# MagVenture **NEWS**

## *Guatemala TMS Center:* We must dispel the myths about depression and spread the word about TMS

*Neurology - Psychiatry Practice, Greece:* Diagnostic TMS is an incredible tool

## University of Aarhus:

cTBS research establishes a causal role of premotor cortex in action understanding

## University of Lyon:

Slow rTMS may be a useful alternative monotherapy for severe depression









## Diagnostic TMS - a valuable neurological tool

When we hear about TMS, the stories will often be about how rTMS is used for the treatment of resistant major depression and how researchers are exploring new possible treatment modalities and protocols. This trend is further strengthened by the increasing number of scientific articles that are also being published.

MagVenture NEWS has already brought you several articles with interviews of both healthcare practitioners and researchers. What we have perhaps neglected, however, is to bring stories from the slightly lesser known but nevertheless wellestablished, clinical field of diagnostic TMS.

TMS – applied either as single or paired pulse – was in fact originally developed for this exact diagnostic purpose. It is primarily used as a tool

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with various types of motor dys-

and other cranial nerves.

to Dr. Deftereos.

function such as multiple sclerosis,

amyotrophic lateral sclerosis, stroke,

movement disorders, disorders that

In this issue of MagVenture NEWS,

you can read our interview with Dr.

Spyros Deftereos, who is head of

the Athens-based clinic Neurology

- Psychiatry Practice. He has more

than 10 years of experience in using

diagnostic TMS. The accuracy of this

method can be up to 90 %, according

affect the spinal cord, as well as facial

diseases and impairments associated

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.



Studies furthermore suggest that diagnostic TMS may serve not "only" as a valuable tool within the diagnostic field but may also be used for prognostic purposes; as a biomarker to predict the response, for instance to a specific drug treatment or surgery.

Of course, for the patient, an early diagnosis (however devastating it may also be to receive a dreaded diagnosis) will allow the doctor to optimize and plan future treatment – whether this is surgery, medication or further investigation of the condition.

## Guatemala TMS Center: We must dispel the myths about depression and spread the word about TMS

A meeting at the American Psychiatric Association (APA) in San Diego in 2007 has had a profound impact in the career path of Dr. Edgar Castillo: Since then, he has opened 3 clinics that offer rTMS for depression treatment. Persistent marketing efforts combined with convincing clinical results ensure an increasing number of patients.

Until that day in May at the annual APA meeting in San Diego, Dr. Castillo had never before heard about TMS. The possibilities, however, immediately raised his curiosity.

For the next few years, Dr. Castillo carefully studied, reviewed literature and spoke to several colleagues. In 2010 he bought his first rTMS equipment and opened a clinic in Fresno, California.

The success came immediately, explains Dr. Castillo, and continues: – Not only was the technology well received by the patients, more effective treatment for depression in Guatemala. Dr. Castillo, himself Guatemalan with a medical degree from the Faculty of Medicine at the Univer-

#### The clinical response to the TMS treatment was dramatic.

#### Edgar Castillo

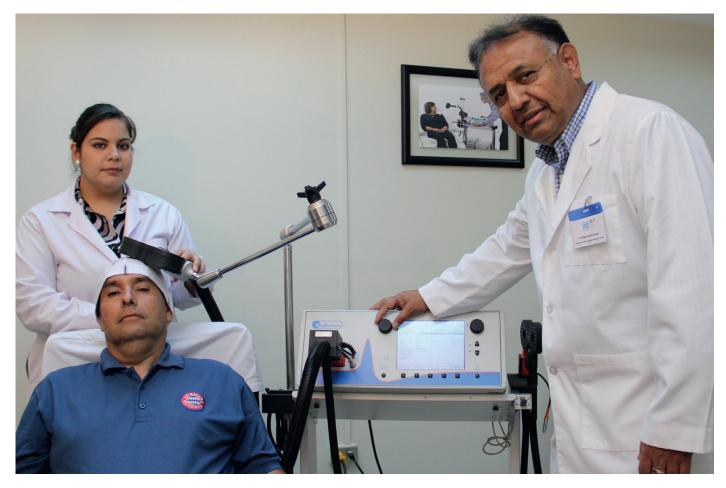
importantly, the clinical response to the TMS treatment was dramatic.

The following year, Dr. Castillo opened his second clinic in Visalia, California.

