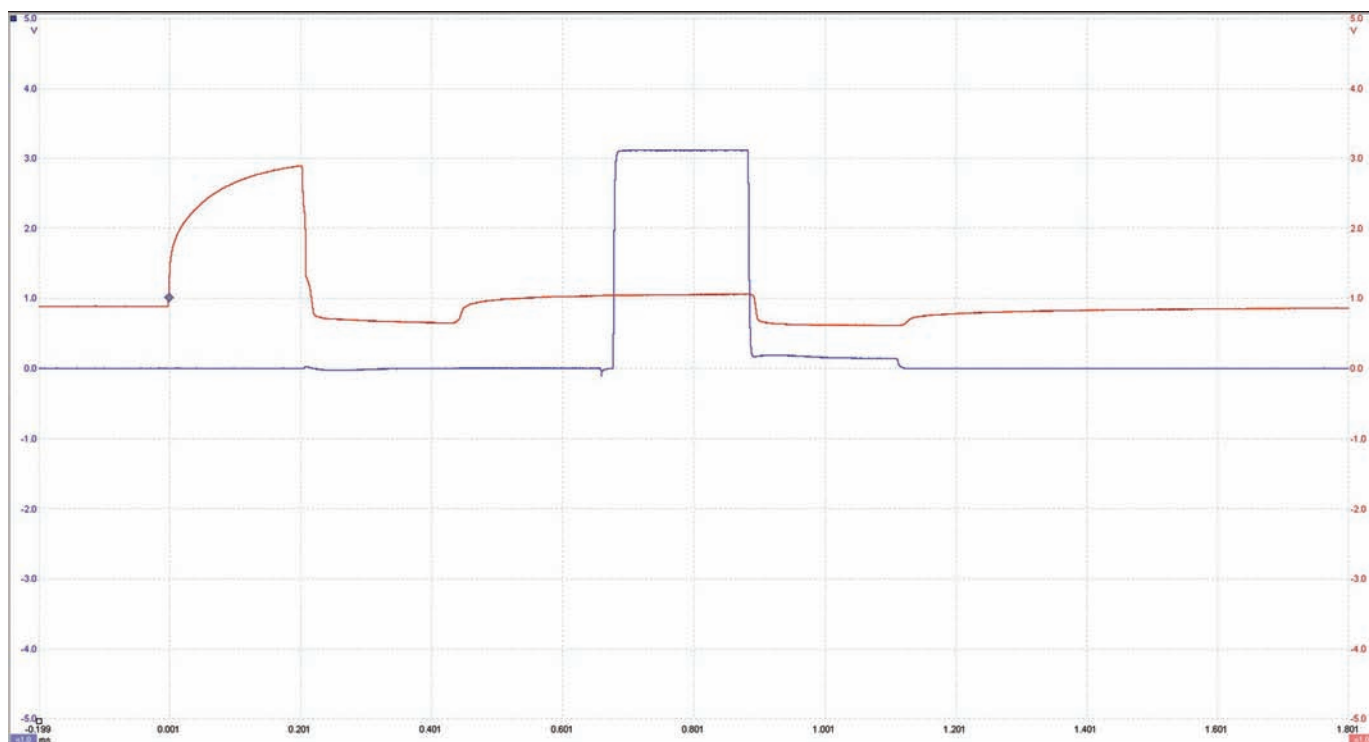


Figure 5 This figure was recorded from a PC-based oscilloscope. The blue tracing records the output of one channel of the device connected across a 1 k Ω resistor, and the red tracing simultaneously records the output of another channel of the same device connected across needles embedded in the author's tibialis anterior muscle in the region of the acupuncture points ST36 and *Zongping*. The red tracing shows a baseline shift of just less than 1 V, and a large deflection from the baseline voltage followed by two smaller deflections of the opposite polarity.

