

MagVenture **NEWS**

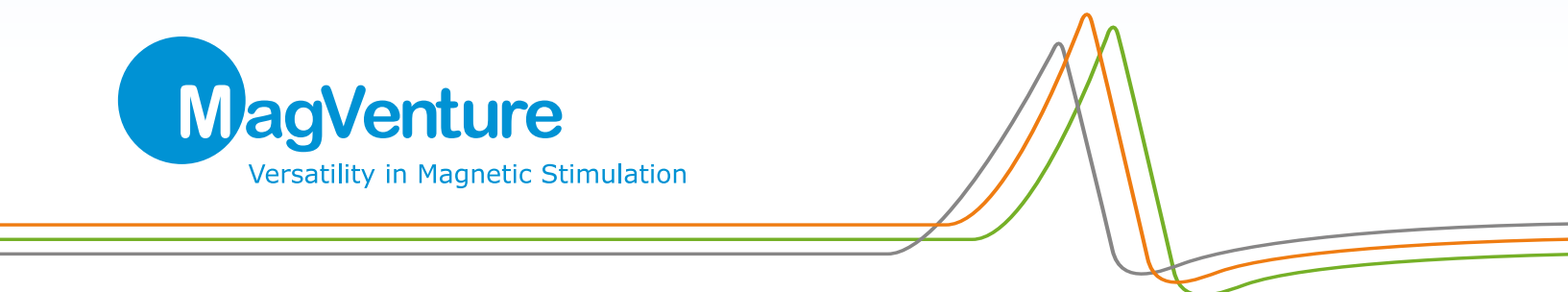
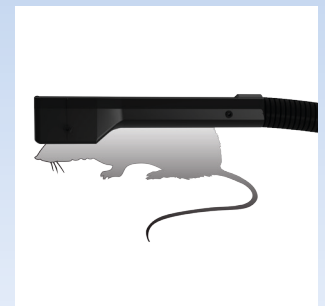
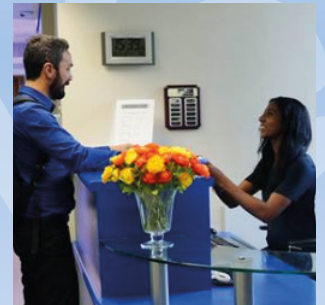
Smart rTMS, United Kingdom:
New approval in the UK will help ensure further dissemination of rTMS

Cocaine addiction:
10 questions for Professor Luigi Gallimberti, IRCCS San Camillo Foundation, Venice

Ghent University:
Accelerated iTBS offers an enormous time gain

University of Antwerp and University of Western Australia:
Rat coil catalyses translational rTMS research

American Brain Stimulation Clinic:
TMS therapy is the beginning of change for the clinician



Broad acceptance of rTMS for depression treatment

In December of 2015, the National Institute for Health and Care Excellence (NICE) in the UK issued full guidance to rTMS depression treatment. With this guidance, rTMS for depression treatment has officially been approved in the UK. This is first of all great news to the many people suffering from major depression as they are now entitled to rTMS treatment if it is recommended by their National Health Service psychiatrist.

The approval is also great news for those who want to help spread the awareness and usage of rTMS for depression treatment. Dr. Leigh Neal from the recently opened Smart rTMS clinic in London is one of these people. Being one of the rTMS pioneers in the UK, he and his business partners have a well-defined goal of educating the general public, as well as the private practitioners and the

psychiatrists about the possibilities of rTMS depression treatment.

In California, Dr. Rustin Berlow offers rTMS depression treatment. He would like to see rTMS being offered as a first-line treatment. At Ghent University in Belgium, Dr. Chris Baeken is leading a Theta Burst Stimulation depression study using an accelerated rTMS protocol involving multiple, separated daily rTMS sessions bringing the treatment period down to just one week compared to the standard 4-6 weeks.

For now, rTMS remains a second-line treatment after medication, but as far as Theta Burst Stimulation is concerned, the great news is that NICE has not limited the approval in the UK to the standard 37-minute treatment protocol. Rather, NICE has approved all forms of rTMS – such as the afore-



mentioned Theta Burst Stimulation, as well as high and low frequencies, and left and right side stimulation.

We hope that other national health care authorities will get inspired by NICE and choose similar approaches in other countries and hereby provide access to rTMS treatment to an even larger number of patients who suffer from depression.