## Need for TMS treatment in Latin America

During a trip to Latin America, Dr. Castillo realized that there was a tremendous need for a safe and sity of San Carlos in Guatemala City, therefore initiated the long process of opening a new clinic in the Central American republic of about 15 million people, in which TMS treatment is virtually non-existent.

The installing and testing of equipment as well as the training of personnel were completed under the close support and supervision of MagVenture.



Since the opening in 2013, 30 patients have been treated for depression at the TMS clinic in Guatemala. Oscar Mayen, a former patient, is here seen seated in the treatment chair. Behind him is TMS coordinator Melisa Noriega and to the right the founder of the clinic, Dr. Edgar Castillo.

The TMS center in Guatemala, which opened in 2013, now has a multidisciplinary staff including a psychiatrist, a psychologist, a clinic administrator and a TMS coordinator.

#### Getting the word out

Public relations and promotional efforts were also launched in order to reach the general population. Besides getting exposure on national radio and TV, lecture presentations were also offered to primary care physicians, psychiatrists, psychologists, psychiatry residents, nurses, and the public in general.

#### **Expectations surpassed**

The strategy soon paid off: – Patients started coming and so far, more than 30 patients have been treated at the Guatemala TMS Center in the first 18 months of operation, surpassing our expectations, says Dr. Castillo.

#### Bringing relief is a great endeavor

When asked whether opening a clinic in Guatemala has been a financial success, Dr. Castillo responds: – Well, certainly it is a good cause and a great endeavor to bring relief from mental illness to a part of the world which is not very advanced technologically. But do not expect to get rich quickly; it takes time to break even. However, if it is done well I believe it can be quite sustainable.

## Desperate to find alternatives to medication

I believe people who suffer from a treatment-resistant depression are very desperate to find a non-invasive, non-systemic treatment that is both safe and effective, says Dr. Castillo.
TMS treatment for depression is an outpatient clinic procedure with minimal side effects which does not require sedation or anesthesia, he continues and further explains that the admission process is quite simple: either the patient or the family can contact the clinic directly to schedule a psychiatric evaluation.



Dr. Edgar Castillo (right) with his staff in Guatemala. From left: clinic administrator Lic. José Miguel Alvarado, TMS coordinator Melisa Noriega, and psychologist Susana Alvarez.

The clinic strongly recommends that the patient is accompanied to the initial interview by a significant other who can also be supportive throughout the whole process.  We use evidence-based effective psychotherapies tailored to the specific needs of each patient.
 In addition, our psychiatrist takes into account the impact of associated co-morbidities such as obesity,

It is a good cause and a great endeavor to bring relief from mental illness to a part of the world which is not very advanced technologically.

Edgar Castillo

#### Too much reliance on "happy pills"

In Dr. Castillo's opinion, the biggest challenge lies in providing more education, to improve the dissemination of knowledge, and to erase myths and taboos about TMS and about depression and mental illness in general. – We also have to change the reliance on "happy pills" for more confidence in the effectiveness of this new advanced technology, he states.

#### Individualized treatment

The Guatemala TMS Center has developed evaluation and treatment protocols which emphasize a comprehensive psychiatric examination followed by close monitoring of the clinical response utilizing researchtested depression scales. Furthermore, the clinic may also enroll in an elective rotation program for an advanced psychiatry resident.

We have to change the reliance on "happy pills" for more confidence in the effectiveness of this new advanced technology.

Edgar Castillo

diabetes type II, high blood pressure, thyroid problems, high cholesterol and lipids, ischemic heart disease, and renal problems, says Dr. Castillo. If needed, a medical stabilization will be coordinated with other specialists.

#### **Focus: Life After Depression**

"Brain Food" training, Life Coaching and the elaboration of "Life Personal Changes" are all part of the center's comprehensive approach to wellness that are offered to facilitate a quicker reintegration to normal life.

