Acupuncture in Medicine

SAFETY ANALYSIS OF PERCUTANEOUS NEEDLE ELECTROLYSIS: A STUDY OF NEEDLE COMPOSITION, MORPHOLOGY AND ELECTRIC RESISTANCE

Journal:	*Acupuncture in Medicine*
Manuscript ID	acupmed-2019-012239.R2
Article Type:	Original paper
Date Submitted by the Author:	n/a
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Keywords:	Electrical stimulation therapy < ACUPUNCTURE, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA, Musculoskeletal < PHYSIOTHERAPY
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Safety analysis of percutaneous needle electrolysis: A study of needle composition, morphology and electrical resistance

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Manuscript Word count (includes main text, references, acknowledgements and figure legends): 3484

Abstract word count: 250

Number of references: 10

Number of Tables: 2

Number of illustrations: 3

Keywords: PNE; percutaneous needle electrolysis; solid needles; electrical resistance; electrolytic ablation.

ABSTRACT

Introduction: Percutaneous needle electrolysis consists in a galvanic current combined with the insertion of a solid needle in the tissues of the musculoskeletal system. The application of a galvanic current through a needle can alter the morphology and composition during treatment application. This procedure may also provoke a localized temperature increase.

Aims: To evaluate the safety of the percutaneous needle electrolysis procedure by analyzing possible alterations to the needles employed.

Material and methods: Physio Invasiva® and AguPunt EPI® brands needles, a commonly used brand of needles for the application of this technique, were analyzed in response to three different treatment protocols. Temperature changes were evaluated with the needles immersed in a test tube containing Ringer's solution, electric resistance was evaluated with a multimeter, the morphology of the needles, pre and post treatment, was examined with a scanning electron microscope (FEI Quanta 600) and the composition of the needles were evaluated using RX diffusion with Oxford Instruments Software, Inca.

Results: The Ringer's solution contained in the test tubes examined did not present temperature changes. No changes were observed in the needles under study regarding electric resistance nor morphology or composition with the 3 mA, three seconds and three applications protocol. However, important morphological alterations were observed which affected needle composition in the 50 applications protocol.

Conclusions: Percutaneous needle electrolysis, applied according to conventional protocols, is a safe, athermal in an in vitro test procedure which does not provoke a loss of metal particles nor modify the morphology of the needles used.

INTRODUCTION

Percutaneous needle electrolysis (PNE) is an invasive physical therapy technique that consists of the application of a galvanic current through an acupuncture needle. This technique produces an analgesic effect on the musculoskeletal soft tissue, triggering a local inflammatory process, which enables phagocytosis and the repair of the affected tissue [1].

In surgery, galvanic currents are used for "electrolytic ablation". This procedure draws upon an important increase in temperature in order to perform surgical resections, together with cauterization, using a high amperage and duration [2, 3]. Current protocols for PNE [4] use lower intensities and are considered athermic. However, this hypothesis has not been confirmed. The increase in local temperature found in a small caliber needle could potentially place the integrity of the tissue at risk.

Additionally, the study of the elements that comprise the acupuncture needle, as well as the effects of galvanic currents on these needles during their therapeutic use, has received greater attention as the popularity of these treatments has increased. Several studies have reported the clinical use of needles with manufacturing malformations. For example, Hayhoe et al. [5] described important alterations affecting the tips of acupuncture needles. More recently, Xie et al. conducted a study that highlighted the deformed appearance of acupuncture needle tips using an electron microscope, prior to their use [6]. In direct relation to the use of galvanic currents, Hwang et al. [7] described the major corrosion of needles used during the application of currents plus an accumulation of metallic components in the tissue treated. This would imply that the repeated use of a galvanic current in certain areas could leave undesirable metallic residue with unknown consequences. Moreover, a loss of needle substance could decrease the needle diameter, thus increasing resistance and generating heat. In recent years, needle quality and design have notably improved; however, no study has reevaluated the needles that are clinically used.

The aim of the present study was to evaluate the safety of PNE based on the analysis of an animal and human model of electrical resistance, measuring temperature changes and the morphology of the needles used during the procedure.

METHODS

Description of the sample

Needles used on humans were obtained post-treatment from the MVClinic in Madrid and the BRUMA Clinic in Tarragona (Spain).

