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Case Studies

Use of a PEMF to Treat Complex TBI with Brain Gauge and Rivermead Outcome Measures

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Introduction

The US Centers for Disease Control (CDC) claims that about 2.5 million cases of death, hospital admissions and emergency visits occurred in 2010 for TBI, but this is expected to be a significant underestimate since it only represents the people presenting for clinical care and receiving a diagnostic code[1]. Nevertheless, of these TBI cases, 75% were from mild head injuries (mTBI). There is an estimated 1.5 million Americans experiencing a TBI each year[2]. In New Zealand it is estimated that 31% of the population will have at least one TBI by age 25. It is also estimated that about 5.3 million Americans are living with post TBI disabilities.

Certain populations are at higher risk for TBI. For sports, between 1.6 and 3.8 million sports – related concussions are estimated to occur annually within the USA[1]. The military population is another major at-risk group, with screening indicating a prevalence rate of about 6.8%.

TBI should not be considered as an acute event but as a trigger of progressive injury which may occur over hours, days, weeks, months and even years[3]. TBI is not only a progressive disease in the early phase, but, may also, evolve into a chronic disease. The development and implementation of guidelines for many aspects of the care of TBI have led to uncritical adoption of a “one-size-fits-all,” standardized approach. This approach largely considers people with TBI to be “average patients.” Because of the complexity of TBI and the uniqueness of individuals sustaining these injuries, care needs to be individualized.

In most cases of mild traumatic brain injury (mTBI), also called concussion, the symptoms disappear in the first 2 to 4 weeks[4]. Symptoms that persist for months or years following the injury are considered persistent post-concussion syndrome (PCS). PCS symptoms include somatic symptoms (i.e., headache, blurry vision, anxiety, etc.) and cognitive (i.e., confusion, memory) deficits. In 20–40% of mTBI cases symptoms can still be present at 6 months post-injury, and in 10–20% of cases they may still be symptomatic at 1 year and beyond.

Similar symptoms can be reported by individuals with more severe brain injuries, by those with physical injuries without TBI and by the general population. Also, symptoms reported on TBI questionnaires may be influenced by a range of factors such as symptom expectations, pain, depression and stress.

TBI symptoms are frequently assessed by using standardized questionnaires. One such questionnaire is the Rivermead Post-concussion Questionnaire (RPQ), which is done by self-report[5]. It consists of 16 post-concussion symptoms including headaches, dizziness, nausea/vomiting, noise sensitivity, sleep disturbance, fatigue, irritability, feeling depressed/tearful, feeling frustrated/impatient, forgetfulness, poor concentration, taking longer to think, blurred vision, light sensitivity, double vision and restlessness. For each symptom, individuals are asked to rate the degree (on a scale of 0 to 4) to which it has been absent or a mild, moderate or severe problem over the previous 24 hours compared with premorbid levels.

TBI has many complex components relating to the injury and the context of the injury. As far as treatment is concerned, neuroprotective agents have not been found to be helpful[6,7]. Even non-

pharmacological treatments and cognitive rehabilitation lack consistent value. As a result of these limitations, many individuals turn to complementary and alternative medicine for their care[8]. At present, no medication has received approval from the US FDA for the treatment of any neuropsychiatric consequences of TBI[2].

Current therapies for TBI are not curative, nor provide substantial healing. Most therapies today are primarily aimed at controlling the psychological, cognitive and physiologic sequelae of TBI, primarily through counseling, occupational/physical therapy and psychiatric medications. These are temporizing approaches, waiting on the body to essentially heal itself or reach a tolerable stable state. As a result of this passive type approach, many individuals are left with permanent disabilities and a major risk of suicide and post-traumatic stress disorder. More recently, recurrent mild TBI's [concussions] have been found, especially in professional sports, to lead to chronic traumatic encephalopathy (CTE)[9].

