Title: Case Series for Microcurrent Therapy in Autism Spectrum Disorder: Evidence for Symptom Reduction and Dose-Response Relationship

Abstract

Background: Microcurrent therapy (MCT) is an emerging field within medicine and its potential effect on autism spectrum disorder has yet to be fully explored.

Aims: Our goal was to analyze the results of a pilot study of autism spectrum disorder (ASD) patients who received MCT to guide a larger clinical trial.

Methods and Procedures: This is a pilot study of 21 pediatric patients and 1 adult with ASD who received MCT using a standardized protocol. The Autism Treatment Evaluation Checklist (ATEC) pre- and post-MCT was used to assess changes in behavior. A paired t-test compared pre- and post-MCT ATEC scores. An unpaired t-test compared MCT ATEC scored with aged-matched historical control ATEC scores. Linear regression was used to determine dose response.

Outcomes and Results: There were no serious side effects, and the therapy was well tolerated. 22 patients completed 32 sessions on average. In paired t-testing, MCT produced a statistically significant average decrease of 28.6 (42.8%) on ATEC ($p = 0.007$; 95% CI = 8.3-48.9). In unpaired t-testing comparing MCT with age-matched historical controls, the treatment group average improvement was 26.4 (42.6%), compared to aged-matched controls of 7.9 (13.2%) ($p=0.0001$; 95% CI 19.9 - 47.5). There is a strong direct relationship between the number of microcurrent sessions and magnitude of improvement $R = 0.693$; $F = 18.5$; $P = 0.0003$; CI: 95%.

Conclusion and Implications: This pilot study provides initial evidence that microcurrents offer a therapeutic effect on ASD given the pre- and post-therapy improvement compared to historical controls and dose-dependent response.

What This Paper Adds

This paper is the first and largest case series of MCT effect on ASD. It shows preliminary evidence that MCT is effective in treating some ASD symptoms when compared to historical controls.

1. Introduction

The purpose of this study is to explore the utility of microcurrent therapy (MCT) to treat symptoms of autism spectrum disorder (ASD). Microcurrent therapy uses low levels of electrical current to interact with the body at the cellular level, speeding up ATP production and waste removal. Additionally, when applied to the head, the frequency at which the current is delivered creates an electrical pattern that brainwaves will naturally align with. Thus, encouraging the brain to use those frequencies independently after repeated exposure.

Modern MCT has proven to have broad clinical applications which first started in the 1960s with their therapeutic effects on skin ulcers[1], wound healing[2] and non-union fractures[3]. It eventually became an effective physical therapy tool to increase circulation, reduce inflammation consequently decrease pain.[4] It has potential therapeutic effects in facial rejuvenation[5],

lymphedema[6], and muscle recovery.[7] The scientific community is still exploring the full therapeutic application of MCT.

The protocol was developed from a literature review of ASD electroencephalogram (EEG) patterns. Compared with normal controls, ASD children exhibit alpha waves less often, with decreased power, and have less ability to maintain alpha and more delta and theta activity when compared to typically developing children.[8-12] They also have higher relative beta and gamma frequencies compared to normal controls.[13,14] This has led to the "U" shape to express high delta, theta, beta, gamma and low prevalence of alpha. Whereas normally developing children are described as expressing a "∩" shape where the middle frequency (alpha) is most common and the slower and faster frequencies in an alpha rhythm most often, with less prevalence of slow and fast frequencies.

The theory behind this protocol is to reestablish the alpha rhythm prevalence and decrease the prevalence of delta, theta, beta and gamma. To that end, the protocol developed for this trial focused on the supporting and reinforcing alpha wavelength through brainwave modulation. The Intelligent Bioenergetic's microcurrent protocols were used as a basis to develop the systemic protocols used in this study to encourage full-body detoxification and optimization of the digestive, lymphatic, and peripheral nervous systems. These protocols were included in the program due to the high number of comorbid issues like digestive dysfunction, sensory processing disorders, and sensitivities to foods, smells, and other common environmental substances seen within the ASD population.

The Autism Treatment Evaluation Checklist (ATEC) single page assessment questionnaire usually completed the parent or caregiver.[15] It consists of four categories; Speech/Language/Communication, Sociability, Sensory/Cognitive Awareness, Health/Physical

Behavior, which gives a score 0-180. A higher score correlates with degree of impairment and severity of symptoms. A lower score means more normal function and less severe symptoms. The ATEC can then be used in serial assessments to estimate the therapeutic effect of a given treatment.