Stig Wanding Andersen
CEO, MagVenture

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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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Smart rTMS, United Kingdom: New approval in the UK will help ensure further dissemination of rTMS

The National Institute for Health and Care Excellence (NICE) in the UK approved rTMS for depression treatment in December 2015. Patients are now entitled to rTMS treatment if it is recommended by their psychiatrist. When the NICE approval came, Medical Director Dr. Leigh Neal and his partners at the well-established private medical facility Smart Clinic had already invested in TMS equipment and were ready to open Smart rTMS in London.

“The decision to open Smart rTMS was made very quickly after a discussion with the owners of Smart Clinic. I have had a long-term interest in biological treatments in psychiatry, I had been following the progress of rTMS as a treatment for depression in the medical literature and decided that now was the time to invest. Based on the scientific evidence, I thought that the full approval issued by NICE was a foregone conclusion,” says Dr. Leigh Neal of his decision to start offering rTMS depression treatment.



Reception of the Smart rTMS Clinic at Brompton Cross in London. Based on the scientific evidence, the full approval by NICE which was issued in December 2015 was a foregone decision, according to Medical Director Dr. Leigh Neal, who hopes to open more rTMS clinics in the years to come.

history of psychiatry, it is undoubtedly the biological treatments which have had the most beneficial effect on the impact of mental illness on society, such as the introduction

of treatment, which has the potential to relieve many people of the burden of depression and without significant side-effects,” says Dr. Neal who chose MagPro as the TMS equipment for the new clinic mainly because MagPro already had a good track record in the UK with some other early adopters.

In 5-10 years from now, I believe rTMS will be a substantial part of the treatment protocol for depression in the UK.

Leigh Neal

“My main motivation for working with rTMS is an interest in biological treatments for depression. In the

of the antipsychotics, antidepressants and electroconvulsive therapy. rTMS is a very safe and different

Potential: 120 rTMS clinics in the UK?

With the NICE approval, rTMS has the potential to become a substantial part of the treatment of depression

The UK NICE guidance on rTMS for depression

The UK National Institute of Health and Care Excellent (NICE) issued full guidance on rTMS for depression in December 2015. The approval not only covers the standard, left sided rTMS protocol, but also allows for right sided stimulation as well as high and low frequency protocols. Theta Burst Stimulation (TBS) which shortens the treatment time markedly compared to standard rTMS is also covered by the approval. (For more information about TBS depression studies, read the article of page 7 in this edition or MagVenture NEWS #5).

More information about the NICE guidelines: www.nice.org.uk/guidance/ipg542

in the UK in the foreseeable future, predicts Dr. Neal.

"In the USA after the FDA approved the procedure in 2008, there were over 500 rTMS clinics in operation by 2015. Proportionally per head of population this would be the same as 120 clinics in the UK. However, the National Health Service (NHS) in the UK will also be offering a free service along-side the private clinics, but there will be financial limits on its rate of introduction. The response of the private medical insurers will also dictate the pace to some extent. However, the service will be provided in the future. In 5-10 years from now, I believe rTMS will be a substantial part of the treatment protocol for depression in the UK," says Dr. Neal.



The Smart rTMS Clinic, which opened in 2016, is located near South Kensington Station in London.

rTMS is a very safe and different form of treatment, which has the potential to relieve many people of the burden of depression and without significant side-effects.

Leigh Neal

Education about TMS needed

"We expect the introduction of rTMS depression treatment in the UK to be quite slow at first, but that it will follow an exponential growth curve once

professional and public knowledge increases. The NICE approval was critical in starting this process. We plan to put a lot of effort into educating the general public, general prac-

tioners, other psychiatrists and NHS medical directors," says Leigh Neal of his future plans for Smart rTMS.

Eventually Dr. Neal would like to expand the number of Smart rTMS clinics and he also wants to look into offering other treatments with rTMS. "I have been looking into other potential forms of treatment of rTMS and the treatment of neuropathic pain in the future looks promising, ends Dr. Neal.



Doctor Leigh Neal

Dr Leigh Neal has a Research Doctorate (MD) in psychiatry. He is the Medical Director at the Smart rTMS clinic and responsible for the day to day running of the clinic with the assistance of a TMS nurse operator. Dr Neal is registered as a specialist by the General Medical Council in the UK.

