University of Toronto: MST is an emerging option for severe and refractory depression

Centre for Addiction and Mental Health, Toronto: rTMS may provide possible treatment for schizophrenia and coexisting substance abuse

University of Toronto: Briefer treatment protocols may help move rTMS into the mainstream

Vaasa Central Hospital, Finland: Waiting list for rTMS depression treatment

rTMS for migraine treatment? New study on the way
Could less actually be more?

The most commonly used depression treatment protocol typically lasts 37 minutes. The frequency is 10 Hz, has a total of 75 pulse trains with 40 pulses per train and is run at a 26 seconds Inter Train Interval. This protocol is known as the FDA-cleared rTMS protocol for treating refractory Major Depressive Disorder.

This, however, may very well change – or at least the picture will most likely be much more multi-faceted in the years to come. What we are seeing is that the methodology of rTMS for depression treatment is currently being closely evaluated, discussed and revised.

In this issue of MagVenture NEWS you can read about some of the researchers who are trying to push the boundaries for what is possible with TMS in order to find new and perhaps better treatment modalities. Theta Burst Treatment (TBS) is just one of the new areas that the researchers are exploring.

An area of particular interest is finding shorter treatment protocols, such as TBS, which could have a big impact on the accessibility of TMS in terms of price and possible reimbursement. Jonathan Downar from the University of Toronto puts it this way: “The solution lies in more cost-effective treatments that match, even if they do not exceed, the efficacy of our current treatments”.

At MagVenture, we also notice this development in terms of an increased feedback from our partner research institutions around the world. Many of them want to test new treatment paradigms and ask us to help ensure that their equipment such as coils, stimulators and software, can actually run these new and often more demanding protocols. In some cases we must modify our equipment or perhaps develop new.

Even though our engineering staff will most likely spend countless hours on developing, testing and revising, we jump at these opportunities.

To us such a request is like a “back-stage pass”, providing us with a rare and valuable insight into the world of TMS research that will help us stay in the forefront of the development.

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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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In the last few years, Magnetic Seizure Therapy – or MST – has been a point of focus for Jeff Daskalakis, Professor of Psychiatry at the University of Toronto, Chief of Mood and Anxiety and Head of the Temerty Centre for Therapeutic Brain Intervention at CAMH (Centre for Addiction and Mental Health). A new study from the University division shows significant potential in MST for the treatment of patients suffering from Major Depressive Disorder (MDD).

– The purpose of the study is to evaluate MST as a treatment for refractory depression, obsessive-compulsive disorder and schizophrenia as well as to determine the most optimal parameters for stimulation to induce effective seizures, says Jeff Daskalakis.

With 84 participants, this trial is one of the largest to date conducted within this field.

**Lower frequency proved most optimal**
In order to establish the best frequency for the magnetic stimulation during the MST session, Jeff Daskalakis and his team tried three different stimulation frequencies of 25, 50, and 100 Hz, respectively.

Rather surprisingly, the researchers not only found it easier to generate seizures in the brain by using the 25 Hz frequency.

Even more significant was the discovery that this frequency level also turned out to be the most optimal in reducing symptoms of suicidal thoughts as well as other general symptoms of depression among the study participants. In a standard rTMS protocol for MDD, the frequency is 10 Hz.

**New trial to compare MST to ECT**
Based on these results, a new trial is planned to determine whether the effectiveness of MST is no different than electroconvulsive therapy (ECT) with a better side effect profile. In this study, Jeff Daskalakis and his team will compare MST to ECT using a randomized treatment trial.

**MST has shown significant potential to be a first-line convulsive therapy for patients who suffer from the most severe, drug-resistant form of depression.**
Jeff Daskalakis

– We will then seek to determine the treatment efficacy, safety and tolerability between the two methods, he explains.

**Promising perspectives**
ECT is the most effective treatment
for refractory MDD. The cognitive side effects remain problematic even with ultra-brief pulse widths. In addition the stigma associated with ECT deters patients from accepting the treatment: Out of all patients who could benefit from ECT, only 1% will try it, according to Jeff Daskalakis. In the study, most of the patients struggled with less stigma and concern when they were considering MST.

**Possible replacement for ECT**

With similar efficacy rates as ECT in the initial trial, MST has shown “significant potential to be a first-line convulsive therapy for patients who suffer from the most severe, drug-resistant form of depression”, says Jeff Daskalakis.

Furthermore, a lot more patients, who would otherwise not have been able (or willing) to receive treatment, will now have a chance to get treatment and get better.

**Canada: A strong position**

Today, a considerable amount of research originates from Canada, and two Canadian provinces also cover rTMS under the provincial Health Insurance Plans – with more likely to follow in the near future.

When asked why he believes that Canada, and especially Toronto, has taken such a strong position within rTMS, Jeff Daskalakis says: – First of all, we were among the first in the world to get so deeply involved in magnetic stimulation so today we have a lot of expertise in the field. Secondly, there is a strong tradition in Canada for focusing on biological treatments for depression.

**Many different TMS protocols**

As for the TMS development in Toronto, it took quite some time to develop the studies and setup CAMH have today but the hard work paid off: – We are now able to offer a large clinical service which integrates all forms of magnetic stimulation and can, as one of the few in the world, offer almost every path of TMS protocol to our patients, ends Jeff Daskalakis.

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**Magnetic Seizure Therapy (MST)**

MST is a method of convulsive therapy which uses rapidly alternating strong magnetic fields. The clinical research reported to date suggests that MST may have similar clinical efficacy as electroconvulsive therapy (ECT) but with far fewer cognitive side effects.