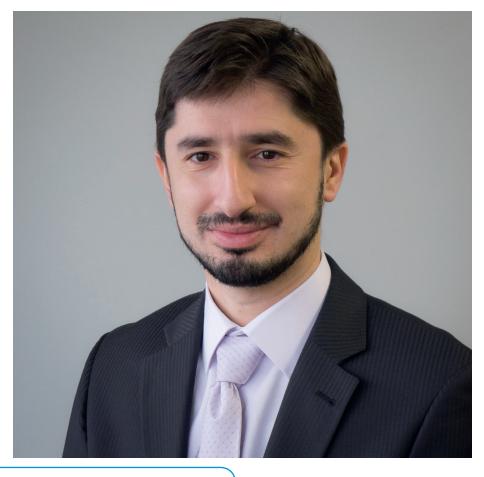
## Goal: Improving Access to TMS Treatment

– For those who cannot pay the full fee, we offer PAP (patient assistance programs), easy financing and program incentives. The goal is to make this treatment accessible to the great majority of people, explains Dr. Castillo, and concludes: – Treating severe, pharmaco-resistant depression is best left to a team of specialists with a psychiatrist at the helm. This way we can identify a number of other therapeutic issues in need of attention and make specific recommendations for treatment and future follow up, concludes Dr. Castillo.

## Neurology - Psychiatry Practice, Greece: Diagnostic TMS is an incredible tool

Dr. Spyros Deftereos, head of the Athens-based clinic Neurology -Psychiatry Practice has worked with diagnostic TMS for more than a decade and evaluated hundreds of patients to determine their need of spinal surgery. Today, Dr. Deftereos relies more on TMS results rather than MRI when it comes to predicting long-term functional outcome, for instance in patients suffering from spinal cord dysfunctions such as cervical spondylosis, a (mostly) age-related condition affect the joints in the neck.

- I was excited early on by the potential to study central pathways and modulate them, says Dr. Deftereos when asked what initially caught his interest in diagnostic TMS. To date, he has used diagnostic TMS on several hundred patients. The patients are often referred by neurosurgeons who want to know whether spinal surgery is necessary or not.



Diagnostic TMS is an affordable and important method that can greatly accelerate the diagnosis and rule out irrelevant possibilities.

Spyros Deftereos

#### An incredible diagnostic tool

Over the years, Dr. Deftereos has followed up closely on the surgery/ no-surgery decisions that he, based on TMS as well as the other neurophysiology tests and MRI scans, has made:

 Our results – which have also been published in Spinal Cord – conclude that diagnostic TMS is an incredible neurophysiological tool that can guide diagnosis towards or away from brain/spinal cord pathology, says Dr. Deftereos.

In his opinion, the decision to operate or not should actually be based more on TMS results rather than on MRI and further mentions that he has registered a steady increase in the number of referrals over the years.

## Early diagnosis benefits the patient

An early diagnosis will first and foremost benefit the patient who, based on the outcome, will either be advised to proceed to spinal surgery – or informed that he or she suffers from a disease involving the central nervous system (such as ALS), allowing for a better treatment plan in the future. – Often, a patient with motor or sensory symptoms who is initially suspected to have a problem in the spinal cord will instead prove to suffer from Parkinson's disease, explains Dr. Deftereos.

#### 90% diagnostic value

The diagnostic value of TMS in spondylotic myelopathy (caused by cervical spondylosis), is very high, up to 90%, according to Dr. Deftereos. This is due to the pyramidal tracts that are involved in the control of the motor functions of the body.

This functionality, which is tested by TMS, is the first to be affected in cervical spondylosis. - Therefore, if TMS is normal then one can be fairly certain that cervical spondylosis is not present, says Dr. Deftereos. - If the MRI scan shows a lesion in the spinal cord, then a different cause should be sought. I have often seen lesions that were caused by Multiple Sclerosis, especially in younger patients. In my experience, MS lesions in the spinal cord frequently appear at the level of a herniated disc, and can be confused with cervical spondylosis. The specificity of TMS, on the other hand, is not as

Often, a patient with motor or sensory symptoms who is initially suspected to have a problem in the spinal cord will instead prove to suffer from Parkinson's disease.

**Spyros Deftereos** 

high. An abnormal TMS evaluation can be the result of many different pathological conditions affecting the brain and the spinal cord. Thus, such results should be interpreted with caution, and always in conjunction with the cervical and brain MRI.

## Combining rTMS and psychotherapy

The Neurology - Psychiatry Practice also offers rTMS for depression treatment, often in combination with psychotherapy.

– It is very difficult to bring somebody to your practice every day for psychotherapy, but when they come for a revolutionary treatment such as rTMS, they have a good reason to come, says Dr. Deftereos. – We take this opportunity to approach their problem in a multidisciplinary, personalized way.

Today, rTMS for depression treatment is not widely available in Greece.