He was first appointed as a Consultant Psychiatrist in 1994 and was appointed as an Honorary Senior Lecturer in Psychiatry at Leeds University and at Kings College University, London.

He has particular expertise in the treatment of chronic depression, addictions, PTSD, and chronic pain. He is the author of 38 peer reviewed scientific articles and is a reviewer of academic articles for various publications. He has been certified in the safe use of repetitive transcranial magnetic stimulation (rTMS) at Maastricht University.



More information at: www.smarttms.co.uk

Cocaine addiction: 10 questions for Professor Luigi Gallimberti, IRCCS San Camillo Foundation, Venice

rTMS treatment may result in a significant reduction in both cocaine use and cocaine craving. Such is the conclusion of a new pilot study involving 32 cocaine-addicted individuals. The specific clinical hypothesis of the study was inspired by experiments in rodents, which involved stimulating the brain with light – also known as optogenetics. But instead of light, the researchers used rTMS – with promising results. A larger, double-blinded study is now on the way. MagVenture NEWS spoke with the main corresponding author of the study, Professor Luigi Gallimberti, about his research within addiction.

1. You have recently conducted a pilot study in rTMS and cocaine use. What were the key findings?

In the pilot study we saw a significant reduction of craving for cocaine in the experimental group (about 70%) vs. the control group (about 30%) and, consequently, an important reduction in the first group of the use of cocaine. This reduction of both craving and actual use of cocaine seems to be persistent over time. In 2013, we started an observational study, treating over 100 patients with rTMS. Here we obtained very similar results to those of the pilot study.

2. How did the protocol differ from a conventional depression treatment?

Our protocol is similar to the conventional depression treatment. However, previous studies where rTMS has been used to treat cocaine addiction seemed quite conservative so we increased the frequency of stimulation from 10Hz to 15Hz. We stimulate on the dorsolateral prefrontal cortex (DLPFC) as described in a typical depression protocol but we reduce the session time from 37 to 13 minutes.

3. What is important before doing rTMS?

In order to understand whether the rTMS protocol works or not, it is

important to perform a good diagnosis of cocaine dependence excluding a psychiatric comorbidity as it is difficult to understand whether problems are related to the cocaine addiction or other issues.

4. Are there plans of conducting more/bigger studies?

Yes, our first study was open label, and now we are going to realize a double-blind study. We have created a strong collaboration with Professor Antonello Bonci at the National Institute on Drug Abuse in Baltimore, and with the Rehabilitation Institute at Northwestern University Feinberg

5. How did you become interested in addiction?

My interest springs from a deep conviction that mental disorders originate in the brain. Back in the 1970's, when I began my research, experts believed that the mind and the brain should be regarded as two separate entities, one organic and one functional, each governed by its own laws. Even today, addiction is still not considered a functional or organic disorder; instead, many believe that it is caused by various individual or social problems.

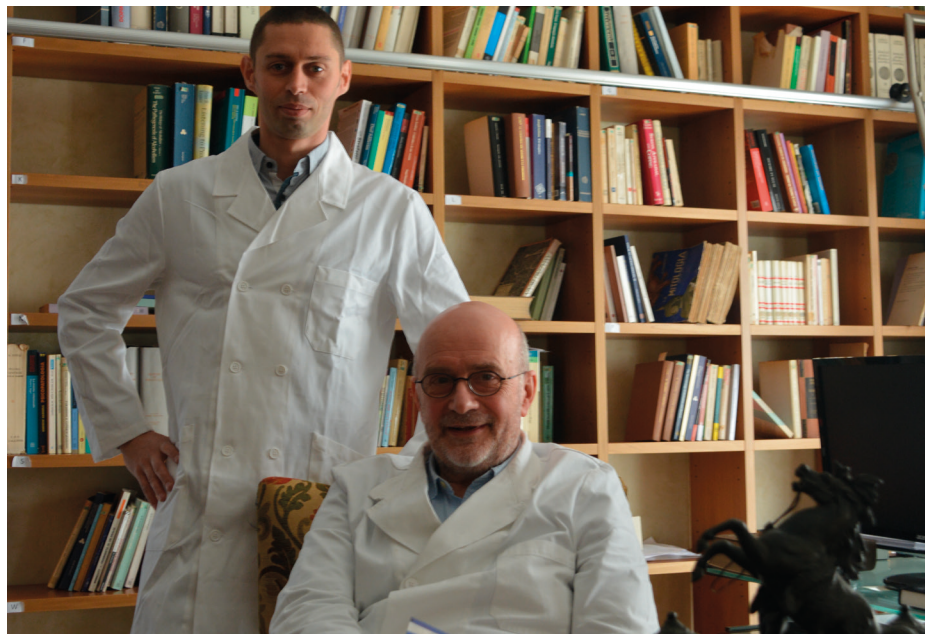
Some of the most significant improvements we have so far seen with TMS treatment are: reduced craving, reduced loss of control, and improvement of sleep quality, mood, concentration, and problem solving.

