

MagVenture **NEWS**

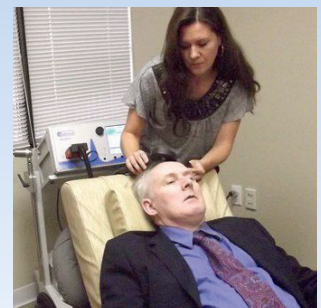
FDA Clearance Edition*)

Medical University of South Carolina:
10 questions for Dr. Mark George at the Brain Stimulation Laboratory

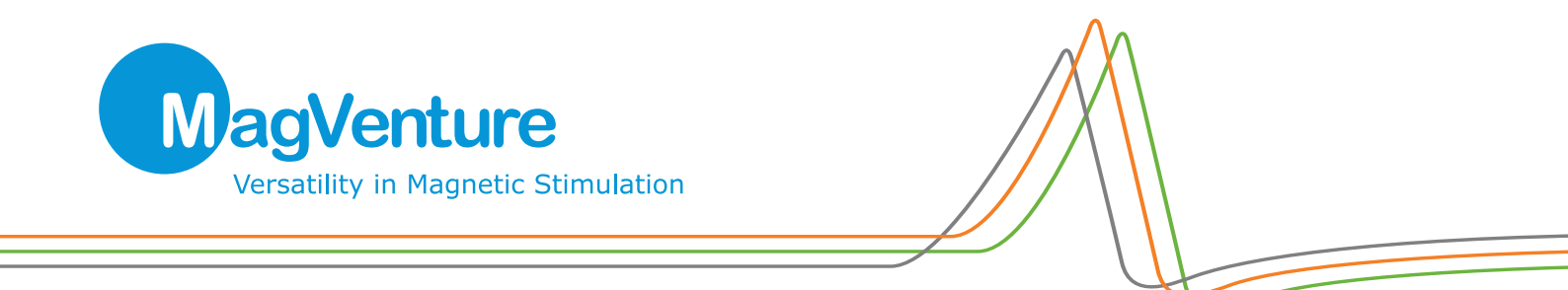
Dr Stubbeman TMS Psychiatry:
TMS is the future of psychiatry practice

Rowan University:
John O'Reardon: FDA clearance will help spread TMS even further

TMS BrainCare:
The success rate is so high that it sounds too good to be true



*) MagVita TMS Therapy System® is FDA cleared for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.



A rising tide floats all boats ...

The recent 510(k) FDA clearance to market our MagVita TMS Therapy system for Major Depressive Disorder^{*)} was, obviously, received with much enthusiasm here in MagVenture. This clearance will enable us to bring our products and services to the clinical psychiatric TMS community in the US. The US is, nevertheless, not a new market for us. We have in fact been present in the research community for more than a decade, and have established ourselves as a strong collaboration partner by developing TMS research solutions including several “first mover” features to several of the largest and most prominent research institutions in the country.

Dr. John O’Reardon, Professor of Psychiatry at Rowan University, is

one of these researchers and he has personally worked with MagVenture’s MagPro device for the past 7 years. On page 7 in this edition of MagVenture NEWS you can read more about his experiences, and his expectations for the future.

Dr. Mark George of the Medical University of South Carolina in Charleston and a true TMS pioneer has used MagVenture equipment for several years. In a new trial, Dr George and his team will, with the use of MagVenture devices, test whether prefrontal TMS works to treat depression in war veterans. When asked what he thinks of the fact that there are now four FDA cleared TMS devices on the market, he responds: “this is good news. A rising tide floats all boats and we have lots of boats now.”



Dr. George’s reaction well reflects the positive responses we have received and the general consensus that this clearance will first and foremost help to disseminate TMS even further, and thus allowing more patients to receive the treatment.

Stig Wanding Andersen
CEO, MagVenture

*) MagVita TMS Therapy System[®] is FDA cleared for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

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The views and opinions expressed in MagVenture NEWS do not necessarily reflect the official policy or position of MagVenture or any of its affiliates.

The usage of rTMS for any other purpose than the cleared indication, in the country in which the product is intended to be used, is considered investigational.

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Medical University of South Carolina: 10 questions for Dr. Mark George at the Brain Stimulation Laboratory



Dr. Mark George, who is here seen during a well-attended TMS workshop at the 12th World Congress Of Biological Psychiatry in June 2015 in Greece, has worked with TMS for almost three decades. He finds that there is “still a lot to work on” but remains confident that TMS for treating depression can and will continuously be refined and improved.