The goal remains to find new, safe and effective alternative therapies for TBI. Noninvasive neuro-stimulatory and neuro-modulatory tools such as transcranial, pulsed electromagnetic stimulation are being considered[2]. The use of magnetic fields in the treatment of TBI has been studied for years now and recently reviewed[10].

With this background, a somewhat complex patient presented, looking for a complementary approach to her TBI-related health challenges.

Below, is presented a case report of a patient looking for a complementary approach to her chronic fatigue, and a mild partial complex, temporal lobe seizure disorder. It is presumed the symptoms and seizure disorder were mostly attributed to her TBIs.

Clinical history

The female patient (M.E.), born 1958, initially presented to clinical care 3/31/08 with complaints of severe fatigue. She had three prior rear-end motor vehicle accidents, two in 2006 and another in 2009. Complaints included mild headache and migraine, mild dizziness and difficulty concentrating and moderate difficulty thinking. Following this she had mild neurologic "spells."

1. June 2011. She reported more frequent "spells", which she called "floppy spells" or "brownouts" with inappropriate laughing. Brain mapping with quantitative EEG (QEEG) was recommended. This came back positive, suggestive of possible mild temporal lobe seizure disorder. Two neurological evaluations considered narcolepsy.
2. November 2011. Inpatient, continuous video electroencephalogram [EEG] monitoring abnormal. EEG showed left temporal, medium amplitude sharp waves during sleep. Narcolepsy and cataplexy were ruled out; definite evidence of seizure disorder was not made.
3. Clinically, she continued with recurrent episodes of "floppy spells", sometimes several times a week. Referred for another independent neurological consultation.
4. October 2012. Second opinion neurology visit noted several episodes of altered mental status. About 7 – 10 days after the 2nd MVA she was found by a coworker to have slid out of her chair. No losses of consciousness (LOCs). No obvious direct head injury. Based on various symptoms neurologist thought she had fairly typical clinical presentation of complex partial, temporal lobe seizures, consisting of altered mental status, confusion, hysterical laughing. Placed on anti-seizure medication, Lamotrigine put a 5 mg and Lamictal 150 mg. MRI of the brain 11/ 2012 compared to MRI of 2011 considered unremarkable. Carotid ultrasound and transcranial Dopplers not abnormal.
5. December 2012. No "seizures" for 13 weeks. Continues anti-seizure medication. Short-term memory has continued to decline while taking the medication. Long-term memory has improved significantly.

6. March 2013. Follow-up neurology visit noted she was having arm heaviness, sensation of a fat lip and slow speech. 50-70% improvement; now 27 weeks without bouts of hysterical laughter or “brownouts.” QEEG mapping: indicative of impaired cognitive functioning, memory deficit; temporal lobe excess Delta and power indicative of mTBI; inattention and trouble focusing. Antiseizure medication, Lamictal, dose increased.
7. March 2014. Follow-up neurology visit. doing much better since starting antiseizure medication with improved cognitive performance.
8. June 2014 - July 2016. Still some “brownouts.” Continues seizure medication.
9. July 13, 2016 entry into TBI/PEMF pilot study, about 10 years post-TBIs.

The TBI/PEMF pilot study

Enrolled in pilot study to determine if PEMF therapy could benefit symptoms of TBI and possibly produce sustainable healing of the brain. Measurement tools were the RPQ[11,5] and the scientifically validated objective Brain Gauge[12] tool. Therapy was with theportable, Micropulse PEMF device[13,14]. This device was chosen because of its portability and the previously reported data on its value in stimulating stem cells[15], anti-inflammatory action[14] and tissue regeneration[13]. The device was modified for the study to deliver 10 Hz at its standard, 10 mT (100 Gauss) per coil.

Methods:

The protocol was toapplythe5 cm circular coils transcranially for 2 hours per day, alternating hourly, during each two-hour treatment session, with one coil bilaterally over each temporal lobe and then the frontal and occipital lobes, for 3 months, followed by one month off with no treatments. All other therapies could be used during the study.