2. Material and methods

2.1 Study Protocol

This was a non-randomized, open-label pilot study using the Intelligent Bioenergetic Electro-Equiscope MCT device on 21 children and 1 adult age 3-32 with ASD enrolled between 2014 and 2023. Inclusion criteria required an existing diagnosis of ASD from a physician and parental consent. Exclusion criteria were children who did not have the patience to tolerate the duration of a full MCT session. Comorbidities and medications were not used as exclusion criteria. All MCT sessions took place in the Microcurrent4Kids Health Clinic in San Diego, CA. For all patients, therapeutic response was assessed by comparing ATEC scores of pre- and post-treatment disease severity. ATEC was filled out by the parent during the first day starting the protocol and on the last day ending the protocol. The exact protocol descriptions were developed by the study lead author, and their exact protocol is detailed in the appendix. In general, this study used 4 different MCT protocols of the Electro-Equiscope device. The Headband Protocol directed MCT toward the head. The Systemic: Bilateral Spinal Protocol directed MCT toward the bilateral vertebral areas along the spine. The Systemic: Intestinal/Partial Lymph Drainage Protocol directed MCT toward the abdomen and major lymphatic vessels. The Systemic: Governing Vessel Protocol directed MCT toward the upper spine and head.

The schedule of events for most patients was three sessions per week for 12 weeks with a total of 24 headband sessions, 4 bilateral spine sessions, 4 Intestine/lymph sessions and 4 Governing vessel sessions. Although there were some cases of shortened or extended treatment courses. Of note, patient 17 received all 12 sessions within 1 week. The follow up ATEC evaluation was given on the last session, which was not standardized, which offered a confounding variable.

We used the STROBE guidelines to write this article.[16]

2.2 Statistical Analysis

We used independent samples t-test to show statistically meaningful differences in treatment response between pre- and post-treatment ATEC scores. We used unpaired t-test to compare aged-matched historical controls taken from a study by Mahapatra, et al. 2018.[17] That study was specifically developed serve as a resource for aged-matched historical controls in ASD research. It served as an ATEC "growth chart" which tracked the year-to-year decrease in ATEC scores in 2,649 children who received "treatment as usual". However, it only included ages 2-12 and therefore we were only able to compare 14 treated patients against aged-matched historical control. A likely confounder the interval time between initial ATEC score and follow up. The treatment group interval time was typically weeks to months, which was much shorter than the control group of one year between ATEC evaluations.

Linear regression modeling was used to investigate the relationship between treatment response and the number of MCT sessions, gender differences in treatment response, and age differences in treatment response.

3. Results

3.1 Pre- and Post-treatment Analysis

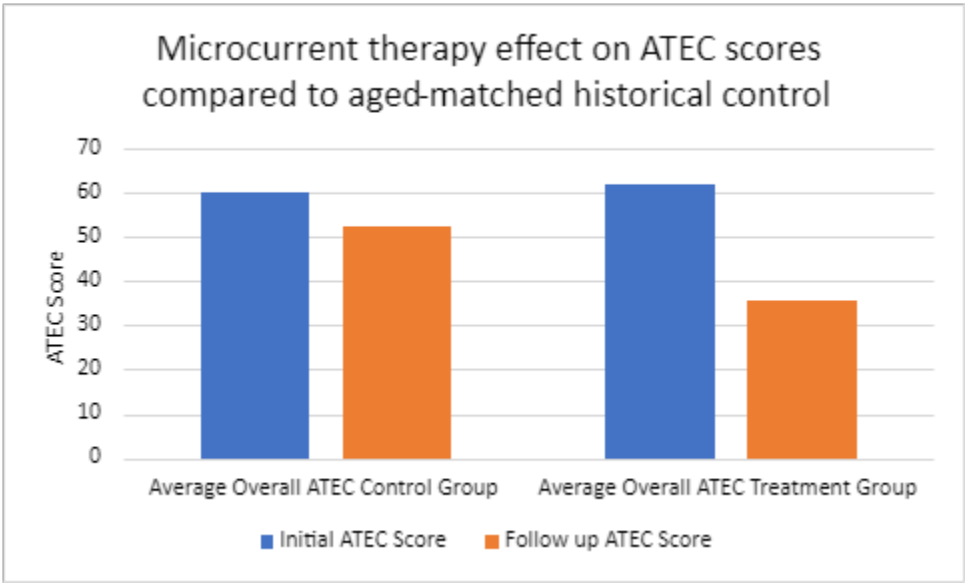
In this non-randomized, open-label pilot study using the Intelligent Bioenergetic Electro-Equiscope MCT there were no serious side effects, and the therapy was well tolerated. The number of potentially eligible individuals was not recorded. The cohort was composed of 21 children aged 3-17 (average age 8.8) and 1 adult aged 32. Males were 18/22 patients. 22 patients completed an average of 32 sessions with a range of 12-72 sessions. On average, there was a 28.6 (42.8%) overall improvement in ATEC ratings ($p = 0.0001$; 95% CI = 20.5 - 36.7) as described in table 1. Average improvements in subcategories within ATEC were Social Awareness = 7.0 (43.2%) ($p=0.0001$; 95% CI=4.6 - 9.3); Sensory/cognition = 6.8 (44.5%) ($p=0.0001$; 95% CI=4.6 - 8.9); Expressive Communication = 3.6 (32.5%) ($p=0.0001$; 95% CI=2.2 - 5.0); Self-care = 11.2 (46.2%) ($p=0.0001$; 95% CI= 7.5 - 14.8). The overall improvement ranged from 9.3% to 91.3%.