1) How did you first become involved in TMS?

I first encountered TMS when I was doing a research fellowship in 1989 at University College London. I was doing brain imaging with PET and

TMS seemed to offer a way to push and pull circuits and test out causality. And maybe if we were lucky, and we are, actually treat brain diseases that involve dysfunction in these circuits.

4) Seen in the infamous hindsight, what would have been especially nice to know back then?

The FDA was concerned about TMS causing a seizure and the potential effects of lots of pulses. They thus limited our early studies in terms of the intensity of stimulation. We underestimated the number of pulses needed, and the number of weeks we needed to stimulate.

Wouldn't it be great if we could get 70% remission with only a few hours work?

Mark George

SPECT, and was interested in the brain regions involved in regulating emotion. When I saw John Rothwell [professor of neurophysiology at the Institute of Neurology at Queen Square, ed.] using TMS in his motor lab to study the motor system, I immediately wondered if we could use it to investigate brain circuits involved in emotion regulation, and perhaps even treat diseases like depression.

2) For you personally, what was your main reason for choosing to work with TMS?

Imaging alone was insufficient. Brain activity during a task or state could be due to the task or state, or could be the brain's reaction to the core activity, or could be merely incidental.

3) How was TMS perceived in the 'early days'?

Back then all of these ideas were heretical – regional neuroanatomy of depression, brain basis of emotion regulation, non-invasively and without causing a seizure stimulating someone out of depression.

I later did the first clinical work at the National Institutes of Health (NIH) in Washington, with Dr. Robert Post. The going was still rough as there was much skepticism – getting asked to leave an ECT meeting, and having my senior boss at the NIMH tell me I could not talk to the press about TMS as they did not want to ‘sully the NIH name.’

I wish we had been more aggressive in pushing the parameters of stimulation. I think we underdosed for well over a decade, and may be still underdosing.

5) What do you consider to be among the most profound discoveries made?

That it worked is truly amazing. We did double blind studies from the beginning, but I was always worried that the effects were not going to replicate for whatever reason. I was very pleased when Dr. Saxby Pridmore, whom I had never met and who was working in Tasmania, Australia, started replicating our results, and showing changes in a biomarker called the dexamethosone

suppression test (DST) [DST is used to assess adrenal gland function by measuring how cortisol levels change in response to an injection of

costly, both to patients, doctors, and insurers. Wouldn't it be great if we could get 70% remission with only a few hours work?

There are lots of studies with TMS in almost every major brain disease. Some of the more promising areas currently are acute or chronic migraine, pain (either post-surgical or chronic), OCD, PTSD and addictions.

I wish we had been more aggressive in pushing the parameters of stimulation. I think we underdosed for well over a decade, and may be still underdosing.

Mark George

dexamethasone. In conditions such as depression, dexamethasone can prevent cortisol levels from going down, ed.].

6) Even though we are seeing very promising results, there are still some patients with MDD whose condition does not improve with TMS. Will it be possible for more patients to respond positively to the treatment?

I am an optimist. I am confident that we can and will continue to refine and improve TMS for treating depression, at least approaching the efficacy of ECT (60% remission). There are lots of candidate clues for improvement.

It is important to remember that many of the methods we use now for treating depression were educated guesses that have not been fully explored. These involve total dose (number of stimuli), different dosing regimens (multiple daily rather than once daily), frequency matching to the individual, or frequencies like theta burst that may be more powerful at changing the brain, better targeting, or combining TMS with talking therapy or special medications.

There is still a lot to work on. It would be unbelievable if our educated guesses turned out to be the best solutions.

7) What, within the field of TMS research for the treatment of MDD, do you consider to be among the biggest challenges you are facing today?

TMS for treating depression, as we do it now, is terribly inefficient, requiring many hours in the TMS chair. We need to figure out how to reduce this inefficiency and thus make it less

8) With MagVenture's recent FDA clearance for depression treatment, four FDA cleared systems are now available. What impact will this have in the US?

I think this is all good news. A rising tide floats all boats and we have lots of boats now. This means that not only one manufacturer has to do battle with insurance companies, but we now have a larger industry to fight these battles. I think this competition will drive down costs and spur competition and innovation.