Luigi Gallimberti

School of Medicine in Chicago, directed by Professor Tommi Raji, with whom we are going to realize a brain atlas based upon the clinical efficacy of the TMS treatment spot.

6. What is your focus within rTMS research?

The focus of our research has been to identify a strategy to reach the impaired neural circuits and, if possi-



Professor Luigi Gallimberti (sitting) and Dr. Alberto Terraneo, both from the Venice-based IRCCS Research Hospital, are planning a larger scale, double-blind rTMS study on cocaine addiction. The study, which is planned to include 80 patients, will be carried out in collaboration with other research institutions.

ble, to repair them in a stable manner. Thanks to the results we have obtained using rTMS, I have been able to confirm our hypothesis; that addiction originates in the brain.

7. What kind of addictions do you treat?

At the moment we treat only cocaine addiction, but we also study other types of addiction such as behavioral addiction.

8. What are some of your most significant discoveries?

We found that although medication may reduce the craving for substances, it has a major limitation: the desire still “lurks in the dark” and intense stress may reactivate the memory of a drug, even though the patient hasn’t used the substance in years.

The withdrawals, which can be activated through the exposure of a trigger – a cue that reminds the addict of the drug – are characterized by an uncontrollable, and often violent, desire to try it again. Some of the most significant improvements we have so far seen with TMS treatment are: reduced craving, reduced loss of control, and improvement of sleep quality, mood, concentration, and problem solving.

9. What challenges did you encounter?

The biggest challenge is keeping the craving under control, especially for cocaine. A hypoactivity of the prefrontal cortex (PFC) seems to be related with the craving for the co-

Patient case

Professor Luigi Gallimberti: “Below is an excerpt of the diary of one of our patients. The history of this patient resembles that of many of the more than 200 patients that we have so far treated with rTMS.”

Diary of male patient treated for cocaine addiction, 55 years:

In late December 2013, my partner told me that he had heard Professor Gallimberti speak of a new therapy against cocaine addiction. [...] I wanted to transform the negativity of addiction and let hope overtake skepticism [...]. As an atheist I have never considered or hoped for miracles. Yet [...] already after the first session with this new equipment, I realized that my miracle could happen.

Any action or thought during abstinence had so far been impossible; I would sleep and sleep and wait for the “courier”. Instead, after the first [rTMS, ed.] session, many withdrawal symptoms were gone and others were bearable. After a few days of treatment and adjustments related to the stimulation protocol, I really had the feeling of winning a lottery! I was definitely better than before I started with cocaine [...]. Wakefulness and natural energy is strengthened with each passing day.

It’s been exactly 41 days since my last “shot” [of rTMS; ed.] and I feel like a different person, a person freed from the condition which forced me to take cocaine: I am free to live, work, walk, watch, reflect [...] And also to be moved and cry with empathy and sensitivity.

caine in both rodents and humans. Professor Bonci has treated the pre- limbic cortex in rats with optogenetic technique, a method that uses light to control neurons which have been genetically sensitized to light and found that the cocaine-seeking behavior of the rats decreased as a result of this treatment. Research gave us the idea to treat the homologous region in the PFC of the human brain with TMS. Optogenetics is an invasive technique and not possible to use on human beings but TMS is non-invasive and therefore suitable.

10. Do conventional treatment strategies have any shortcomings?

As reported by the National Institute of Mental Health, traditional drug treatments for treating addiction appear to have stalled. Up to date, there is no clear “conventional” treatment that truly works when it comes to cocaine addiction (pharmacological, psychotherapeutic and other). This is without a doubt the biggest shortcoming of conventional protocols for treating addiction.