Assessments were done at baseline, weekly after for 4 weeks, monthly for 2 more months, and then at the end of the month with no treatment. The Brain Gauge used was the professional model, using the dominant hand.

In M.E.’s case, for various practical reasons, Rivermead questionnaires were completed at baseline, weekly after treatments for 1 through 4 weeks, missing the two monthly follow-ups, and the final one after about 3 weeks off treatment. She continued treatments for the full 3 months. M.E. was only able to tolerate being off treatment for 3 weeks, versus the protocol required 4 weeks, before having to restart treatment. M.E. thought treatment was so helpful she did not want to stay off PEMF treatment for yet another week per protocol. So, the Rivermead assessment was done at the end of the 3 weeks after cessation of treatment.

Rivermead assessment results – See Table 1

Rivermead Symptom	Baseline (7/13/16)	~1 wk after PEMF (8/1/16)	~2 wks after PEMF (8/9/16)	~3 wks after PEMF (8/16/16)	~4 wks after PEMF (10/31/16)	~3 wks off PEMF	Symptom Score Min	Symptom Score Max
HA	0	1	1	2	2	1	2	0
Sound Intensity	3	0	0	2	1	1	3	0
Sleep	0	1	0	0	0	0	1	0
Fatigue	2	2	1	2	1	1	2	1
Irritabilitiy	0	0	0	0	0	0	0	0
Depressed	0	0	0	0	0	1	0	0
Frustration	2	1	1	0	1	1	2	0
Forgetful	4	1	1	1	1	2	4	1
Concentration	3	1	1	1	1	2	3	1

Cognitive	4	1	1	1	1	2	4	1
Light Sensitivity	4	1	1	1.5	0	1	4	0
Daily Test Total	22	9	7	10.5	8	12	22	7
Daily Test Avg	2	0.82	0.64	0.95	0.73	1.09		

Table 1. *Clinical scores using Rivermead symptom questionn*

At baseline, M.E.'s most distressing scores were for sound sensitivity, fatigue, frustration, forgetfulness, concentration, cognitive function, and light sensitivity, ranging from 2 – 4. Total score for all symptoms for that assessment was 22. Total score at the end of 4 weeks of treatment was 8. For individual scores: forgetfulness, cognitive function, and light sensitivity were the most problematic. Over 4 weeks of treatment, these scores improved from: forgetfulness, 4 to 1; cognitive function, 4 to 1; and, light sensitivity, 4 to 0. Interestingly, the total score changed from 22 to 9 within one week of treatment, indicating a dramatic benefit of the PEMF therapy within even one week for someone with 3 previous probable mTBI's.

When considering the Rivermead scores after 4 weeks of treatment, being off treatment for a month caused regression of benefit for many of the areas that started off with the worst scores, particularly: forgetfulness, concentration, cognitive function, and light sensitivity. One symptom, headache, did not appear to regress. Others, such as sound sensitivity, fatigue and frustration, showed no change.

Overall, the total daily test score went from 22 at baseline to a minimum of 7, for a 68% reduction in overall symptoms.

During the course of her protocol, M.E. had suffered some significant anxiety/stress provoking events with a parent's health between weeks 3 and 4, where her total score went from 7 to 10.5. Otherwise, the trajectory of her improvements appears to be progressive.

Another way of looking at the Rivermead data is to look at the average scores per test date. The average score at baseline was 2. The average score at the end of the course of 4 weeks of treatment was 0.73, the lowest being 0.64 after 2 weeks of treatment. At the end of the course of treatment, following 3 weeks with no treatment, the Rivermead average test score worsened from 0.73 to 1.09, or, by 49%. From the patient's perspective this was a dramatic worsening of symptoms. Based on baseline score, the score at the end of 3 weeks of no treatment still produced an ultimate benefit of 46%, compared to a 64% benefit after the initial 4 weeks of treatment. Most of the benefit happened in the first week, and stopping treatment for 3 weeks resulted in about a 28% loss of clinical, symptomatic benefit.