This, however, might be about to change: – Recently, colleagues who want to implement rTMS have started to visit my practice for demonstration of the methods and for brief training, says Dr. Spyros Deftereos.

#### **Education is essential**

As for the future of motor evoked responses for diagnostic purposes, Dr. Deftereos is optimistic: – Diagnostic TMS is an affordable and important method that can greatly accelerate the diagnosis and rule out irrelevant possibilities. I expect it to be increasingly used in the coming years.

He further stresses that education of the end users, mainly spinal cord surgeons, neurosurgeons and orthopedicians, is a key element in this process and also points out some potential challenges: – Not many of them are currently acquainted with TMS and there is some resistance to be expected here; TMS may advice against surgery, which might not be

#### Diagnostic TMS

The method is used to measure the activity and function of specific brain circuits in humans.

Diagnostic TMS is applied as single or paired pulse stimuli.

Diagnostic TMS is especially used to measure the connection between the primary motor cortex and a muscle in order to evaluate the damage from stroke and multiple sclerosis, amyotrophic lateral sclerosis, movement disorders and injuries and other disorders affecting facial nerves as well as the spinal cord.

desirable by some. However, I find that those surgeons who want to make the right treatment decisions consider TMS evaluations seriously. And they are absolutely right: the surgical outcome can only be good if surgery is indeed indicated, concludes Dr. Deftereos.

#### **Doctor Spyros Deftereos**

Dr. Deftereos is the head of the Neurology - Psychiatry Practice in Athens, Greece.

He completed his studies at the School of Medicine, University of Athens, with particular emphasis on clinical neurophysiology.

Furthermore, he conducted research work on Transcranial Magnetic Stimulation, focusing on the pre- and post- surgical evaluation of Cervical Myelopathy. Dr. Deftereos completed his PhD at the University of Athens.

He is the Senior Vice President for Drug Discovery at Biovista, a Greek-American company that specializes in (drug repositioning) and Adverse Event prediction.

Dr. Deftereos publishes extensively in Clinical Neurophysiology and Biomedical Informatics and is a reviewer for several international journals in these fields.





## University of Aarhus: cTBS research establishes a causal role of premotor cortex in action understanding

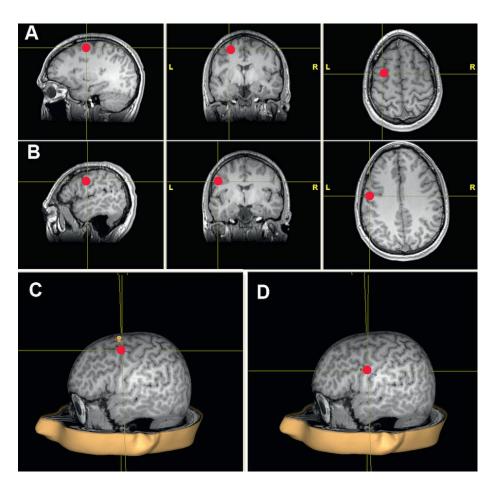
At the Center of Functionally Integrative Neuroscience at University of Aarhus, Denmark, Postdoctoral researcher Dr. John Michael and his colleagues used offline cTBS to demonstrate that the same neural circuits are involved in both production of actions and in understanding actions.

– We were able to show that the hand area and the lip area in premotor cortex – the areas that specialize in executing actions with the hand and the lip – are also involved when people perceive and make judgments about other people's actions, says John Michael of his recent action understanding study in which continuous Theta Burst Stimulation (cTBS) proved to be the best and most sensible method for the experiment.

## Causal role in understanding actions

– A lot of imaging studies show that the hand area and the lip areas are indeed active when watching others perform actions. Imaging studies, however, only establish correlations, so it was important to employ a causal method like cTMS in order to establish that these areas really do play a causal role in understanding actions, says John Michael of the study setup.

In the study, 20 participants received cTBS over the hand and lip areas of the left premotor cortex.



Stimulation sites for cTBS. The red circle (a) marks the hand area in premotor cortex. The red circle in (B) marks the lip area in premotor cortex. In (C) the hand area is at the red circle, and in (D), the lip area is at the red circle.

tion as the participants were less accurate in recognizing pantomimed hand actions after receiving cTBS over the hand area than after receiving stimulation over the lip areas, and vice versa.

As far as I know, it is the first time that cTBS has been used for such a high-level social cognition task.