9) Do you expect to see many new TMS treatments emerging in the next 10 years or so? Where do you see the most potential in terms of treatment?

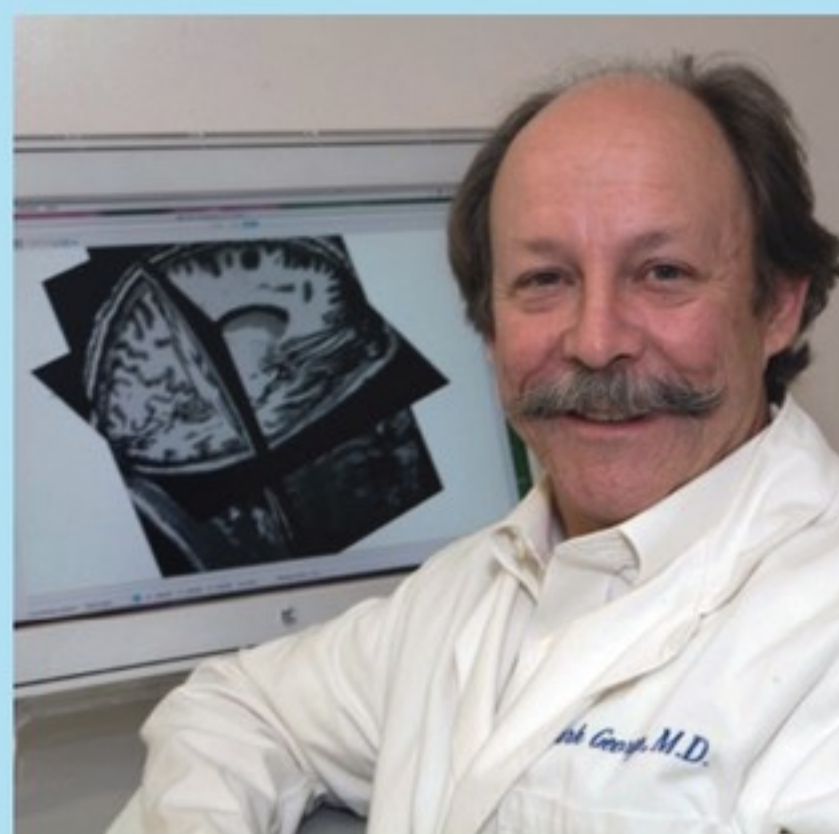
10) Can you tell a little about your current study with the U.S. Department of Veterans Affairs (VA)?

Cooperative Study Protocol #556 is chaired by Dr. Jerry Yesavage at the Stanford VA and designed to test whether prefrontal TMS works to treat depression in veterans. It is thus more 'realistic' than the pivotal NIH, Neuronetics and Brainsway trials, which were antidepressant medication free studies in patients without substantial comorbidities.

The VA trial allows patients to stay on their medications, and many of them have PTSD and prior substance abuse.

MagVenture won the competitive bid for the TMS device. We hope to complete enrollment in the late spring of 2016.

Mark George



Dr. Mark George received his medical degree from the Medical University of South Carolina in Charleston. He was a Visiting Research Fellow at the Institute of Neurology, University College London, England.

At the National Institute of Mental Health (NIMH) he was among the first to work with functional imaging which led to his pioneering use of TMS. Since then, he has worked continuously to grow the science of TMS.

In 1995 he moved back to Charleston and built the functional neuroimaging division and brain stimulation laboratories, now known as the MUSC Center for Advanced Imaging Research. In 2008, with the academic publishing company Elsevier, Dr. George launched the journal *Brain Stimulation: Basic, Translational and Clinical Research in Neuromodulation*, of which he is also the editor-in-chief.

Dr. Mark George has received numerous awards, and published over 400 scientific articles or book chapters.

Dr. Stubbeman TMS Psychiatry: TMS is the future of psychiatry practice

With a remission rate of 80%, Dr. Bill Stubbeman's clinic attracts patients from across the USA, Japan and Canada who have struggled with depression for years. Stubbeman hopes that Theta Burst treatment in combination with neuronavigation will one day become the standard of care instead of the currently used protocols.