Professor Luigi Gallimberti

Professor Luigi Gallimberti has, since the late 1970’s, conducted research within the field of addiction. He has collaborated in the past with the Department of Neurosciences of University of Padova and is now a researcher at the IRRCS at San Camillo Foundation in Venice.

In the last two years, his staff has performed more than 3,000 TMS treatments and treated 200 patients, with about half of them typically suffering from cocaine addiction.

Professor Gallimberti is also the main corresponding author of a new pilot study^{*)} that suggests the potential therapeutic role of TMS in reducing cocaine use.



^{*)}Terraneo et al., Transcranial magnetic stimulation of dorsolateral prefrontal cortex reduces cocaine use: a pilot study. *European Neuropsychopharmacology* 2015, ed.

Ghent University: Accelerated iTBS offers an enormous time gain

What if a full rTMS depression treatment protocol didn't have to last 6 weeks but could be completed in just 4 days? A new research study, led by Professor Dr. Chris Baeken of the Department of Psychiatry and Medical Psychology at Ghent University, seeks to answer this question. The answer may lie within the rapidly growing field of accelerated TMS, also known as Theta Burst Stimulation (TBS).

“The time gain is enormous, not only for the patients but also for the people administering them,” says Chris Baeken about the potential of so-called accelerated rTMS protocols which involve multiple, separated daily sessions rather than one session per day which is common practice in a standard rTMS depression treatment protocol.

Full rTMS treatment in 4 days

A conventional rTMS protocol for treating major depression typically consists of 5 treatment sessions per week, with one treatment session per day – usually Monday through Friday – spanning over a period of up to 6 weeks. The accelerated iTBS protocol used by Chris Baeken and his team in this research study consists, however, of 5 sessions per day for a total of 20 treatment sessions, which cuts the entire treatment period down to just 4 days.

Faster prognosis

iTBS also offers the possibility of a much faster prognosis when predicting the treatment efficacy on a patient. After just ‘one week’ of treatment it is possible to estimate



The full Theta Burst Stimulation treatment protocol used in the study led by Chris Baeken is completed in just 4 days.

whether a TBS protocol will prove to be successful on a particular patient, he says, further adding that “the lost time to change treatment strategy is significantly shorter than to change again for a new drug trial or even an add-on agent to see if it is effective after a couple of weeks. Additionally, with an identical clinical setup, more patients can be treated with the same resources – thus making it more appealing to use, also in smaller clinical settings.”

There are, however, still patients who only partly or not at all respond to TBS. “We need to pinpoint the reason for this and develop combination therapies. Not only within neurostimulation but also combined with known pharmacotherapy approaches,” says Chris Baeken.

Possible delayed onset

With regards to remission rates, the

clinical outcome of the accelerated iTBS procedure is similar if not superior compared to classical daily single sessions delivered over several weeks: “Neurophysiological data actually suggest that TBS more strongly affects neuroplasticity. In theory, it may be possible that TBS is clinically more beneficial, and that the strongest antidepressant effects may occur after a longer period of time,” says Chris Baeken.

The biggest challenge may therefore be not only to refine the TBS parameters but to prevent a possible relapse once the full, 4-day TBS protocol is finished. A careful evaluation, which also involves possible medication and/or psychotherapy, is vital, along with the number, duration, and timing of possible booster sessions, concludes Professor Baeken.

iTBS protocol in the Ghent University study

50 antidepressant-free depressed patients were included in the study, and all were at least stage I treatment resistant with a minimum of one unsuccessful treatment trial.

The registered randomized double-blind sham-controlled crossover treatment protocol consisted of in total 20 iTBS sessions. Treatment was spread over 4 days with five sessions per day, mounting a total of 32,400 stimuli. In each session, patients received 1,620 pulses in 54 bursts of 3 with train duration of 2 seconds and an intertrain interval of 8 seconds.

Rat coil catalyses translational rTMS research

Performing rTMS on small rodents pose both immense possibilities and various challenges. In 2014, a collaboration between neuroscientists at the University of Antwerp and engineers at MagVenture resulted in a magnetic coil specifically designed to neuro-stimulate rats – the Cool-40 Rat Coil. Since the coil was launched in 2014, several research institutions have invested in the coil.

University of Antwerp and University of Western Australia have chosen some very different approaches in how to utilize the potential of the rat coil.