John Michael

The cTBS stimulation was given in separate sessions before completing a pantomime recognition task in which half of the trials were pantomimed hand actions and half were pantomimed mouth actions.

The results reveal a double dissocia-

#### A very strong case

– As far as I know, it is the first time that cTBS has been used for such a high-level social cognition task. Our findings teach us that the mechanisms for action production overlap with the mechanisms for action understanding. It is important to emphasize that the effect was bodypart specific, unlike the other TMS studies so far. This makes the case very strong that it is indeed the same neural circuits that are involved in both the production of action and in the understanding of actions. Otherwise, a skeptic might argue that neurons in the motor system are exclusively involved in producing actions whereas other neurons are exclusively involved in understanding actions. This skeptical position must now appear to be quite unlikely, because it would mean that some neurons are specifically involved in producing hand actions and some are specifically involved in understanding hand actions, and they just happen to be in the same spot by some sheer coincidence. And the same is true for lip actions, says John Michael.

#### **Advantages of cTBS**

It is the first time John Michael has worked with cTBS. It has been a positive experience, although it took some practice to learn how to use the navigation system correctly in order to target specific locations in the brain and return to the same targets in subsequent sessions. But the advantages were bigger than the challenges, according to John Michael. - One advantage was that we could apply cTBS before the experiment. The effect lasted for about 20 minutes so we did not have to worry about timing the TMS pulses perfectly to match the presentation of stimuli during the experiment. Furthermore, we did not have to worry about people moving around making it difficult to target the same site since all of this was done before the experiment, says John Michael who plans to do a follow-up study soon.

#### Follow-up study on the way

– The last study did not show any difference in the effect according to how complex the actions were. For more complex actions, especially ones in which context is relevant, we believe that other brain areas play a greater role. So I would like to investigate this in the next step, says John Michael.

## cTBS in studies of real social interactions.

– In the future, I would like to try using TMS – or most likely cTBS – in studies of real social interactions as opposed to having people passively observe actions. I think cTBS would be a great way to go about this since the stimulation is administered prior to the experiments so during the experiment people can actually move around freely, says John Michael who



Dr. John Michael has used offline cTBS for a high-level social cogniation task and has showed that the same neural circuits are involved in both production of actions and in understanding actions.

is also interested in learning more about cases in which social cognition does not function smoothly such as autism and schizophrenia.

- There is also a lot of focus on general models of the brain functions.

After many years of research in cognitive neuroscience, and despite having wonderful new technology, we are still missing a general theory of brain functioning to guide and structure research, ends John Michael.

#### Continuous Theta Burst Stimulation (cTBS)

John Michael used the following protocol given at 70% of the resting motor threshold (RMT): 300 pulses were administered in 100 bursts of three pulses each over a 20 second period.

The frequency within each burst was 50 Hz, and the bursts were repeated with a frequency of 5 Hz. The three pulses were given in a span of 40 milliseconds (pulse 1, 20 ms pause - pulse 2 - 20 ms pause - pulse 3), followed by a 160 ms pause before the pattern was repeated for a total of 20 seconds.

#### **Doctor John Michael**

Dr. John Michael is the author of about 20 articles. In his research, John Michael focuses on social cognition, trying to understand the cognitive mechanisms that enable people to predict each other's actions, to coordinate with them, and to respond appropriately. In particular, he has worked on the theory of mind debate, joint action, mirror neurons and embodied cognition.

At present, he is developing a psychological theory of trust and commitment.



www.interactingminds.au.dk http://au.academia.edu/JohnMichael



## University of Lyon: Slow rTMS may be a useful alternative monotherapy for severe depression

Low frequency rTMS of 1 Hz lasting just 8,5 minutes instead of the conventional 37 minute 10 Hz protocol may prove to be a useful alternative for patients suffering from treatmentresistant unipolar depression (TRD). This is the conclusion made by the researchers behind a recent multicenter study, involving 18 centers in France and a total of 170 patients.

The study, which was conducted as a randomized controlled double-blind trial, is the first of its kind using low frequency (1 Hz) rTMS, or LF rTMS in short. The participants were randomly allocated to one of three arms of the study: the first group was given active rTMS combined with placebo venlafaxine, the second received sham rTMS combined with active venlafaxine and the third group, the combination group, received both active rTMS and active venlafaxine.

All 170 participants had a high level of treatment resistance; all had failed prior treatment, and 38% had even failed three prior treatments. None of the patients had, however, tried rTMS prior to being enrolled in the trial.