At his psychiatric clinic in West Los Angeles, Dr. Bill Stubbeman is treating patients suffering from refractory major depression. Five years ago he began offering TMS treatment at his practice after having extensively researched TMS and felt that it was the future of psychiatry practice. His patients have typically had a life-

When current patients are in remission or moving toward remission, that is a good day. When TMS is a known option for those who are not getting medication benefits, and they are in my office getting well, that's a great day.

Dr. Stubbeman

time struggle with depression and have failed to receive benefits from medication or even Electroconvulsive Therapy.

"We have an 80% remission rate using a high frequency protocol combined with neuronavigation. All of our patients who have reached remission with TMS were previously severely refractory," explains Dr. Stubbeman.

Usually the patients find his clinic after having well-researched TMS and neuronavigation, but he also gets referrals from colleagues who have been unable to bring their patients to remission.

"Many of my patients are skeptical when they first come to my clinic because nothing else has worked for them. Luckily, TMS has a low placebo effect, yet high remission rate. Education about TMS and attentive care allow patients to better

evaluate TMS results. When nearing the end of treatment, all patients are generally amazed that the results are unbelievable yet real, and they hope that it lasts," says Dr. Stubbeman who is afforded a lot of gratitude by patients finally in remission who are very appreciative of their treatment results.

When nearing the end of treatment, all patients are generally amazed that the results are unbelievable yet real, and they hope that it lasts.

Dr. Stubbeman

A great day at the office

"When current patients are in remission or moving toward remission, that is a good day. When TMS is a

great day," says Bill Stubbeman who is motivated by the fact that he is able to help people who have failed all other treatments get their lives back. Unfortunately TMS is not that well-known among psychiatrists.

"It is my impression that most psychiatrists in the USA are not very

familiar with TMS and its high potential for treating patients who have failed everything else. Gradually, TMS is becoming more known to the general public through word of mouth and it is being covered on more and more insurance policies," says Dr. Stubbeman.

An expensive treatment, but...

The price for a TMS treatment remains the Achilles' heel for many patients, but according to Dr. Stubbeman it is also necessary to take into account the long term cost of psychiatric care, including therapy, medications, hospitalization, and loss of



Dr. Stubbeman started offering TMS at his psychiatric practice in 2011. He is here seen with Administrative Director Raya Khairkhah who is responsible for the day-to-day management of the practice.

All of our patients who have reached remission with TMS were previously severely refractory.

Dr. Stubbeman

work days when the price is evaluated.

“When all this is taken into account, the total cost of TMS treatment becomes relatively low. We also emphasize the cost of depression on relationships and the joy of living. All of our patients are private patients at the moment, but given the high rate of remission we have had, we wish to offer this treatment to as many depressed patients as possible, including those who are unable to afford the treatment themselves. In the near future, we are planning to work directly with insurance carriers

who support TMS,” says Dr. Stubbeman.

More suppliers, more competition, lower prices

MagVenture’s recent FDA clearance of the MagVita TMS Therapy brings the number of FDA cleared TMS devices for depression treatment up to four. According to Dr. Stubbeman this is likely to make TMS available to a greater number of people.

“Every new FDA clearance creates some level of noise in the ears of the public, medical and health insurance entities. Competition for the same technology drives down costs and

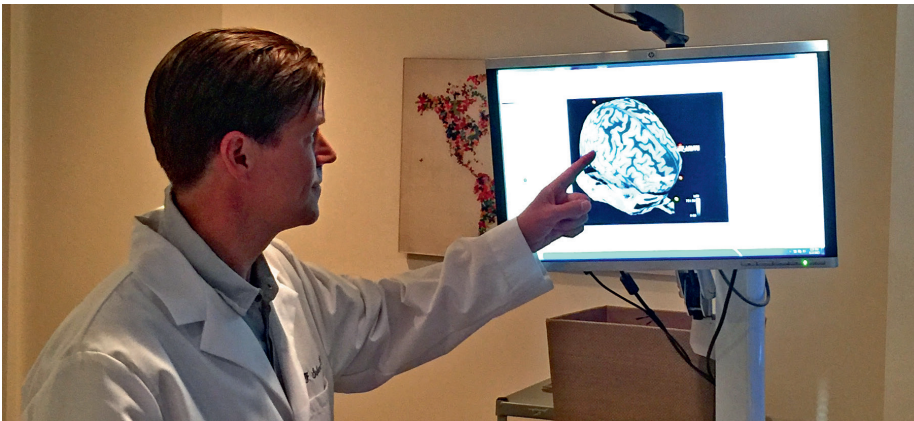
thus makes it more available to physicians with TMS becoming available to a greater number of people – but unique and clinically effective treatments provide the value to warrant higher reimbursements,” stresses Stubbeman.