A study on animals was performed at the Unit of Histology and Neurobiology (UHN) of the Faculty of Medicine and Health Sciences of Rovira i Virgili University in Reus, Spain. Experiments were performed in 35 adult young male Swiss mice of 45 to 50 days postnatal age (Charles River, L'Arbresle, France). The mice were treated according to the regulations established by the Directive of the Council of the European Community in November 1986 (86/609/EEC) for the manipulation of laboratory animals. These mice were anesthetized with 0.7 ml of intraperitoneal tribromoethanol (TBE 2%: 2 g tribromoethanol in 100 ml of distilled water). To confirm that the mouse was sedated, ocular and plantar reflexes were assessed.

Possible alterations of needles were examined after the application of PNE based on the most common clinical treatment protocols, as described by Valera & Minaya [4], together with the application of more extreme parameters, in an attempt to fully test the needle integrity. The parameters analyzed were intensity, time (in seconds) and the number of repetitions. These were described by three numerical values in the same order (for example, 3 mA for three seconds and three repetitions, i.e. 3:3:3) [4].

The device used to generate the galvanic current percutaneously in all experiments was the Physio Invasiva® CE0120 (PRIM Physio, Spain). The needles used were of the Physio Invasiva® and AguPunt EPI® brands.

Electrical resistance

The study was performed using Physio Invasiva® needles (141002 and 160101) and AguPunt EPI® needles (181106 and 180927) measuring 0.30 mm in width and 40 mm in length. The resistance was evaluated with a Velleman DVM92 Digital Multi Voltimeter (Velleman NV, Gavere, Belgium). Twenty needles were randomly selected and PNE was performed with the immobilized anesthetized mouse placed in a prone position. After removing hair from both the posterior and the lateral insertion area of the rear limbs, a needle was inserted into the right gastrocnemius (stimulus) and the left gastrocnemius (control) (Figure 1). The application parameters were 3:3:3 with a one minute rest period in between. For each needle, the resistance of the proximal (non-inserted) portion was evaluated together with the distal (inserted) portion and the percentage variation between the data was calculated (Figure 1.A).

Temperature

This study was performed using Physio Invasiva® needles measuring 0.35 in diameter and 100 mm in length (181123 and 170512) immersed in Ringer's saline solution (composition in mM: NaCl 135, KCl 5, $CaCl_2$ 2.5, $MgSO_4$ 1, NaH_2PO_4 1, $NaHCO_3$ 15, glucose 11). Temperature was evaluated using the TMP 812 digital thermometer (Letica, Barcelona, Spain). The temperature and relative humidity of the room where these experiments were carried out were controlled at 26ºC and 50% respectively. The anode needle and the cathode needle were inserted into a test tube containing 10ml of Ringer saline solution (Figures 2), into which the digital temperature sensor was also introduced. Then a protocol of electrical currents were applied and the maximum temperature obtained was recorded. This procedure was repeated in five test tubes for each protocol studied. Five anode needles were randomly selected for each experimental series. The protocols employed were: 3mA for three seconds and three applications (3:3:3); 3mA for 60 seconds and three applications (3:60:3) and 3mA for 60 seconds and seven applications (3:60:7). During all protocols, a one minute rest period was observed between applications.

Scanning electron microscopy and microanalysis

Needles of 0.30mm in diameter and 40mm in length were used (Physio Invasiva® and AguPunt EPI®). The needles studied were randomly selected from different product batches (Physio Invasiva® 141002, 160101 and 180722; AguPunt EPI® 181106 and 180927). The protocol of electrical currents used in patients was the usual one in the clinics that provided the needles. Each needle belonged to a different patient treated with electrical current. In order to determine that the protocols commonly used in patients are safe and far from those that are dangerous, first, we repeated that protocol in mice (Figure 1) and then we increased the number of applications until obtaining the loss of metals which were detected by microanalysis. The protocols used were:

- Protocol 1: 3mA for three seconds and three applications (3:3:3). We studiedPhysio Invasiva® needles used in human patients [from the BRUMA Center in Tarragona (six needles) and from MVClinic in Madrid (nine needles)] and from the UHN laboratory (10 needles) after their use in animals.
- Protocol 2: 3mA for three seconds and 10 applications (3:3:10). Five needles were evaluated in animals.
- Protocol 3, 3mA for three seconds and 50 applications (3:3:50). Five needles were evaluated in animals.