During the course of the study, both the patient and her husband were delighted and satisfied with the improvements in symptoms even after one week of treatment but especially after 2 weeks. The most impressive to them was the improvement in forgetfulness, concentration and cognitive function. They both noted that she was able to produce more coherent sentences and better judgments on information needing assimilation, values that were very important to them and made it worth their continuing with the study and the somewhat demanding 2 hour per day treatment protocol. These benefits were made even more compellingly evident when treatment was stopped. The regression was notable enough that she did not want to continue being off treatment for another week per protocol. As a result, clinically, and ethically, it was unconscionable to deny a study patient recourse to breaking protocol.

Brain Gauge Assessment Results

To obtain more objective measures on the impact of PEMF therapy in the setting of TBI, it was elected to use a somatic sensory brain function measurement tool, the Brain Gauge[12]. Measurements with the Brain Gauge, take about 20 minutes and were done per protocol schedule.

Baseline assessment done 7.19.16 showed significant reductions in several parameters. Figures 1 – 3 provide radar plots and bar charts of specific test parameters. Also included are the overall cortical metrics scores (Figure 4). At baseline, focus and plasticity were off significantly (Figure 1), with the TOJ (temporal order judgement) score being most severely affected. After 4 weeks of treatment, on 08.16.16 (Figure 2), all parameters improved dramatically, with 6 out of 8 parameters being almost normal. The TOJ score improved by over 90% from baseline to peak.

The overall cortical metrics score (Figure 4) improved by 53% from baseline to peak. Following the peak score, the subsequent two monthly scores showed reductions in benefits despite continuing PEMF therapy.

Also, similar to the Rivermead scores, the Brain Gauge scores showed significant reductions in the gains previously seen when PEMF therapy was stopped for about 3 weeks (Figure 4). TOJ decreased from a peak of 75 to 13 and the overall cortical metrics score dropped from 92 to 58 (Figure 3).