The future of TMS

According to Dr. Stubbeman the future of TMS depression treatment lies not in the rTMS protocol currently in use, but rather in Theta Burst stimulation.

“I think that the future of TMS is in patterned treatment protocols like Theta Burst, and MagVenture’s TMS devices have much greater flexibility than other devices on the market. This should allow for higher remission in the US. I hope that someday 20Hz Theta Burst treatment will become the standard of care because in my experience, this works much better than the protocols currently used. Theta burst is arguably both safer as it uses lower intensity, and more tolerable with less total time per treatment than conventional TMS. This would allow even more patients to benefit from TMS treatment,” says Dr. Stubbeman who encourages doctors to use TMS in combination with neuronavigation.

“In the future, I hope to convince more doctors to use MRI-guided neuronavigation for precision targeting as well as take weekly motor threshold measurements on the patient using EMG electrode to accurately account for fluctuations,” ends Dr. Stubbeman, of his hopes for the future of TMS depression treatment.



Dr Bill Stubbeman hopes to convince more doctors to use MRI-guided neuronavigation. With Neuronavigation you can plan stimulation areas and monitor the correct positioning of patient and coil.

William Stubbeman, MD

Dr. Stubbeman graduated with high honors from Princeton with a degree in Mechanical and Aerospace Engineering and received his MD from Columbia University. He began his training at UCLA as an Ear, Nose and Throat Surgeon specializing in auditory pathology, but his growing interest in the brain caused him to switch focus to psychiatry.

He subsequently built a private psychiatry practice in West Los Angeles specializing in treatment-refractory psychopharmacology.

After realizing the potential of TMS to help patients that were beyond the reach of medication, he changed the focus of his practice to TMS treatment.

+ More information at: www.drstubbeman.com



Rowan University:

John O'Reardon: FDA clearance will help spread TMS even further

Dr. John O'Reardon, Professor of Psychiatry at Rowan University and noted researcher of neuromodulation techniques, welcomes the FDA clearance of MagVenture's MagVita TMS Therapy System for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

In July 2015, MagVenture was the fourth and thus the latest TMS manufacturer to receive an FDA clearance. Dr. John O'Reardon, who has extensive research experience within the field of TMS, sees this as a positive development, both from the perspective of a researcher and a clinician. He believes that the clearance will not only provide a healthy competition to the market, but will also further encourage insurance companies to provide meaningful reimbursement for the procedure.

Global perspectives

On a global scale, John O'Reardon believes that the FDA clearance could also impact the dissemination of the TMS technology, both within clinical practice as well as in research. "More psychiatrists will start doing TMS and when good clinical results are observed this will create a strong word of mouth effect which will also encourage research specific to this particular device," he says.

MagVenture has some advantages. There are no extra costs for disposables. This will encourage other psychiatrists sitting on the sidelines to get into the marketplace.

John O'Reardon

Potential pricing advantages, reliable cooling and low noise

John O'Reardon has been using MagVenture's TMS equipment for the past 7 years. "From a psychiatrist's point of view, MagVenture has some advantages," he explains. "There are no extra costs for disposables. This



Dr. John O'Reardon of Rowan University School of Osteopathic Medicine takes on the role of the patient while Amanda Helmer, a registered nurse and TMS operator, locates his Motor Threshold. John O'Reardon has worked with the MagVenture Mag-Pro for 7 years.

Photo by Kelly Roncace, NJ.com.

will encourage other psychiatrists sitting on the sidelines to get into the marketplace. Furthermore, the cooling system has been very effective and reliable. It never overheats. The operator places the magnet directly on the scalp thus having a lot of freedom of movement in placing it accurately. Since everybody's skull is

session," John O'Reardon stresses.

ECT research led to TMS interest

John O'Reardon's interest in TMS emerged in the mid 90's while doing a fellowship in Psychopharmacology and administering ECT. He read a report in Neuro Report which described the treatment of 6 patients using a new technology called TMS written by Mark George MD [see our interview on page 3, ed.]. It piqued his interest as for the first time it appeared possible to do brain stimulation in the office. "I saw the potential advantages over ECT which included time efficiency, convenience for the patient and lower side effects, including the absence of cognitive impairment," he says.