The scanning electron microscope used was FEI Quanta 600 with a microanalysis device by diffusion (RX Oxford Instruments, Inc.) of the Technical Scientific Service of the Rovira i Virgili University. The magnification settings were 2000X.

For each needle, the morphology was studied and microanalysis was performed comparing the tip (which had been inserted into the tissue) with the area close to the handle (which had remained external).

The needles studied had been used during the treatment of the gastrocnemius muscles of humans and mice. The application of the galvanic current in humans was performed by inserting the cathode (needle) within the muscle tissue to be treated, whereas the anode remained external and was held in the hand of the patient. In the case of the study in mice, the cathode was inserted inside the muscle bundle behind the right leg of the mouse (1 cm) and the anode was inserted subcutaneously in the mouse's back (Figure 1.A). In addition, a control needle was inserted into the left leg (not receiving galvanic current).

Statistical analysis

The Statistical Package for the Social Sciences (SPSS)s version 17.0.1 (SPSS Inc., Chicago, IL, USA) was used to analyze the results. The values were expressed as the mean ± SD. To evaluate differences within groups the Student's t-test was used. The differences were considered significant at $P < 0.05$.

RESULTS

Electrical resistance: Twenty needles were evaluated with the 3:3:3 protocol. For each needle, the resistance of the distal portion was determined, which was inserted into the animal, and the resistance of the proximal portion was assessed as a control. No change in the proximal-distal resistance was observed (% of mean variance: Physio Invasiva®, 0.40 ± 3.33; AguPunt EPI®, 0.16 ± 0.01; $P > 0.05$ in both cases). Therefore, the use of the galvanic current employed in PNE does not alter the electrical properties of the needle.

Temperature: Five needles were evaluated, in five different test tubes for each protocol. Table 2 shows the values of the temperature expressed in ºC before and after applying different electrical current protocols. In protocol 3:3:3, no temperature variance was observed (% of mean variance: 0.4 ± 1.2, $P > 0.05$). Neither was any variance observed applying 3:60:3 (% of mean variance: 0.0 ± 0.0 $P > 0.05$). In the most aggressive protocol: 3:60:7, no temperature variance was observed (% of mean variance: 0.0 ± 0.1 $P > 0.05$).

Morphology and composition of needles after use: A study of the morphology of the needles exposed to the galvanic current in human muscle tissue and in mice revealed the following : with protocol 3:3:3 (protocol 1), no relevant structural changes were observed in any of the needles studied. Figure 3 displays examples showing how the needle tips (part exposed to the muscle tissue, figures 3.A and 3.B) do not show any ultrastructural changes. The impurities that can be observed on the surface are cells and metal shavings from manufacturing, as observed in a previous study [9]. Figures 3.C and 3.D correspond to the protocol 3mA during three seconds and 10 applications, displaying similar results with those obtained in protocol 1, despite the greater number of repetitions. As no alteration was obtained, an excessive protocol of 50 repetitions was applied in protocol 3 (3mA during three seconds and 50 applications), in which an alteration of the needle morphology was observed, presenting erosions and cavities (Figures 3.E and 3.F). These changes were found in the two brands of needles tested.

The metal composition of the needles was evaluated using microanalysis. The most common metals used were chromium, iron, nickel and manganese. To rule out the possibility of the metal from the needles remaining and attached to the treated tissues, the quantity of the metals present in the inserted part of the needle was measured and compared with the external part of the needle. Table 1 shows that there was no loss of any of the metals in the needles exposed to protocol 3:3:3. However, in Physio Invasiva® needles exposed to 10 repetitions of

3mA during three seconds, a non-significant loss of iron and nickel was observed. By increasing the repetitions of 3mA currents up to 50 during three seconds, statistically significant losses of all metals were obtained on both brands of needles tested.

DISCUSSION

This study has examined the needles used in clinical practice for the application of galvanic currents using the technique known as percutaneous needle electrolysis [4]. This is the first study to analyze the safety of the application of percutaneous needle electrolysis based on the analysis of the needles used in the technique.