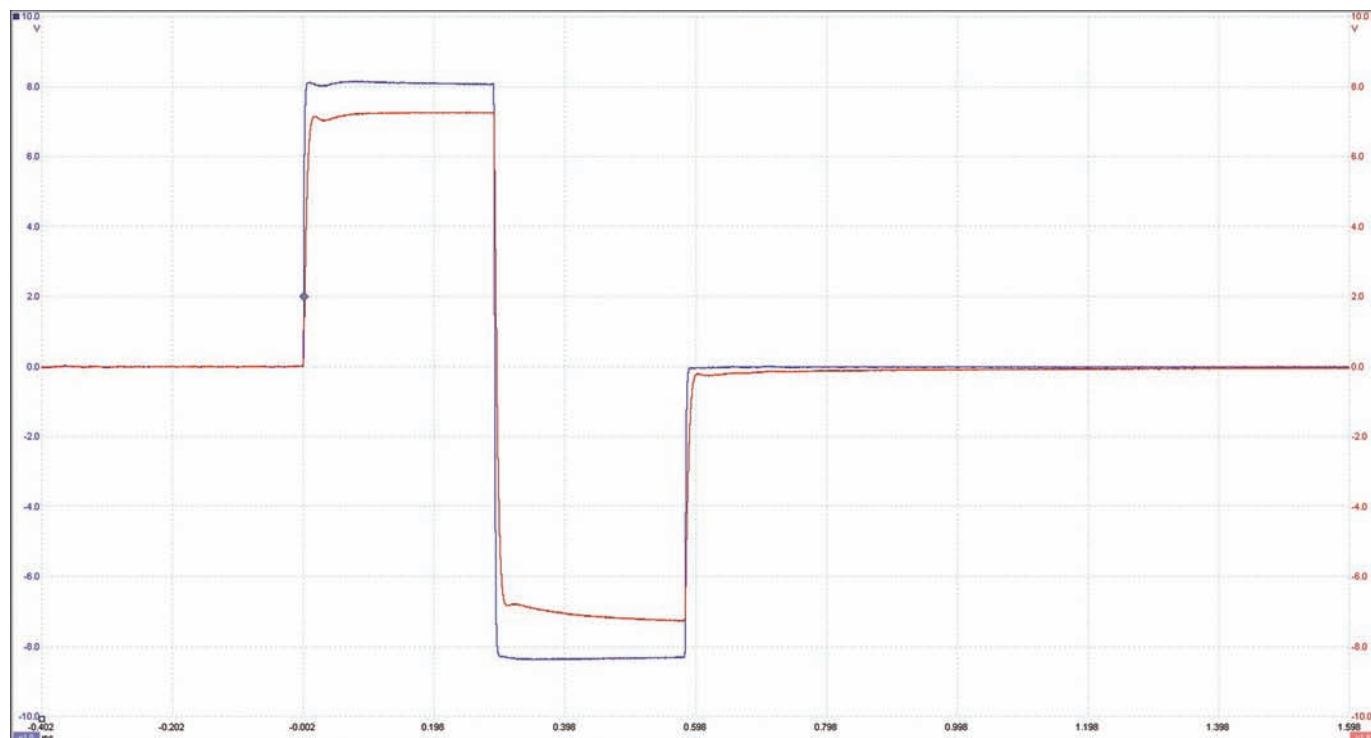


Figure 6 This figure was recorded from a PC-based oscilloscope in exactly the same way as that in figure 5. In this case a device that produces a fully charge-balanced waveform was used.

and liquefaction of proteins. Positive charge at the anode results in an acidic environment and coagulation of proteins.⁶

So if it is well recognised that DC causes tissue damage, why are modern EA and transcutaneous electrical nerve stimulation (TENS) devices not all designed with charge-balanced bipolar waveforms? Perhaps it is because this problem rarely becomes apparent in practice at normal or average stimulation intensities and durations.

The waveform of the stimulator concerned had been analysed by the author prior to this adverse event (see figure 5). As the waveform was not charge-balanced (see figure 6, which illustrates a charge-balanced waveform), the manufacturers were contacted and asked specifically about this. A representative of the company sent details of the 'skin protection system' used in the device. This system was developed for their TENS stimulators some 20 years ago. It involves the device actively making an internal short circuit between the anode and cathode following every monopolar impulse. This was

designed to prevent any excess accumulation of charge, and minimise or eliminate the skin irritation that could be associated with prolonged use of TENS.

Figures 5 and 6 show the output of two different devices that were recorded with a PC-based oscilloscope (3425 Picoscope; Pico Technology, St Neots, Cambridgeshire, UK: <http://www.picotech.com/address.html#contact>) in a similar way to that described in a previous paper.⁷ The blue tracing records the output of one channel of the device connected across a 1 k Ω resistor, and the red tracing records the output of another channel of the same device connected across needles embedded in the author's tibialis anterior muscle in the region of the acupuncture points ST36 and *Zongping*. The red tracing in figure 5 shows a baseline shift of just less than 1 V, and a large deflection from the baseline voltage followed by two smaller deflections of the opposite polarity. The author's interpretation of this is that the 'skin protection system' does not fully compensate for the presence of a charge-imbalanced waveform.

SUMMARY

In this case report, minor tissue damage occurred apparently as a result of high intensity (20 mA) EA for 30 min with a device that produced a predominantly monophasic waveform. Numerous previous treatment sessions of similar intensity and length, using balanced biphasic waveforms had not produced any detectable tissue damage. Manufacturers should be encouraged to develop EA stimulators that use charge-balanced waveforms.

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Acknowledgements The author is grateful to Professor Thomas Lundeborg and Professor John W Thompson for their helpful comments on this case report.

Competing interests None.

Patient consent Obtained.

Ethics approval Not required as it is a case report from routine clinical practice.

Provenance and peer review Not commissioned; internally peer reviewed.

Accepted 11 April 2011

Acupunct Med 2011;**29**:147–151.
doi:10.1136/acupmed-2011-010020

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