Table 1: Average Pre- and Post-treatment AHEC scores reported in overall

Category (N=22)	Pre	Post	Difference	Improved (%)	P-value	95% Confidence Interval
Social Awareness	16.1	9.1	7.0	43.2	0.0001	4.57 to 9.34
Sensory/Cognition	15.3	8.5	6.8	44.5	0.0001	4.65 to 8.99
Expressive Communication	11.2	7.5	3.6	32.5	0.0001	2.20 to 5.07
Self-Care	24.2	13	11.2	46.2	0.0001	7.54 to 14.82
Overall	66.8	38.2	28.6	42.8	0.0001	20.51 to 36.67

3.2 Historical Control Analysis

The overall ATEC score of 14 treated patients aged 3-10 were compared with the overall ATEC score of aged-matched historical controls. The treatment group average improvement was 26.4 (42.6%), compared to aged-matched controls of 7.9 (13.2%) (p=0.0001; 95% CI 19.9 - 47.5) shown in graph 1. Overall ATEC score on initial and follow up assessment for treated group was 61.9 and 35.5 compared to control of 60.3 and 52.4, respectively. The 14 treated patients received an average of 31.4 sessions over 72.3 days between initial ATEC score and follow up. Control group averaged 1 year between ATEC scores.

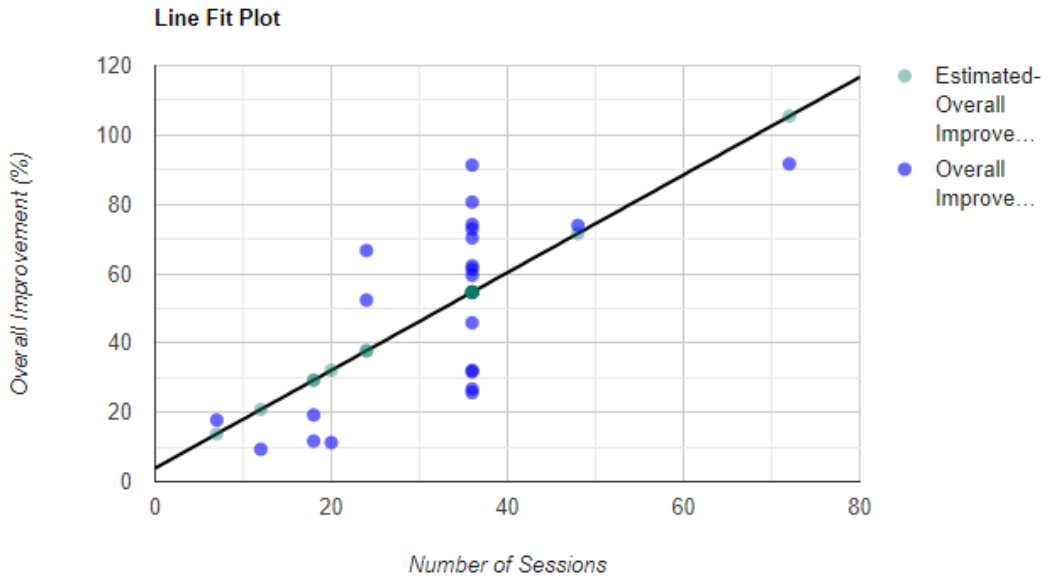


Graph 1: Chart comparing MCT-treatment group with historical aged-matched controls.