Historically, galvanic currents have been used in surgery to provoke thermal ablation. Thus, for example, in pioneering studies based on electrolytic ablation of hepatic tumors, not only is the surgical action described, but also reports have focused on the beneficial actions related to the revascularization of the hepatic tissue or the ability to influence the inflammatory reaction [2, 3]. The thermal cauterizing action of these treatments require a very high amperage (60-80mA), which is also prolonged over extremely long periods of time (20-35 min). It is important to note that, in this study, the parameters were very low, both regarding amperage (approximately 2500 times lower than those of other authors as reported by Finch et al. –[3]-), as well as the periods of time of continuous application (approximately 3000 times lower than those of other authors as reported by Wemyss-Holden et al. -[2]-). These justify the observation that treatment with galvanic current has been entirely athermal in an in vitro test. The examination of the change in resistance of the needles due to the application of a galvanic current indicated a null variation between the inserted portion and the non-inserted or external portion of the needle. This explains the lack of temperature change, and according to the ohm behavior or the resistance of the materials, an increased resistance implies a near proportional increase in temperature [10].

In the scientific literature available on this subject, several studies described the existence of needles with manufacturing defects. For example, Hayhoe et al. [5] and Xieet al. [6] described a wide variety of alterations in the tips of acupuncture needles before use of the same. In the present study, no manufacturing imperfections were observed on any of the needles. This finding was recently reported elsewhere [9]: the manufacturers of needles have notably improved the quality of the same in recent years. Hwang et al. [7] evaluated needles post treatment with electrical currents and found considerable corrosion of the needles after their use. The same study also demonstrated the accumulation of metallic substances in a gelatin model used to practice acupuncture techniques. These authors used two protocols, one of 2 Hz at 0.05 mA, and another of 10 Hz, 1 mA, both used over a notably long time period (30 minutes). Similarly, Lee et al. [8], using another type of needles, also found deterioration to the surface of needles. It seems obvious that the 3mA of the present study, with a far shorter duration of stimulus, does not generate any variation, neither structural nor of loss of

materials. In contrast, when the 3mA, 3 second protocol is repeated for a notably higher number of times, this produces important structural alterations. Apparently, the loss of metals visible by electronic microscopy should be greater in the study of microanalysis using this latter protocol. The microanalysis performed by scanning electron microscopy shows the proportion of metals on the surface of the needles. Thus, the loss observed in this last protocol indicates that all the metals have remained within the tissues of the mouse to a similar degree regardless of the brand of needle used.

CONCLUSIONS

Percutaneous needle electrolysis applied according to conventional protocols is a safe procedure. The use of galvanic current does not produce local thermal alteration in an in vitro test, neither does it alter the electric properties of the needle, nor do the needles lose metals or modify their morphology during use. However, if the parameters are abusive, an alteration of the needle and a potential risk occurring is possible.

Acknowledgements: The authors wish to thank Dra. Mariana Stankova, from the Service of Scientific and Technical Resources of the URV for her crucial technical guidance regarding the scanning electron microscope. Furthermore, we are grateful to PRIM Physio, who have generously provided the needles and the Physio Invasiva® device for the generation of the galvanic currents used in this study. Special thanks also to the BRUMA center in Tarragona for kindly providing part of the needles used in their daily practice.

Funding. The authors received no financial support for the research, authorship, and publication of this article.

Declaration of conflicting interests: The authors declare that there is no conflict of interest.

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TABLE

Table 1. Analysis of needle composition.

Protocol [1]	Origin of Needles	Brand of Needles	Cr	Fe	Ni	Mn
3:03:03	Patients	Physio Invasiva®	1.1 ± 1.7	1.0 ± 1.6	2.1 ± 1.9	5.3 ± 7.7
3:03:03	Mice	Physio Invasiva®	2.5 ± 1.0	2.8 ± 1.5	1.4 ± 1.5	0.0 ± 0.0
		AguPunt EPI®	4.6 ± 1.5	2.8 ± 1.1	5.7 ± 1.4	3.9 ± 1.6
3:03:10	Mice	Physio Invasiva®	2.1 ± 2.1	5.8 ± 1.8	17.5 ± 7.2	11.9 ± 10.1
		AguPunt EPI®	6.1 ± 1.5	6.1 ± 1.3	4.0 ± 2.6	2.1 ± 0.1
3:03:50	Mice	Physio Invasiva®	19.3 ± 1.1*	13.5 ± 0.8*	16.5 ± 2.0*	0.0 ± 0.0
		AguPunt EPI®	18.8 ± 0.4*	16.4 ± 1.5*	22.3 ± 1.4*	2.03 ± 1.8