University of Antwerp: A true breakthrough in translational rTMS research

During the development process of the rat coil, the team of professor Steven Staelens at The Molecular Imaging Center Antwerp (MICA) performed extensive tests of the coil performance. This resulted in a comprehensive scientific validation package of the Cool-40 Rat Coil, which has recently been published in the scientific journal *Neuromodulation*¹.

By combining advanced computer simulations with technical measurements and hands-on rTMS experiments in rats, the group was able to complete this extensive description of the coil performance.

Unprecedented high electromagnetic fields

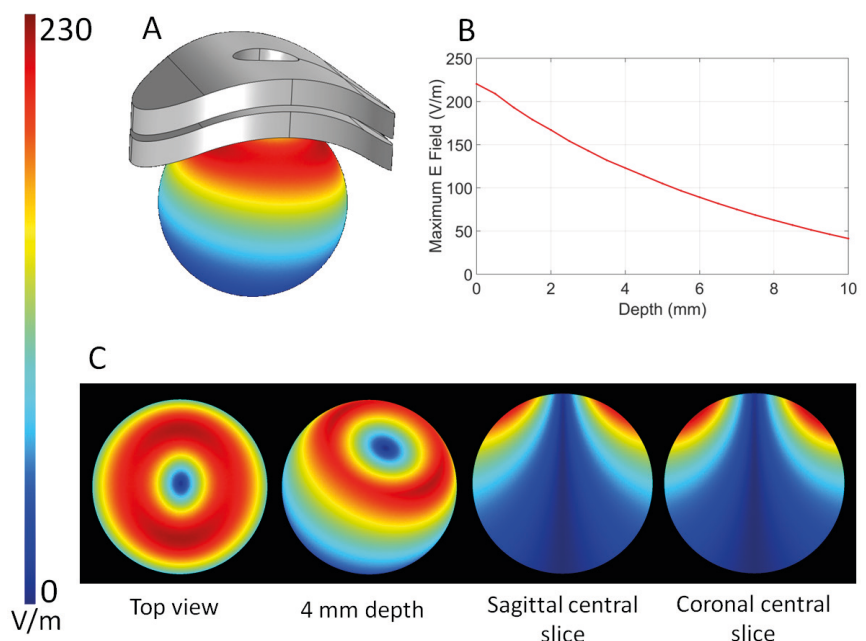
“Our simulations showed that the Cool-40 Rat Coil achieves unprecedented high electromagnetic fields,” says Professor Steven Staelens. “The coil produces a local, ring-shaped E-field with a strength of 100mV/mm at a depth of 5 mm in the rat brain. This field is comparable to the E-fields that can be elicited by human TMS systems. Motor evoked

potentials in rats can be reached at a very reproducible motor threshold of less than 30% of machine output. At this intensity, the active cooling of the Cool-40 Rat Coil makes it possible to stimulate continuously at 1Hz and generate 1,000 pulses consecutively

at 5Hz, and 272 pulses at 10 and 50Hz before the stimulator is shut off by the thermal protection.

Clinical biomarkers

In a pilot study, we used the clinical biomarker [¹⁸F]-FDG to measure the glucose metabolism in the rat brain (n=10) under rTMS stimulation with the Cool-40 Rat Coil. Each rat received 30 minutes of (i) continuous 1Hz, (ii) trains of 10Hz, 6-s duration and 54-s intertrain intervals, (iii) trains of 50Hz, 1.2-s duration and 58.8-s



The electric field distribution of the Cool-40 Rat Coil is here seen on the brain surface model (top view) and at various slices through the sphere.

Our simulations showed that the Cool-40 Rat Coil achieves unprecedented high electromagnetic fields.

Steven Staelens


intertrain intervals at 110% Motor Threshold, and (iv) sham stimulation.

For all frequencies, clusters with increased [¹⁸F]-FDG-uptake were located bilaterally in the entorhinal cortex and the amygdala and decreased [¹⁸F]-FDG-uptake was observed in dorsal cortical regions, situated bilaterally underneath the coil windings (i.e. the visual, retrosplenial and somatosensory cortices and the anterodorsal hippocampus). The significance of the response was highest for 1Hz.

“The fact that this validation information package now becomes publically available is important to advance translational rTMS research in rodent models, and we encourage other research teams to build on these data and start exploring rTMS in various disease models”, says Professor Steven Staelens. “The future within this field looks bright and I look forward to upcoming preclinical rTMS data produced by our group or by other research centers. Together with MagVenture, here in Antwerp, we are aiming for increased focality in the next design iterations,” concludes Professor Steven Staelens.