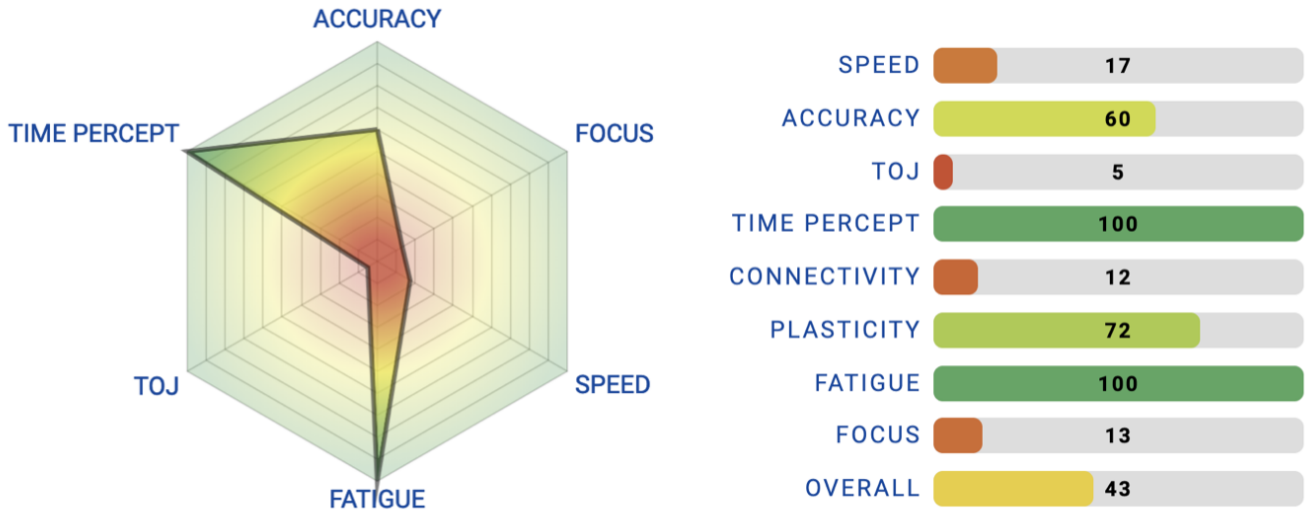


Figure 1. *Figure 1. Baseline Brain Gauge results 07.19.16*

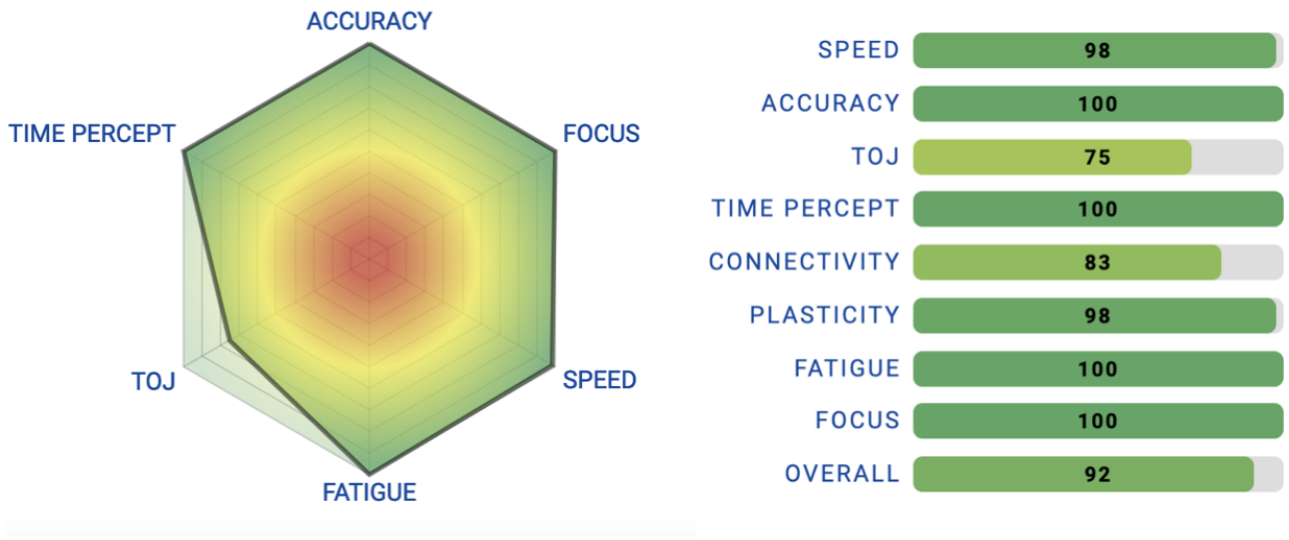


Figure 2. *Brain Gauge results a fter 4 weeks of treatment 08.16.16.*

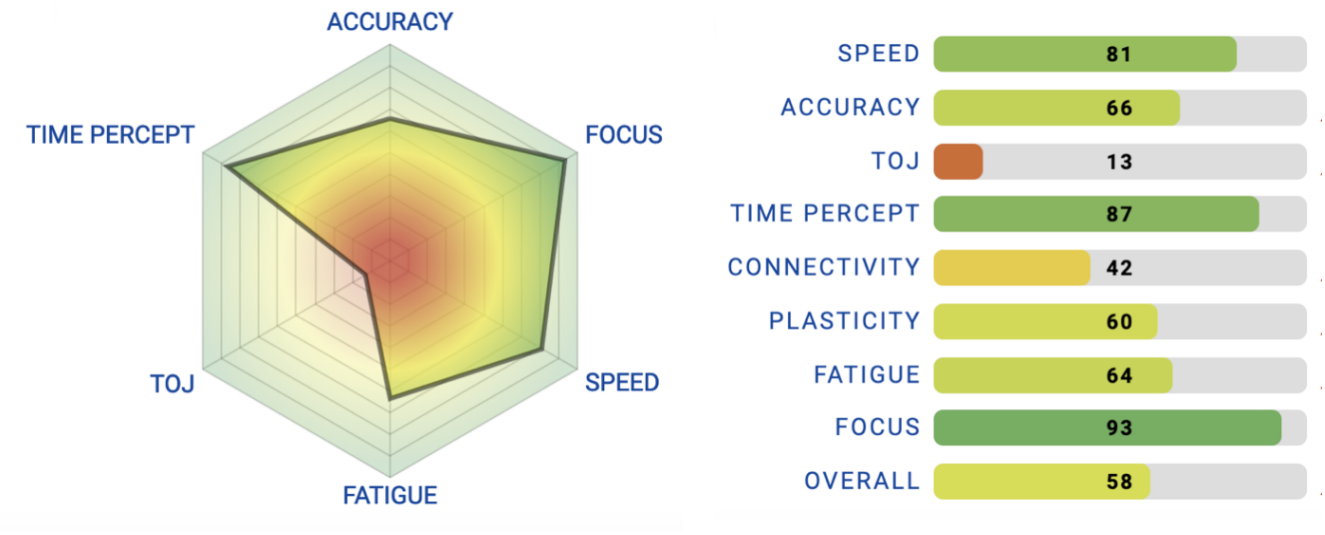


Figure 3. *Brain Gauge results after stopping treatment for ~3 weeks 11.01.16.*

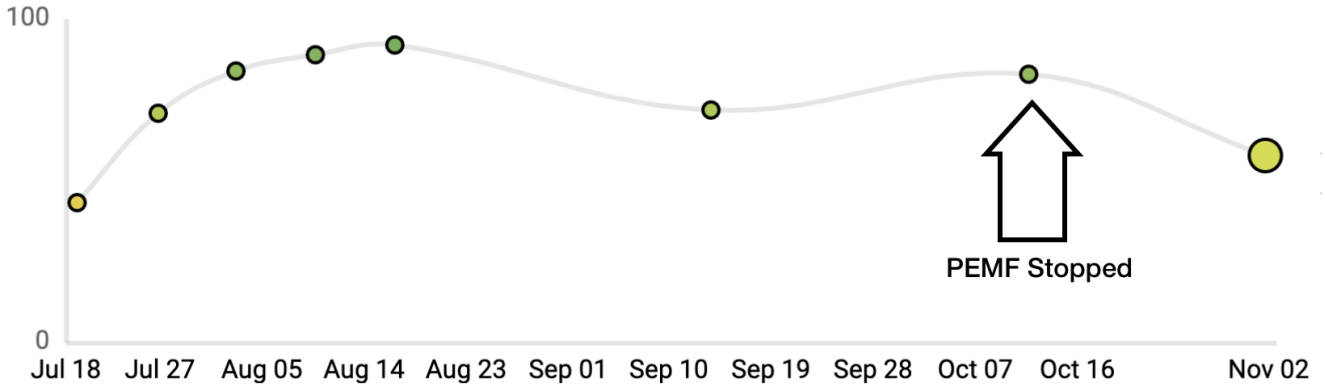


Figure 4. *Brain Gauge Cortical Metric scores.*

As can be seen from these Brain Gauge results, there were significant improvements in somatosensory cortex function after treatment with PEMF began, i.e., brain function, tracking similarly with improvement of clinical measures.

Discussion

This patient did not have LOC after her TBIs, placing her in the mTBI category. However, her mTBI was complex in that she developed a seizure disorder and continued to have symptoms over 6 years beyond the time of the injury. This and her continuing symptoms would also classify her condition as having PCS.

mTBI affects 25% of those injured in a traffic collision. Median time to recovery is 100 days, but 23% have still not recovered by 1 year[16]. TBIs may be complicated by a seizure disorder. The incidence of non-convulsive seizures is much more common than convulsive seizures in the first week after even severe TBI. The cumulative incidence of seizures over 30 years after TBI is 2% for mild injuries, 4% for moderate injuries, and over 15% for severe injuries[17].