The results show the % variation between the portions inserted into the biological tissues and the most distal, non-inserted area (see Figures 1.A and 2.A). The needles used in patients were provided by the centers MV-Clinic in Madrid and Bruma in Tarragona. Each needle belongs to a different patient treated with electrical currents. The results are expressed as mean ± standard deviation.*, $P < 0.05$.Cr: chrome, Fe: iron, Ni: nickel, Mn: manganese. [1]Protocol (intensity: time in seconds: number of repetitions)

Table 2. Temperature study in vitro after three different electrical current protocols

Protocol[1]	Before	After
3:03:03	26.11 ± 0.40	26.21 ± 0.10
3:60:03	25.62 ± 0.43	25.62 ± 0.43
3:60:07	25.33 ± 0.25	25.33 ± 0.26

The values of the temperature expressed in ºC before and after applying different electric current protocols used for percutaneous electrolysis are shown. The needles were inserted into the test tubes in a laboratory rack, separated from each other and connected to the device (see Figures 1.B and 2B). The results are expressed as mean ± standard deviation. [1]Protocol (intensity: time in seconds: number of repetitions).

FIGURE LEGENDS

Figure 1. Application of percutaneous needle electrolysis in the mouse. 1.A. Some experiments have been done by inserting needles into mouse gastrocnemius muscle. Then electric currents have been applied. By removing the needles, two parts are obtained: one that has been inserted into the animal and the other non-inserted. Then, the inserted part and the non-inserted part have been evaluated: the electrical resistance and microanalysis of the metal composition. **1.B.** Photograph showing how needles are inserted into a mouse to apply electric currents. The cathode is inserted in the posterior muscle bundle of the mouse's right leg (1) and the anode is inserted subcutaneously at the back of the same animal (2), More so, a needle is inserted in the left leg (3) acting as a control (without receiving galvanic current).

Figure 2. Temperature study in response to percutaneous needle electrolysis. 2.A. The temperature has been determined in vitro. The temperature and relative humidity of the room where these experiments have been carried out have been controlled. The anode needle and the cathode needle have been inserted into a test tube containing 10ml of Ringer saline solution. In the same test tube the digital temperature sensor has been introduced. Then a protocol of electric currents has been applied and the maximum temperature obtained recorded. This procedure has been repeated in 5 test tubes for each protocol studied. **2.B.** Photograph showing how in vitro electric currents are applied.. The needles were inserted into the test tubes in a laboratory rack, separated from each other and connected to the device. Photography shows an example. The anode and the cathode are placed in the same test tube, immersed in Ringer's solution and connected to the galvanic current generator.

Figure 3. Examples of needles used in different percutaneous needle electrolysis protocols. Two types of needles have been tested, Physio Invasiva® (Figures A, C, E) and AguPunt EPI® (Figures B, D F). The protocol used was 3mA during 3 seconds and 3 repetitions (figures A and B), 10 repetitions (figures C and D) and 50 repetitions (figures E and F). Note that only in the situation of repeating the application 50 times, was an alteration of the morphology of the needle tip obtained. Initial magnification is 200x.