More information at:

¹⁾ Parthoens J., Verhaeghe J., Servaes S., Miranda A., Stroobants S., Staelens S. Performance Characterization of an Actively Cooled Repetitive Transcranial Magnetic Stimulation Coil for the Rat. *Neuromodulation* 2015; E-pub ahead of print. DOI:10.1111/ner.12387

 Download full article: www.ncbi.nlm.nih.gov/pubmed/26846605

University of Western Australia: Rat Coil enables rTMS closer to clinical conditions

One of the biggest limitations of rTMS treatment of human depression is the lack of understanding of how rTMS actually works. This may lead to inconsistency between treatment parameters.

Animal models of depression may help us not only investigate but also get a better understanding of the mechanisms of rTMS. This also offers an opportunity to optimise treatment parameters that can eventually be translated to human patients.

“At our lab we use animal models to address the neurobiological mechanisms of rTMS,” says Jennifer Rodger from the University of Western Australia. She is the lead scientist of a recent pilot study in which rTMS has been applied to mice models of depression.

The mice received an olfactory bulbectomy, a surgical procedure which disables the transmission of smell from the nose to the brain, and disrupts downstream circuits in other brain regions. This procedure has previously been used to model symptoms of depression in mice.

New opportunities

Applying rTMS to rodents has previously posed some challenges but the



The mice used in the pilot study at University of Western Australia were awake and unrestrained during stimulation.

arrival of the new Cool-40 Rat Coil opened new possibilities: “Human coils are extremely large relative to the rodent head but the MagVenture rat coil provides an opportunity to deliver rTMS to small animals under conditions that are closer to clinical conditions,” says Jennifer Rodger.

The team applied 10Hz rTMS on the mice models with a duration of 3 minutes for each session and 20 sessions in total. The rodents were fully awake and not restrained during stimulation.

“Although the small sample size of our pilot study precludes any statisti-

cal analysis, our preliminary findings may suggest increased neurogenesis in the hippocampus following rTMS in a mouse model of depression,” says Jennifer Rodger. “This is important because neurogenesis has been implicated in both the pathology and treatment of depression.”

More studies on the way

Jennifer Rodger further stresses that further experiments will be carried out in order to increase animal numbers and to study additional neurobiological outcomes following rTMS including behavioural changes and regulation of gene expression.

American Brain Stimulation Clinic: TMS therapy is the beginning of change for the clinician

After 15 years of considerations on whether or not to invest in TMS equipment, Dr. Rustin Berlow reached the turning point while filling in for a local psychiatrist who was doing TMS. Today, he cannot imagine running his psychiatric practice without TMS.

“There is a deeply rewarding feeling of helping more people and having more treatment options,” says Dr. Rustin Berlow, whose clinic in Del Mar, California, has a remission rate of about 40% for patients getting treatment for their depression.

To put things into perspective, this means that “they are relieved of symptoms and able to function better than they ever have. C students become A students, a salesperson breaks previous sales records, a husband can finally listen and be present for his wife and deepen connection and intimacy in the relationship,” explains Dr. Berlow.

EEG helps improve results

Applying EEG prior to rTMS treatment has helped cut down failure rates by half, explains Dr. Berlow, referring to studies suggesting that if a certain EEG pattern is registered, rTMS will not be as effective. In those cases it is possible to “reprogram” the brain by using a different type of stimulation, thus enabling a much higher chance of success for the actual rTMS depression treatment.

TMS: safer and more permanent than medicine

In Dr. Berlow’s view, “TMS is both safer and more permanent than medication,” and since there are patients who refuse medications and opt for TMS even if not severely chronic and treatment resistant, Dr. Berlow would strongly welcome rTMS as a first-line treatment. Today, rTMS may – according to FDA and CE requirements – be prescribed to patients who have failed to receive satisfactory improvement from prior antidepressant medication(s) in the current episode.

Surprisingly high reimbursement rates

As for reimbursement, “it can be a challenge but gets easier after a few times,” says Rustin Berlow who in fact has been surprised at how much has been covered by the insurance companies, sometimes up to 90% of the costs.