In O'Reardon's view, TMS will remain complementary to ECT but will not replace it. "ECT has the advantages of being more rapidly acting, more efficacious overall, and better if there

is marked suicidality. TMS, however, will be earlier in the treatment algorithm than ECT with fewer side effects and may in fact work if ECT has failed. We found [Connolly et al, 2012 J Clin Psy, ed.] that there was 40% chance of success with TMS if ECT had already failed," he says.

New TMS modalities

Theta Burst, a patterned form of rTMS, is another treatment modality which John O'Reardon believes may ultimately have more promise than the standard 10Hz TMS protocol and further mentions sTMS (synchronized TMS) which is currently in trials and offers the potential of EEG-based TMS. According to Dr. O'Reardon, the possibility of at-home treatment may become a new frontier in treatment delivery as it would, obviously, be enormously convenient for the patient.

Combination and augmentation approaches

Another important issue will be the development of combined medication and psychotherapy strategies. There are two basic approaches here, combination and augmentation approaches. With a combination approach, an antidepressant and TMS are started together at the same time in the hope of a more complete result. In the augmentation approach, in the case of non-response or non-remission,

The 3 biggest TMS challenges according to John O'Reardon:

- Make TMS more time efficient – 15 rather than 30 sessions
- Demonstrate efficacy for theta burst, a much faster way to deliver TMS and possibly more effective
- Develop a much wider range of indications for TMS where there is already promising work: Auditory hallucinations in schizophrenia, PTSD, OCD, depression during pregnancy, bipolar depression, neuropathic pain

TMS is added at 6 weeks to augment or enhance the antidepressant effect. Cognitive therapy can also be used to activate the prefrontal cortex immediately prior to TMS delivery to enhance its efficacy. This is a type of augmentation strategy for TMS but these approaches have yet to be studied, according to Dr. O'Reardon.

shape of the head, with guidance from research as to how to optimize the TMS effect with medications and psychotherapy, and ability to deliver a treatment protocol in 1/5th of the time currently needed."

TMS 'dream machine'

When asked to define his 'TMS dream device', John O'Reardon describes it this way: "It would be more compact, cheaper, provide an all-in package including theta burst, with a coil curved better to fit the

John O'Reardon

Dr. John O'Reardon received his medical degree from University College Cork in Ireland in 1984. He is board-certified in primary care in Ireland and the UK.

He completed his residency in Psychiatry at the University of Pennsylvania. Post-residency he did Fellowships in Psychopharmacology and Cognitive Therapy.

His areas of interest clinically are treatment-resistant mood disorders and neuromodulation therapy (ECT, TMS, DBS, VNS, dTMS, sTMS and tDCS). Research wise his main interest has been the development of new neuromodulation treatments.

He has been involved in large scale trials in TMS, VNS, DBS, sTMS and tDCS. He has over 100 scientific publications, including 29 in the TMS field.



 More information at: www.rowan.edu/som/index.php

TMS BrainCare:

The success rate is so high that it sounds too good to be true

35 years ago, Robert McMullen, MD opened his private practice in general psychiatry on the West Side of New York City. In 2010, he added TMS depression treatment to his long list of treatments.

Being a psychiatrist, Dr. Robert McMullen found himself looking for a way to treat his many patients suffering from major depressive disorder who did not respond to the medication he prescribed to them. To Dr. McMullen, TMS was the solution. "I was first interested in TMS because I had been reading about its benefits for years, and I needed an alternative for the many patients who failed to achieve full remission from antidepressants," says Robert McMullen of his decision to finally invest in TMS equipment to make the – at the time – novel treatment available to his many patients.

No per-use fee

"The purchase price of the TMS equipment that I first bought was very expensive, and it has actually cost me a lot of money that I had to pay a fee to the company for every treatment I did. I am therefore very pleased that it is now possible to get FDA cleared TMS equipment from other manufacturers such as MagVenture who do not operate with a 'per-use fee'. That makes a big dif-

ference to me and my practice," says Robert McMullen.

enormous benefits, as well as long acting benefits, for so many of my patients," says Robert McMullen,

The success rate is so high that it sounds too good to be true, so many psychiatrists do not believe it.

Robert McMullen

TMS is worth travelling for

So far, around 300 patients with major depressive disorder have undergone TMS treatment at TMS BrainCare.