FIGURE 1

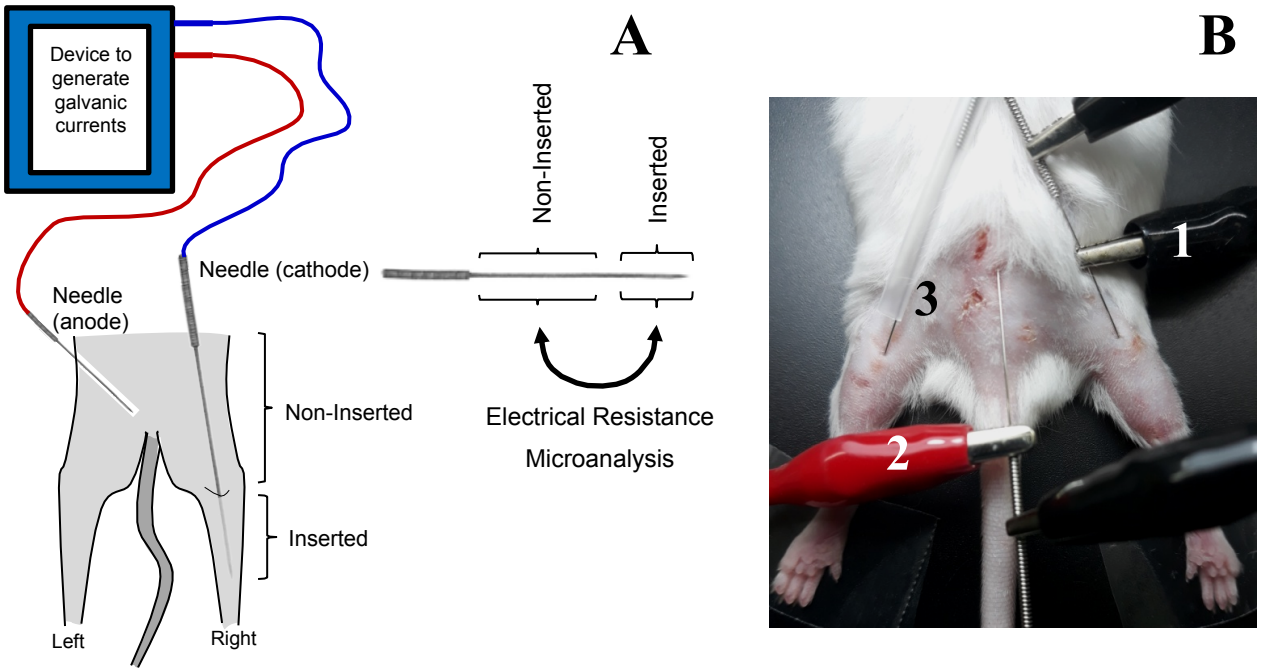
A
B
Device to generate galvanic currents
Needle (cathode)
Needle (anode)
Non-Inserted
Inserted
Left
Right
Non-Inserted
Inserted
Electrical Resistance Microanalysis
1
2
3

FIGURE 2

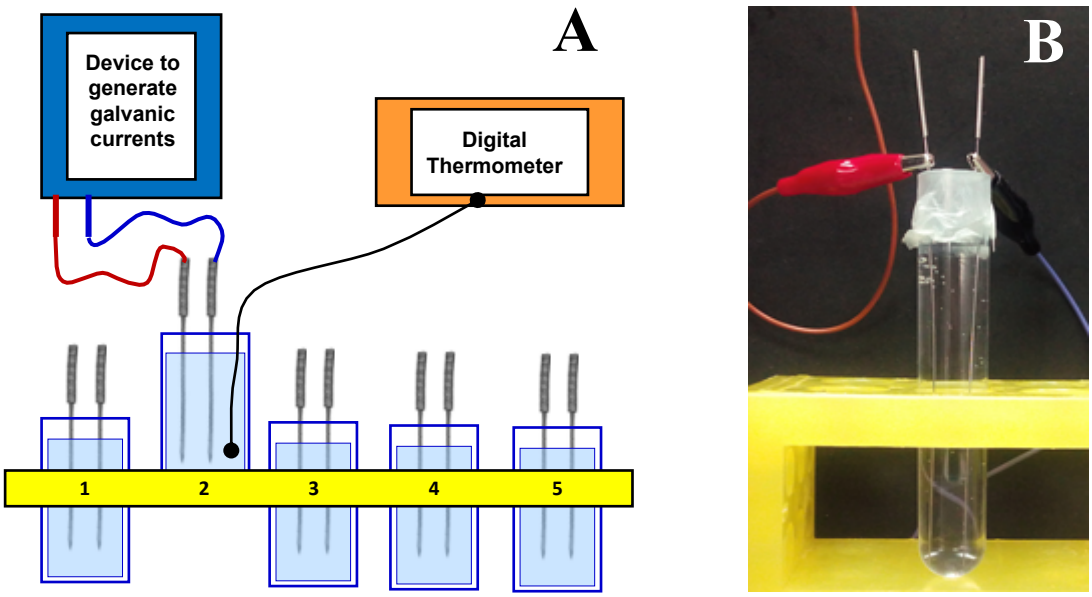
A
Device to generate galvanic currents
Digital Thermometer
1
2
3
4
5
B

FIGURE 3