The presence of seizures may be the source of her significant light and sound sensitivities, since headache was not a significant complaint. Light and sound sensitivities are more often associated with migraine-type headaches.

The temporal lobes are the most common site for late post-traumatic seizures[17]. Temporal lobe seizures are often associated with an aura, which she had. The auras can be autonomic, psychic or olfactory and gustatory hallucinations. As the seizure evolves, there may be alteration of consciousness and patients may stare and be unresponsive.

Partial seizures with alteration of consciousness can happen in a postictal period, during which the patient is difficult to arouse. This stage usually lasts a few minutes but even after regaining consciousness patients are often confused and may have poor memory for up to several more hours.

Based on her history, her seizures decreased dramatically and returned partially when PEMF therapy was stopped for three weeks. In a recent review[18], electromagnetic stimulation has been found in several studies to reduce seizures in over 150 patients. Higher intensity transcranial magnetic stimulation (TMS) reduced temporal lobe seizure frequency by 7-36%. Even drug-resistant epilepsy was found to have a 30% average rate of 50% seizure reduction.

Most of her symptoms were in the cognitive realm and improved significantly with PEMF therapy. Rivermead Questionnaire research has found that with mild TBI, vomiting/nausea, blurred vision, slowed thinking, and poor memory may persist even four years later, without definitive therapy[19]. Despite the fact that her symptoms, at varying levels, lasted for about 10 years before starting PEMF therapy, her cognitive symptoms decreased by between 67 – 75%. When PEMF therapy was stopped for 3 weeks, she lost ground, but still maintained some benefit to the level of 33 – 50%. I am not aware of any research showing this level of therapeutic benefit from any type of treatment started this long after TBI.

Research shows that PEMF therapy supports the brain in many ways, whether in the setting of TBI or not, including improvements in cognitive function, PTSD, depression, stress reduction, headaches, and more[10]. In one post-concussion study[20], TMS reduced the overall post-concussion symptom score by 45% and the cognitive score by 40% after 20 TMS sessions, delivered 5 days per week for 4 weeks. Outcomes were measured within 2 weeks following the last TMS session and after three months. Nine of twelve participants improved and one worsened. In this study, the symptoms that improved the most were difficulty remembering, difficulty concentrating, fatigue, and feeling slowed down. In the 3-month follow-up after the course of treatment, one third of the participants had worsening of their symptoms. The symptom improvements and the worsening of

symptoms after cessation of therapy are comparable to those seen in the case report.

In M.E.'s case, the PEMF used was considerably lower in intensity than TMS, and still impacted symptoms. Otherwise, treatment was 2 hours/day for 36 "sessions." The TMS study above[20] did treatments for about 2 minutes for 20 sessions. Experience shows that higher intensity PEMFs may need to be used for shorter periods to achieve reasonable benefits. Nevertheless, it appears that lower intensity PEMFs, as used in this pilot study may produce comparable benefits, both clinically and objectively.

While M.E.'s Brain Gauge results show significant progressive improvement over 4 weeks from baseline, there was a drop in improvement over the next 2 months even with PEMF, as a result of personal circumstances in her life. The brain gauge is sensitive to these environmental/social/emotional influences. As a result, an individual person's measures should be interpreted with caution and be considered in the setting of multiple measures and circumstances to assess consistency.

The cause of regression in the benefits after stopping PEMF seen both clinically and objectively is unknown and likely to be a result of the influence of the PEMF in improving cortical function and reducing neural excitability. The 10 Hz signal used is in the alpha range of EEG frequencies and has been found to be generally psychologically relaxing[21]. So, it is not known whether a relaxation effect is the cause of the clinical and objective improvements seen during treatment and the loss of improvement seen on withdrawal of treatment. 10 Hz TMS stimulation has also been found to be very helpful in anxiety and PTSD[22]. The mechanism of action is thought to be through the normalization of metabolic activity, as shown by PET imaging and rebalancing of the hypothalamic pituitary axis involved in stress responses.