3.3 Dose-dependent response and ancillary analyses

There was a very strong direct relationship between the number of microcurrent sessions and magnitude of improvement shown in graph 2; Correlation (R) = 0.693; F = 18.48; (p= 0.0003; CI: 95%). There was a very weak inverse relationship between age and response to treatment; R = -0.05; F = 0.06 (p=0.81; CI 95%). There was a statistically significant difference in therapeutic

response between males and females. Unpaired t test average male and female overall improved by 43.6% and 76.1%, respectively (p = 0.0262; 95% CI = 4.3 - 60.9). Though there was a small female population n = 4. There was not a statistically significant difference in number of sessions completed between sexes (p=0.6; 95% CI = –11.15 to 20.15). It was anticipated that starting treatment at an earlier age would lead to better treatment response, however, there was a very weak inverse relationship between age and treatment response.



Graph 2: Linear regression model with best fit line correlating overall improvement (%) of AHEC scores pre/post MTC and the number of MCT sessions received.

4. Discussion

4.1 Study considerations and Limitations

This non-randomized, open-label trial using the Intelligent Bioenergetic Electro-Equiscope MCT was the largest published clinical trial of MCT effect on ASD with 22 patients. These results are encouraging and warrant further investigation. The therapeutic effect over the

historical control was statically significant and the clear dose-dependent treatment response was highly suggestive that MCT has a real therapeutic effect on ASD.

The time between ATEC scores was greater in historical control than in the treatment group, and there is a normal decrease in ATEC score as a child grows and receives standard therapies. Therefore, the difference between control and treatment groups is likely greater than documented, because the shorter time window did not allow for the full reduction in ATEC score from year to year. Another limitation with the historical control was that we were not able to use the entire treatment cohort to compare with historical controls because there were no historical controls for eight of the patients. Yet, the treatment effect size within that 14-patient cohort was about the same as the 22-person cohort.

This study had a small sample population and was therefore at risk of confounding variables, false positives and limited generalizability. Also, results relied on self-reporting through the ATEC which can subject to recall bias, social desirability bias, and expectations.

4.2 Future Direction and General Thoughts

This pilot study is the first step in determining MCT applicability in ASD. The results here may be used to justify and guide a larger clinical trial. A future study might incorporate the Childhood Autism Rating Scale (CARS) to introduce an inter-rater reliability component between the physician-filled CARS and the parent-filled ATEC. Additionally, adding CARS to the assessment better categorizes changes in specific areas of symptoms, such as social or emotional ability.

General thoughts from the authors will be shared here, given that MCT is an emerging therapy for ASD. The lead author has used MCT in 100-150 cases of ASD – likely the largest cohort of

ASD patients receiving MCT. Anecdotally, MCT has proven to be a well-tolerated and often preferred therapeutic intervention for children with ASD. Most patients appreciate the relaxation benefits and the minimal demands required for participation. Though, initial apprehension is common, and occasional sensory overstimulation during sessions has been observed. This contrasts with traditional therapeutic interventions, which can be more challenging and require more effort to participate. MCT, in this context, can serve as a respite from the constant demands of school, Applied Behavior Analysis (ABA), speech therapy, and other behavioral therapies.

However, MCT should not be considered a stand-alone intervention for ASD. Anecdotal data from the Microcurrent4Kids health clinic shows that developmental gains during and after MCT are notably lower in children who are not concurrently enrolled in other therapies. This suggests that MCT alone may not be sufficient for optimal progress, and other therapies should be encouraged.

It is hypothesized that MCT facilitates increased alpha brainwave activity, which in turn enhances receptivity to new skills and behaviors taught through traditional therapies. Anecdotal reports from therapists and teachers to the clinic note accelerated developmental progress in various domains following the initiation of MCT. This suggests that it may act as an adjunct therapy to potentiate the effects of other interventions.

Further research is warranted to investigate this potential synergistic effect and to determine the optimal combination of therapies for children with ASD. Specifically, randomized controlled trials are needed to assess the efficacy of MCT in conjunction with other established interventions. Additionally, neuroimaging studies could elucidate the underlying neural mechanisms by which MCT may influence brainwave activity and enhance learning in ASD.

5. Funding and Conflicts of Interest

Authors received no funding for this original study. Authors have no conflicts of interest to declare.

