

CLINICAL RECOMMENDATIONS FOR THE FISHER WALLACE STIMULATOR

Dictation Transcript

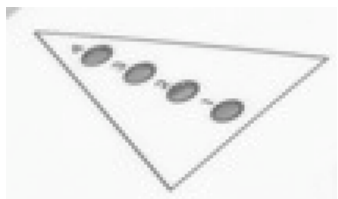
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I. The level of current and the frequency of treatment



Clinicians and patients should note that there are four (4) levels to the device. In general, with rare exceptions, we would recommend using levels one (1) and two (2) for psychiatric disorders. These are the levels that have been primarily used clinically for many years since the FDA approved the prototype form of the device; however, there are some patients who may benefit from levels three (3) or four (4). I do believe patients with a severe history of drug abuse, immense physical pain, or with severe depression may at times need to use the device at levels three (3) or four (4) in order to respond. These patients do not seem to have the same response that most people have at levels three (3) or four (4), which is an uncomfortable, painful stinging sensation at the site of the leads on their temples. However, some patients may have considerably more resistance to the passage of current through their tissues and will only get a response at a higher level.

Generally, in a patient with insomnia, anxiety, depression, or in fact any major psychiatric disorder, we would start him/her on level one (1), once or twice a day. The machine is automatically set to run for 20 minutes. Most moderate to mild conditions in outpatient practice would start with 20 minutes a day for the first week or two. If the patient has a more severe condition and is willing to comply with twice a day treatment for 20 minutes each time, then it may be appropriate to start them with sessions two times a day at the initiation of treatment. Patients generally feel nothing at level 1, however in a somewhat dark room they may notice a slight flickering of the background light in their eyes. They can be reassured that this is not a problem. If there is no response after 1-2 weeks, depending on how urgent the symptom relief is, one would then go to level 1 twice a day, or if the patient started with that and has not experienced any change, I would then have them go to level 2 in the morning and level 1 in the afternoon or evening.

Most patients find that at the end of 20 minutes on level 1, they are more relaxed, calmer, and a bit drowsy. However, many may not feel these effects for 2 or more weeks after the start of treatment. If you have the patient use the device with you in the office, you can typically see a relaxation in their facial, neck, and shoulder muscles, and a slowing down of agitated speech and movement. As with antidepressants, though, patients may not in the initial phases be aware

of such a positive change. Level 2 is usually calming, but also energizing. I generally recommend that patients who use the device on level 2 do so in the morning. Most patients are able to do level 1 close to bedtime, which enhances compliance as they relax into sleep more easily. Patients can do pretty much any activity while they use the device, whether its checking email, working on the computer, doing paper work, reading, listing to music, watching TV, walking on an exercise machine, or having it in their pocket while they do chores around the house. Some of my patients who are advanced meditators and/or do breathing find that their meditation is enhanced when done in conjunction with the device. Patients who use the device before bedtime often like to read, listen to music, and relax. Some patients find the device hard to use in the morning or afternoon because of the demands of everyday life, and so this bedtime option is best for them. Rarely a patient may find that even level 1 gives them so much energy that they want to stay up and do things, and that level 1 even disturbs their sleep cycle. In that case, they should move the time of using the stimulator to earlier than four hours before bedtime or any other time that is earlier in the day.

After 2 weeks on level 2 in the morning and level 1 in the evening, if there is no significant change seen in the patient or only a partial response, I would then increase the device to level 2 twice a day. Level 2 may more often disturb sleep than level 1, but again this can usually be dealt with my moving the treatment session to a different part of the day. Note that patients may have a hard time complying with twice a day treatments, especially over the long run. It helps to reassure them that in general, once they are doing better, you will be able to cut down treatments to once a day (and rarely, in milder conditions, one might be able to go down to 3 or 4 days a week and maintain a good response). It is also important to remember that this device has minimal or no side effects, and ends up being more cost effective in the long run.

II. Electrode placement

Proper placement of the leads is important. It is crucial that the patient know where to place the leads on their temples. I generally show them where to place the leads in my office with my own stimulator. I ask them to review it on the website after our appointment, and then I check in with them in a follow up session, asking them to show me where have been placing the leads.



Agitated patients may not process some of this information well and therefore physicians should check to make sure the patient is placing the leads properly. It is a good idea for clinicians to

have the patient do it for the first time or two in the office with them, especially for more anxious, phobic patients who may need a partner to relieve their anxiety.

If the leads are not placed properly, a patient may have side effects or a lack of positive effects. If someone falls asleep with the device on, and the lead is pressed hard against the skin during the 20-minute treatment session, this can cause irritation and cause the skin to redden. If a patient uses the device on a high level, the skin may also be irritated, and this is a sign that the level is too much for their skin. Sponges should be replaced every month to ensure that the current is transmitted properly, and they are very inexpensive. I also indicate that patients should take the sponges out of the electrodes to dry in between sessions, otherwise they tend to get moldy and dirty. Also, women with thick hair might have to wet their hair before a treatment session in order for the machine to conduct successfully.

III. Patient reactions

In terms of what I expect to see with a patient using the device, there are certain things that are quite typical. Some articulate patients, after only 3-7 days, may say “This is how I used to feel when I took Xanax or Valium, but my brain feels so much sharper.” Typically, when used for the first 2 weeks at the proper level, the patient will have improved sleep; they report deeper and more restful sleep; they don’t need as much sleep anymore; they have more energy in the morning; it is easier to fall asleep. They can typically be tapered relatively quickly off of sleep medications that they have been using for a long time. Also, typically by the end of 2 weeks, the patient’s anxiety symptoms are considerably better. I find that the patient smiles much more, and sometimes I see smiles on patients that I haven’t seen smile for many, many years.

Their family members are often shocked to see the improvement, especially since patients often do better with this device than they ever did with medication. Over the 4 weeks following that initial decrease in anxiety, the patient’s mood improves and depression lessens. More importantly, several months later the patient often begins to be able to do creative things that require a lot of mental energy, that they have not been able to do in many years. For many patients, this is the most exciting part of using the device.

Some patients who have had electroconvulsive therapy (shock treatment) are afraid of the device, feeling that it is a form of electroconvulsive therapy. I tell them that the amount of current used is 1/1000th of that used in ECT, and works in a totally different way. I also explain increases in neurotransmitters after a 20 minute treatment session, but more importantly that the device works at a deeper level of the brain, through the limbic system and thalamus. This is why I think it causes a better response.

In studies of these devices the response rates are typically 65%-75%, and these statistics are the same in my practice even though my patients are in general worse than the patients in the studies. Patients and families have been extremely happy about the response. I believe that this country could save millions of dollars in health care costs for antidepressant treatment if this device were one of the first line choices for clinicians.

Some patients worry about taking the device on plane trips. I have not had problems with this but I suggest to my patients that they place it in their carry on, take it out and show it as they would their computer, for security personnel.

There is a long money back trial period. I tell patients that we should first try it and see if they respond. The odds are good that they will. If they do, we will then submit a letter to their insurance to attempt to obtain reimbursement.