"What has sustained us has been the

who in the past five years since he first began to offer TMS has been treating men and women of all ages from all over New York City and even further away.



Dr. Robert McMullen, founder and owner of the TMS BrainCare in New York, has treated around 300 patients suffering from Major Depressive disorder with TMS.

Robert McMullen

MD Robert McMullen graduated from Georgetown University Medical School in Washington DC in 1976.

He is founder and owner of TMS BrainCare in New York. For 35 years he has had a private practice in general psychiatry. He treats patients with a wide range of mental illnesses. He specializes in the treatment of mood disorders and anxiety disorders and is particularly experienced with the treatment of resistant depression.

In 2010, he began offering TMS treatment.



More information at: www.tmsbraincare.com



50% success rate

Only a few of Dr. McMullen's patients have to travel a long distance to get to the clinic. However, even to those patients who have a long commute, the benefit is so large that it is worth it, he explains. The high success rate of over 50% also explains why the patients willingly pay for the treatment themselves even though it is not covered by their insurance.

"It makes it more affordable for patients if we charge them \$100 and accept that as full payment if we cannot collect from insurance. We are much more likely to have a patient agree to treatment if they only have to pay \$100 per treatment," says McMullen who sees great advantages in the research currently being done with Theta Burst Stimulation (TBS) which can shorten the treatment time by more than 30 minutes per session.

"If I could use TBS for many of my patients, it would make it much

easier to just charge \$100 per treatment," says McMullen.

Number of treatments is important

The usual and FDA cleared full treatment protocol for TMS depression treatment is 5 treatments a week for 6 weeks, but McMullen believes that the number of treatments is what is important. Therefore he is open towards giving the treatment less often.

"If the distance and logistics are very difficult for my patients, I will allow them to come in much less frequently – if for example the patient is only able to come in once a week, that patient will in my belief still benefit from the treatment. It will just take longer to get the full benefits of the treatment," says McMullen.

Strange sounding treatment with magnets

Even though depression treatment with TMS is successful, the success is ironically enough also keeping the number of referrals to McMullen's

practice down. TMS is simply too good to be true, believes McMullen who still gets almost half of his patients from his own practice, although other psychiatrists are finally beginning to refer their patients who do not respond to antidepressants to TMS treatment.

"It has been slow for other psychiatrists to begin to refer to me, although this is picking up. I think that referrals are difficult because of three things. First, the success rate is so high that it sounds too good to be true, so many psychiatrists do not believe it. Secondly, it is difficult to induce a patient to go to a strange doctor for a strange sounding treatment with magnets that cost thousands of dollars with no guarantees that there will be results. And thirdly, TMS is not as widely known and accepted as ECT. It is always surprising to me that some people will choose to have ECT rather than TMS," says McMullen and concludes that he would definitely like to promulgate TMS more.

FDA cleared*: MagVenture's MagVita TMS Therapy System® for treating Major Depressive Disorder

Benefits include:

- Very low operating costs: **no per-use fees** or costly disposable components to the system.
- Safety and efficacy rates that are **equivalent to other FDA cleared rTMS devices**, including a simple design and workflow for optimal ease of use.
- FDA cleared and CE approved.



More information at

www.magventure.com

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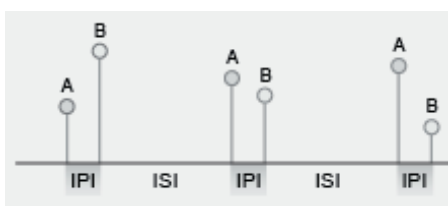
Courses and product news



MagVenture donates new TMS coil to humanitarian hospital in Ukraine

For the past 5 years, The Gerontology Institute at the National Academy of Medical Sciences of Ukraine has successfully been using a MagPro stimulator from MagVenture for the rehabilitation of patients suffering from stroke and head injuries (including members of the anti-terrorist association). MagVenture has now donated a new Cool-B65 coil as well as a super flex arm for the institute.

Above, Dr. Alexandra Semenova from the Gerontology Institute is seen with the new MagVenture Cool B65 coil.