Statement: During the preparation of this work the author(s) used Google Gemini Advanced in order to improve readability and language. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

6. Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Appendix

Protocols used for Autism Microcurrent therapy

Headband Protocol

Tools Needed:

- 2 splitter boxes - 2 coil leads - Electrolyte Solution
- 4 1x1 plates - 4 lead wires - Cohesive-flex bandage

Set-up of Local Session to the Head

- Plug coil leads into channel 1 of Mode 1 on the electro-equiscope
- Plug other end of coil leads into each splitter box
- Attach a 1x1 plate to each of the other 4 lead wires, and then plug each wire into the splitter boxes
- Secure band or co-flex around patient's head, along forehead.
- Squeeze enough electrolyte gel onto each 1x1 plate to cover entire surface.

Electrode Placement:

The 2 electrodes from the first splitter box: Place 1 just above **right temple** & place the other above and slightly behind the **right ear**. The next 2 electrodes from the 2nd splitter box: Place 1 just above **left temple** and place the other above, and slightly behind **left ear**. *Ensure that the corresponding electrodes from both splitter boxes are lined up across the head.

** After 2 weeks of therapy change electrode placement. The 2 electrodes from the first splitter box: Place each on forehead just above center of each eyebrow. The next 2 electrodes from the 2nd splitter box: Place each directly behind the first two electrodes on the occipital bone. Ensure that the corresponding electrodes from the splitter boxes are lined up from the front to the back of the head.

Frequencies and Duration

Settings to start with for Mode 1

- Intensity: 25 or 50 depending on client comfort
- Time: Continuous
- Gain: 20

Stimulate with above settings for the corresponding duration.

Frequency	Duration
0.5	3 min
2.5	3 min
5	3 min
10	8 min
20	8 min

10 8 min

Systemic: Bilateral Spinal Protocol

Tools Needed:

- Trigger Probe - Small cup/disposable - Straight lead wire
- Straight lead wire - Electrolyte Solution - Warm, damp washcloths

Set up of Bilateral Spinal

- Plug straight lead into Indifferent Probe and into Mode 2 on the electro-equiscope
- Plug trigger probe into Mode 2
- Squeeze electrolyte into cup
- Place moist washcloths into towel warmer (or likewise)

Frequencies and Duration

Settings on Mode 2	Settings for Mode 1
Intensity: 100	Intensity: 100
Time: 6 seconds	Time: 6 seconds
	Gain: 20+

Stimulate with above settings for the corresponding duration.

Frequency	Duration
0.5	6 sec in each section
2.5	6 sec in each section
5	6 sec in each section
10	6 sec in each section
40	6 sec in each section
10	6 sec in each section

Session Procedure

Have patient lay face down on massage table (or on their stomach propped up on elbows, or on their side). Begin with probes plugged into Mode 2 with above settings. Dip ends of both probes into cup of electrolyte solution. Starting at the base of the coccyx, place probe tips just on each side of the spine (right where the peripheral nerves enter the spinal column). Start device stimulation by pushing trigger on probe. Gently trace probe tips in small lines (about 1 inch long), parallel to spine, for approximately 6 seconds. Then move probes up about 1-2 inches above the first lines, and trace new 1-inch lines further up the spine, again for about six seconds. Reapply electrolyte solution as needed, while you work your way up to the base of the skull, stimulating each small section of the spine for ~6 seconds. When you reach the base of the skull, change the frequency and move back down the spine in the manner described above. Continue until you have traced along the spine for all 6 frequencies. Then switch electro-equiscope to Mode 1, move plugs over to Mode 1 and repeat entire procedure, however ensuring that each

section is “clear” (by stimulating for another 6 seconds as needed) before moving onto the next section of the spine. Then clean electrolyte off of patient’s back with the warm washcloth. Apply sealing cream.

Systemic: Intestine/Partial Lymph Drainage Protocol

Tools Needed:

- Lymph Disc Probe
- Carbon Flex Electrode
- Electrolyte Solution
- Small cup/disposable
- Warm, damp washcloths
- Loose fitting pants

Set up of Intestine/Partial Lymph

• Plug Carbon Flex electrode into mode 1 on the electro-equiscope
• Plug Lymph Disc probe into mode 1
• Squeeze electrolyte into cup
• Place moist washcloths into towel warmer (or likewise)

Frequencies and Duration

Settings to start with for mode 1	Settings to start with for mode 2
Intensity: 100	Intensity: 100
Time: Continuous	Time: Continuous
Gain: Max	

Stimulate with above settings for the corresponding duration.