Individual treatment and cost reduction

To Rustin Berlow, the future dissemination of TMS mainly depends on two major areas: individualized treatment and bringing down the cost of the treatment.

The research within individualized rTMS treatment is – according to Dr. Berlow – currently undergoing rapid development by for instance exploring several forms of new treatment patterns, locations, and forms. “The advantages of this include the ability to stimulate far more neurons in the brain at a higher level of power,” he says.

TBS: a powerful addition

The answer to reducing the treatment costs of rTMS may lie within the patterned form of rTMS also known as Theta Burst Stimulation, which was CE approved for the treatment of depression in 2015. With a treatment time of only 6 minutes per session, TBS provides “a very powerful addition to our therapeutic options,” says Dr. Berlow, adding that TBS could further work as a back-up plan to the default 37 minute rTMS protocol and could reduce the cost by 50%.



Setting up a TMS practice obviously requires some adjustments, according to Dr. Berlow, such as a new office layout as well as increased staff requirements.

Dr. Berlow is also a strong advocate for exploring the possibility of using neuronavigation which he finds “breathtakingly beautiful.” The ability to – within millimeters – see what is being stimulated also provides confidence in both patient and staff. However, to the ‘TMS novice,’ this investment is not vital in the beginning, since the DLPFC which is used in rTMS for depression, is quite easy to locate.

To Dr. Berlow there is no doubt that setting up a TMS clinic has been well worth the effort: “To the clinician, it is really the beginning of change.”

Dr. Berlow’s advice to those who consider offering TMS:

- Don’t be afraid, it will pay for itself. You will learn it quickly, and after the adjustment period, you will not be working more hours.
- Buy the best equipment, you will be glad that you did.
- Stimulate everyone who needs it. Those who may not be able to afford it will spread the word about the great results.



More information at brainstimulationclinic.squarespace.com

Courses and product news

TMS courses

2016 offers several opportunities to attend a TMS course. Below are some of them.

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

What: Intensive TMS course
When: April 23-25, July 16-18, October 22-24
Where: Duke University, Durham, USA

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

What: TMS Training Course
When: June 14-15
Where: Neurolite, Berne, Switzerland

+ More information:
www.magventure.com

Approval of rTMS for depression in the UK

The UK National Institute of Health and Care Excellence (NICE) has issued a full guidance on TMS for severe depression.

“The evidence on repetitive transcranial magnetic stimulation for depression shows no major safety concerns [...] repetitive transcranial magnetic stimulation for depression may be used with normal arrangements for clinical governance and audit.”

+ More information:
www.nice.org.uk

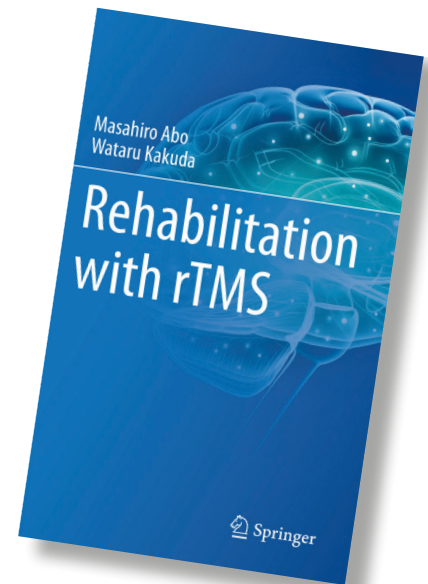
New book on stroke rehabilitation

The first and only handbook on rTMS for stroke rehabilitation is now available in English.

The book, which is based on clinical data obtained from more than 2,000 patients, was originally published in Japanese and written by renowned researchers Masahiro Abo and Wataru Kakuda.

It includes illustrations, photos, and step-by-step guidance to treatment protocols and practical applications, suited for both clinicians and researchers working with or learning about rTMS in stroke rehabilitation.

+ Copies may be ordered at:
www.springer.com



Cool D-B80 A/P

for truly double-blinded research protocols

The optimal choice for demanding studies requiring stimulation of specific deeper neuronal structures without stimulating larger areas of the brain.

Protocol is blinded even for the operator, as the software controls the active/placebo stimulation.

- Active and placebo stimulation in one coil
- Deep focal stimulation
- For protocols requiring a high number of stimuli

More information about the Cool D-B80 A/P coil at

+ www.magventure.com



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).

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 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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