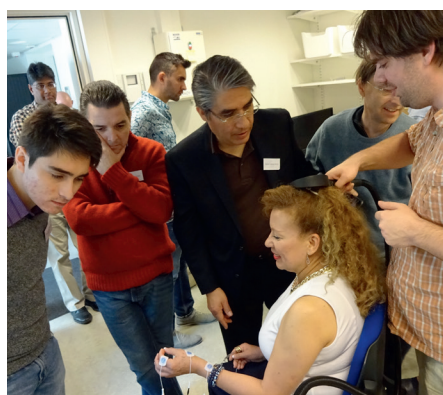


Paired-Pulse Composer for MagPro X100

With this program it is possible to set all the upper and lower randomization ranges and create a randomized paired pulse protocol within these ranges which can be executed on a MagPro X100. The protocol can easily be exported to a CSV file format, where it is possible to customize a protocol before loading it again. An unlimited number of protocols can be saved and loaded again at a later

stage. Press play and the protocol is executed on the MagPro. In order to get fully reliable research results, the realized outcome of the paired-pulse protocol is displayed.

It is possible to choose between monophasic, biphasic and half sine waveforms as well as current direction. Further, a specific randomized protocol is easily repeated with a different Motor Threshold ratio. Reports of all the executed protocols including the realized outcome of the MagPro can be printed.



Upcoming TMS courses

What: TMS Workshop
When: 7-9 December 2015
Where: Danish Research Centre for Magnetic Resonance, Hvidovre, Denmark

What: Advanced TMS Symposium
When: 10-12 March & 22-24 September 2016
Where: San Francisco, USA

What: Maastricht TMS Certification Course
When: 26-27 May 2015
Where: Maastricht University, The Netherlands

More information:
magventure.com/About/TMS-Courses

MagVenture at rehabilitation convention

The European Congress of Neuro-Rehabilitation (ECNR) takes place in Vienna on December 1-4.



At booth #5 MagVenture will display equipment used for neurorehabilitation research. The German Society of NeuroRehabilitation (DGNR) and the Austrian Society of NeuroRehabilitation (OeGNR) will also have their annual meetings for their members within the framework of ECNR.

More information:
www.ecnr.org



New A/P coil available

Due to increased use of our Cool D-B80 coil and a derived increased interest in conducting double-blinded clinical research studies with this exact coil, MagVenture introduces an A/P version (Active/Placebo). The Cool D-B80 A/P coil functions as both active (A) and placebo (P) coil. The symmetrical design with no indication of active vs. placebo side makes it ideal for double-blinded studies.

It has a simple software set-up allowing for blinding of both the patient and the operator. With a built-in orientation-switch to determine which side of the coil to be placed towards the patient, the software tells the operator whether to turn the coil or not. The coil has an adjustable output for current stimulation of the patient's skin synchronously with the magnetic stimulation pulses.

About MagVenture

MagVenture is a medical device company, established in 2007, specializing in non-invasive magnetic stimulation systems for depression treatment as well as for clinical examination and research in the areas of neurophysiology, neurology, cognitive neuroscience, rehabilitation, and psychiatry.

From its headquarters in Denmark, MagVenture develops and markets advanced medical equipment based on the use of pulsating magnetic fields.

MagPro magnetic stimulators are sold on the world market through direct sales subsidiaries in Germany and the USA, and through a global network of distributors in Europe, Asia, Middle East, and the Americas.

Regulations in the USA

In the USA federal law regulates the sale of Medical Devices through the US Food and Drug Administration (FDA). This is done to ensure safety and effectiveness. Devices which are permitted to be marketed for their intended use must either have a 510(k) or PMA clearance.

MagPro® stimulators R30, R30 with MagOption, X100, and X100 with MagOption are all FDA 510(k) cleared (k061645, k091940 and k150641). The intended use is treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

k061645, k091940: The intended use is for stimulation of peripheral nerves for diagnostic purposes.

The use of devices for other than their FDA cleared intended use is considered as investigational. Such use is only permitted if the Investigational Device Exemption (IDE) guidelines have been followed. For full information on this procedure, please consult FDA's website (www.fda.gov).

All investigational devices must be labeled in accordance with the labeling provisions of the IDE regulation (§ 812.5) and must bear a label with this statement:

“CAUTION Investigational Device. Limited by Federal (or United States) law to investigational use.”

Please note that transcranial magnetic stimulation (TMS, rTMS) with MagPro stimulators is considered investigational in the USA (except the above cleared intended use).

For further information please contact MagVenture.

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