Frequency	Duration
2.5	3 min
2.5	6 sec in each small section
10	3 min
10	6 sec in each small section
40	3 min
40	6 sec in each small section

Session Procedure

Have patient remove their shirt, or lift it up as high as they are comfortable, and lay face up on massage table. Squeeze a small amount of electrolyte onto the carbon flex electrode and place it in the middle of their low back (often just tucked under the waist band of their pants/shorts). Pour some electrolyte onto the patient’s belly (warming the electrolyte in the towel warmer prior to beginning this protocol is often helpful), and use the lymph disc to slowly spread it around their entire abdomen. Start device stimulation by pushing trigger on probe. Gently trace probe in increasing concentric circles starting at the navel, and once your circles reach the very edges of the abdomen, decrease the size of the circles, re-tracing your way back to the navel. Reapply electrolyte solution as needed, and/or as you move to new areas. Trace a long line down patient’s sternum, always working towards the abdomen. Have patient lift up their arm, and stimulate the armpit. Pulling the disc downwards, and back over the sternum, again, towards the

abdomen. Repeat with the other arm. Tuck the disc of the probe under the waistband of the patient's loose fitting pants, to stimulate both the right and left groin lymph node areas, pulling the probe upwards towards the abdomen. After you have covered all those areas (should take 3 - 5 min) change the time setting to 6 seconds. Stimulate a small area of the abdomen until clear, and then do another small area. Once the entire abdomen reads clear, change the frequency to 10 and the time back to continuous Repeat the entire process for both frequency 10 and 40. Then repeat that process for each frequency on mode 2. Then clean electrolyte off of patient's abdomen, chest, etc. with the warm washcloth. Apply sealing cream.

Systemic: Governing Vessel

Tools Needed:

- Trigger Probe - Indifferent Probe - Electrolyte Solution
- Small cup/disposable - Straight lead wire - Warm, damp washcloths

Set up of Governing Vessel

• Plug straight lead into Indifferent Probe and into mode 2 on the electro-equiscope
• Plug trigger probe into mode 2
• Squeeze electrolyte into cup
• Place moist washcloths into towel warmer (or likewise)

Frequencies and Duration

Settings to start with on mode 2
Intensity: 100
Time: Continuous

Settings to start with for mode 1
Intensity: 100
Time: Continuous
Gain: Max

Stimulate with above settings for the corresponding duration.

Frequency	Duration
0.5	6 sec in each section
2.5	6 sec in each section
5	6 sec in each section
10	6 sec in each section
40	6 sec in each section
10	6 sec in each section

Session Procedure

Have patient lay face down on massage table (or on their stomach propped up on elbows). * For patients with long hair, it may be easiest to center part their hair into pigtails, and secure each half of hair, so that you can easily see the centerline of their scalp. * Dip ends of both probes into cup of electrolyte solution. Then starting with one probe at the base of the coccyx, place probe tips directly on top/center of spine, about 1-2 inches apart. Start device stimulation by pushing trigger on probe. Gently trace probe tips in small lines (about 1 inch

long), straight up and down spine, for approximately 6 seconds. Then move probes up about 1- 2 inches above the top line, and trace new small lines further up the spine, again for about six seconds. Reapply electrolyte solution as needed, while you work your way up to the base of the skull, stimulating each small section for ~6 seconds. When you reach the base of the skull, **change the intensity to 25**, and place trigger probe tip at the base of the skull and the indifferent probe about 2 inches directly above that, along centerline of scalp. Gently make small circles with probe tips for about 6 seconds. Then move trigger probe tip to a spot on scalp about 2 inches directly above the indifferent probe, and then place the indifferent probe to a new spot on scalp about 2 inches directly above the trigger probe. Again make small circles for about 6 seconds. Repeat the moving of probe tips to new stimulation spots along centerline until you reach the hairline at the center of the forehead. Then change the frequency and trace your path back along the centerline of scalp, stimulating each pair of stimulation spots for about 6 seconds. When you finish the scalp and reach the base of the skull, **change intensity back to 100**, and move back down the neck and spine in the manner you did before. Continue until you have traced along the spine and center of scalp for all 6 frequencies, ensuring to use the low intensity when stimulating the scalp. Then switch electro-equiscope to Mode 1, move plugs over to mode 1 and repeat entire procedure, however ensuring that each section/pair of stimulation spots is "clear" (by stimulating for another 6 seconds as needed) before moving onto the next section of the spine. Then clean electrolyte off of patient's back and scalp with the warm washcloth. Apply sealing cream.