## 41% remission rate from LF rTMS treatment

Contrary to the initial hypothesis of the research group, there was no considerable difference between the three groups, although previous studies have indicated otherwise.

– Our study showed that for patients suffering from treatment-resistant depression, LF rTMS is as effective as serotonin-norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine, or as receiving the combination treatment of both LF rTMS and SNRI, says Dr. Jérome Brunelin from Centre Hospitalier de Vinatier who is also the first-author of the article which was published in 2014 in Brain Stimulation.

As for the results, the 60 participants who only received only LF rTMS treatment had a remission rate of 41% and a response rate of 59%. For the combination group, the remission rate was 28% and the response rate 54%. The number of remitters in the group who only received venlafaxine was 41%, and the number of responders was 60%.

## More research needed within combination treatment

- The best combination between non-invasive brain stimulation and pharmaceutical approach is still under debate, explains Dr. Brunelin



 Our study showed that for patients suffering from treatment-resistant depression, LF rTMS is as effective as SNRIs, or as receiving the combination treatment of both LF rTMS and SNRI,

Jérome Brunelin



Dr. Jérome Brunelin (right), sees great advantages in using low frequency rTMS for the treatment of MDD. Dr. Brunelin is here seen during a TMS workshop at the 12th World Congress of Biological Psychiatry in Athens along with Dr. Mark George (sitting), Director of the Medical University of South Carolina Brain Stimulation Laboratory. who also stresses that the interaction between SNRI and LF rTMS is hard to explain and will therefore need further investigation. He further points out that previous research reports that combining transcranial direct current stimulation – where a constant, low current is delivered to the brain via electrodes on the scalp – and sertraline is also superior to each treatment alone.

– Future research should investigate the predictive marker of response to determine which kind of patient will respond to which kind of brain stimulation combined with which kind of antidepressant, mainly SSRI, which is a Selective Serotonin Reuptake Inhibitor, or SNRI, says Dr. Brunelin.

## Finding the balance between hypo- and hyperactivity

Neuroimaging studies have shown an imbalance in the activity between the left and right DLPFC in patients with MDD with a hypoactivity in the left DLPFC and a hyperactivity in the right DLPFC. Furthermore, neurophysiological studies that have investigated the effect of rTMS applied over the motor cortex, report that high frequency rTMS (HF rTMS) can increase cortical excitability whereas LF rTMS can decrease it.

- This means that we basically have two treatment options, explains Dr. Brunelin: - The first one is to use HF rTMS to increase the activity of the hypoactive left DLPFC. The second one is, as we proposed in the study, to apply LF rTMS over the right DLPFC to decrease the hyperactivity. Previous studies report that both approaches are equally effective to decrease the symptoms for patients with MDD.

#### **Increased safety and shorter** treatment time

To Dr. Brunelin, the biggest advantage of LF rTMS as compared to HF rTMS is the safety aspects. The risk of having a seizure as a result of receiving HF rTMS is already considered exceedingly low. However, with LF rTMS this minimal risk is reduced even further – with only one seizure reported, according to the international safety guidelines [Rossi et al., 2009]. Some patients also report of a slight headache in the initial part of a HF rTMS treatment. This side effect is also reduced when using LF rTMS. Finally, as Dr. Brunelin points out, the advantage of the duration of one session of 8.5 minutes is, of course, also an advantage. In connection with shorter treatment protocols it is also

important to note that Dr. Jonathan Downar's team at the University of Toronto has reported a comparable efficacy from a 6 minute 10 Hz rTMS and intermittent Theta Burst Stimulatin (iTBS) applied over the left DLPC in 202 patients with MDD [which has also been described in MagVenture NEWS #5, ed.].

#### Low Frequency rTMS (LF rTMS)

The low frequency protocol and study set-up described in this article has been developed by the STEP section (Association française de Psychiatrie Biologique\* involved a 1 Hz protcol for 8,5 minutes. A total of 360 pulses per LF rTMS session were applied on the right DLPFC with one treatment per day, five times per week for a period of 6 weeks.

LF rTMS differs from the primary line of treatment as well as approved stimulation pattern for treating refractory MDD in which 3,000 pulses are delivered at a high frequency of 10 Hz on the left Dorsal Lateral Pre Frontal Cortex (DLFPC) for a complete duration of 37,5 minutes.