As far as PEMF actions on the brain and TBI are concerned, these are reviewed by Pawluk[10], and include brain biologic actions, neurocognitive function and psychological effects and benefits. This is the first known use of PEMF treatment at this level of magnetic field intensity (10 mT/100 Gauss), 10 Hz frequency and duration of application for the treatment of TBI.

While there is limited research on the use of the Brain Gauge in the setting of concussion, one study[23] found that individuals who were persistently symptomatic post-concussion, were more likely to have a greater number of previous concussions and significantly higher levels of fatigue and related symptoms. Persistently symptomatic individuals had increased levels of intra-cortical inhibition with brain stimulation resulting in ongoing fatigue, evident in our patient's (M.E.'s) clinical situation.

M.E. had a very low reaction time (RT) at baseline (score 17), which improved after 4 weeks of PEMF treatment to a score of 90. The RT then dropped to a score of 81 after being off treatment for one month. Because of the cognitive issues present in her situation, the initial RT may have been lower than expected, as part of the learning process of doing the testing. Nevertheless, the dramatic improvement in the RT and relatively stable maintenance following 3 months of therapy, should be indicative of an improvement in fatigue. M.E.'s fatigue score was only at a level of 2 (out of a possible worst case of 4) at baseline, improving to 1 but not less, with subsequent treatments. It's possible that these persistent symptoms of fatigue in her situation may have been due either to the underlying seizure disorder, a medication effect, continued stress or other physical issues she had.

The Brain Gauge has been studied in student athletes who had concussions and had repeated testing for up to 18 days postconcussion[24]. This study showed significant improvement by more than 50% in the cortical metric score by 14 days with some students having almost complete normalization by 18 days post-concussion.

Despite the fact that this Brain Gauge study on concussion found significant improvements, as

noted earlier, some individuals continue to have symptoms and develop PCS, which can then last for years or even permanently, after TBI. This was certainly the case with M.E., and the impact of the PCS was able to be detected by the Brain Gauge test, and this tool was also useful to objectively demonstrate improvement in scores with PEMF treatment.

The treatment protocol was designed to see the value of the effects of TBI treatments with PEMFs compared to no treatment, both pre- and post-treatment. The question ultimately for the value of PEMF therapy, is whether it's healing the lesions of TBI in its effects and/or symptomatic or functional improvement. This protocol does answer this question.

Conclusion

This case report and discussion provide substantial support for the use of this specific 10 mT/100 Gauss pulsed magnetic field 10 Hz signal for 2 hours daily to not only significantly improve clinical function, but also to objectively produce positive neurological functional changes. Further research is clearly needed on a larger sample of individuals with TBI, whether complex or not, with different times after onset of injury. It is still unknown whether 2 hours per day of this type of PEMF therapy is optimal. Clearly, in this patient, 2 hours/day of therapy made significant improvements in subjective and objective measures of function, and with internal validity, significant loss of benefit with cessation of therapy. This loss of benefit with stopping treatment has been seen in other transcranial PEMF research. It remains to be seen whether durable, long-term benefits can be seen with longer-term PEMF therapy, whether other signal parameters could be optimized, including PEMF frequencies and intensities, and whether more permanent structural improvements in the injured brain may be found.

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The protocol was designed to see the value of the effects of TBI treatments with PEMFs compared to no treatment. Previous research has often shown that once PEMF therapy is stopped for many neurological problems, symptoms tend to come back. The question ultimately is the value of PEMF therapy, whether it’s healing the lesions of TBI in its effects or symptomatic or functional improvement. This protocol does not seem to answer this question.