\* Brunoni AR, Valiengo L, Baccaro A, Zanão TA, de Oliveira JF, Goulart A, Boggio PS, Lotufo PA, Benseñor IM, Fregni F. The sertraline vs. electrical current therapy for treating depression clinical study: results from a factorial, randomized, controlled trial. JAMA Psychiatry. 2013 Apr;70(4):383-91.



Theta Burst Stimulation (TBS) is a patterned form of rTMS which has recently shown to produce similar if not greater effects on brain activity than standard rTMS.

MagVenture's solution includes:

- 6 minutes Theta Burst protocol
- Same efficacy as 10 Hz standard protocols
- CE-approval for major depression

More information about TBS at www.magventure.com





## Courses and product news



#### MagPro Configuration

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#### CED's Signal software now supports MagPro stimulators

A new interface to support the MagPro product range has now been developed which will allow for an easy system set-up of complex TMS research studies. The software interface, which has been developed by the data acquisition company Cambridge Electronic Design for their Signal software, makes it easy to connect the CED 1401 unit to the MagPro to record waveform data, digital (event) and marker information. It also makes it possible to generate waveform and digital outputs simultaneously for real-time, multitasking experiment control.

The Signal software system provides direct control of MagPro stimulators during sampling, including adjusting stimulus amplitude and timing and checks on stimulator condition. All settings are stored with the corresponding data frame.

The program can generate stimulus outputs of up to 8 analogue and 16

digital lines from a CED 1401 interface.

In addition to controlling the MagPro stimulator for motor evoked potentials, the Signal program is also able to control Somatosensory evoked potentials, Auditory evoked potentials and Visual evoked potentials – and of course combine them all.



#### Clinical TMS Certification Course in Maastricht

MagVenture and Maastricht University will once again offer their Clinical TMS Certification Course. This course is aimed at clinicians, researchers, and healthcare professionals and is offered at two levels: a basic level for beginners and a medio-advanced level for participants already working with TMS who wish to be brought up to date and to discuss directly with experts and colleagues within the field.

The course, which has not only attracted healthcare professionals from Europe but also North America, South America, and Asia, will take place on September 24-25, 2015, at Maastricht University's Brain Imaging Centre.

The center has optimal facilities, including fully-equipped TMS laboratories, brain imaging, and electrophysiology, for hands-on sessions and demonstrations, auditoriums as well as lecturers from both the psychiatric and neurological fields and combine the following elements:

 Academic sessions and research presentations within TMS for psychiatric disorders and rehabilitation

- Hands-on training
- Individual feedback on intended protocols or procedures

Please register as soon as possible to ensure a seat.

**Place**: Maastricht Brain Imaging Center, Maastricht University, The Netherlands

Date: September 24-25, 2015 Number of participants: 25 max. Price: €600, including coffee, lunches, and dinner event





#### Certificate TMS Course in Sydney

The Black Dog Institute offers a 2-day course in Transcranial Magnetic Stimulation theory and practical techniques, including hands-on practice in administering TMS.

This course is suitable for clinicians and researchers who want to better understand TMS and gain practical skills in administering TMS.

The course will be taught by leading international experts in Neurostimulation, Mood disorders and Neuropsychiatry: Professor Colleen Loo (Course Director) as well as lecturers Professor Philip Mitchell, Professor Perminder Sachdev, and Professor Janet Taylor.

**Date**: 17-18 September 2015 **Place**: Black Dog Institute, Randwick, Sydney, Australia.

> Further information and registration: a.alonzo@unsw.edu.au www.blackdoginstitute.org.au

## 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). The intended use is stimulation of peripheral nerves for diagnostic purposes. The use of devices for other than their FDA cleared intended use is considered 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.

For further information please contact MagVenture.

Get the latest news on Magnetic Stimulation – sign up for MagVenture NEWS at

#### www.magventure.com

#### MagVenture A/S

Lucernemarken 15 3520 Farum Denmark Phone: +45 4499 8444 info@magventure.com

#### MagVenture, Inc

303 Perimeter Center North Suite 300 Atlanta GA 30346 USA Phone: +1 888-MAGPRO-4 infousa@magventure.com





#### MagVenture GmbH

Schmelzerstraße 25 47877 Willich Germany Phone: +49 (0) 2154 814 56 50 infodeutschland@magventure.com

#### www.magventure.com