Furthermore, a faster recovery of orientation compared to ECT has been reported.

The first use of therapeutic magnetic seizure induction in a psychiatric patient took place in Bern, Switzerland, in May 2000. Since then, 102 patients have been reported treated with MST for depression.
Patients with schizophrenia have higher rates of substance abuse than the general population. rTMS may not only contribute to the understanding of both the pathophysiology of schizophrenia and the process of addiction but may also represent an optimal tool for treating these diseases. This is also the main research focus for Dr. Mera Barr from the Biobehavioural Addictions and Concurrent Disorders Laboratory (BACDRL) at the Centre for Addiction and Mental Health (CAMH).

– Cigarette and cannabis use in patients with schizophrenia may be related to the pervasive cognitive deficits observed in this group, says Mera Barr and continues:

– There is evidence that cigarette and cannabis use may improve cognition in co-morbid patients compared to patients who are non-users. The modulation of cognition with cigarette and cannabis use suggests that similar brain regions are involved in the pathophysiology of schizophrenia and mediation of these drugs. Understanding the interaction of drug use and cognition may therefore help us towards treating the symptoms of schizophrenia and addiction.

Cognitive deficits evoked with rTMS

Neural circuits, including gamma oscillations, play a potential role in encoding and integrating information between regions in the brain, but are often impaired in schizophrenic patients. The research team discovered that by applying a single session of 20 Hz rTMS bilaterally to the dorsolateral prefrontal cortex (DLPFC), it was possible to modulate gamma oscillations that mediate working memory function in both patients and healthy subjects.

rTMS improved memory

Mera Barr and her fellow researchers subsequently conducted a double-blind randomized sham controlled trial with a total of 20 active rTMS sessions. – The working memory of those who received active rTMS improved significantly, and was in fact similar to the performance level of healthy subjects, compared to those who received sham, explains Mera Barr.

She further mentions that this was the first demonstration of rTMS improving pervasive working memory deficits in schizophrenia.

Our findings [...] suggest that high frequency rTMS may treat both cognitive deficits and drug cravings in schizophrenia.

Mera Barr

Nicotine craving reduced

– Given that cigarette smoking has shown to improve working memory in schizophrenia, we also investigated if the same rTMS protocol could reduce cigarette craving and consumption in schizophrenia with co-morbid nicotine dependence, says Mera Barr.

– One week of active rTMS reduced cigarette craving compared to sham. Our findings therefore suggest that high frequency rTMS may treat both cognitive deficits and drug cravings in schizophrenia. This may ultimately translate into reduced burden and improved functional outcome for those suffering from these co-morbidities, explains Mera Barr.

Cortical inhibition can be modulated with rTMS

Cortical inhibition is an important mechanism in the brain which is dysfunctional in patients with schizophrenia and modulated with drug use. The principle neurotransmitter to cause this inhibition is called GABA.

– Modulating these neurotransmitters with rTMS for instance, may therefore provide a potential treatment. First, we know that rTMS enhances GABA receptor-mediated inhibition in healthy subjects.

Second, rTMS also modulates GABA mediated working memory in patients with schizophrenia and in healthy subjects. Third, our research shows that rTMS can even improve the working memory in schizophrenia – a cognitive domain that is modulated with cigarette smoking.

Finally, rTMS has been shown to reduce cigarette craving and consumption in schizophrenia, says Mera Barr.

More research needed

Mera Barr stresses that although
An increasing number of researchers are investigating whether alternative protocols, as opposed to conventional rTMS protocols, can reduce the treatment time — without compromising safety and efficacy. Intermittent Theta Burst Stimulation (iTBS) may prove to be the novel solution they have searched for.

Dr. Jonathan Downar from the University of Toronto and Co-Director of the United Health Network MRI-Guided rTMS Clinic explains:

– We get over 400 referrals a year, and treat about 30-40 people a day in our three rTMS suites in Toronto. Most of our referrals come from general practitioners and psychiatrists in the community.

Our partner site at the Centre for Addiction and Mental Health, also in Toronto, sees at least as many patients, if not more. More than 5 million people live in the Toronto area, so with only two rTMS clinics currently operating here, demand is quite high.

3 vs. 37.5 minutes of treatment
– iTBS uses a different pattern of stimulation, which more closely mimics the brain’s theta rhythms, says Jonathan Downar and further explains that this appears to match or exceed the potency of more conventional stimulation patterns for strengthening the activity of the target brain region but requires much less time to administer: only 3 minutes, versus 37.5 minutes for the standard FDA protocol for major depression.

More patients treated at a lower cost
According to Dr. Downar, one of the central problems in psychiatry is access: even if effective treatments are available, they are either too costly or too labor-intensive to be offered to every patient who needs them, non-inferior, it still allows for treating about five times as many patients per hour per machine and thereby reducing costs fivefold as well.

An rTMS session of only 3 minutes would make it possible to offer the treatment at a much lower cost to a much larger number of patients. This may be the critical shift that moves rTMS into the mainstream, as a solution to the longstanding problem of access, he says.

Similar results with iTBS and rTMS
As for the efficacy, iTBS treatment does not seem to be less effective, less well-tolerated, or less safe than the standard, longer rTMS treatment, says Jonathan Downar, referring to recent results from an open study based on a review of 165 patients who have undergone treatment.

The article, which has been approved for publication in the journal Brain Stimulation, is co-authored by Jonathan Downar, who is both surprised and encouraged of these results but also points out that other groups around the world are encountering similar findings.

– With consistent findings over time, the shorter, less expensive sessions for larger volumes of patients will eventually become the norm.

Furthermore, the patients are naturally much happier to undergo three

iTBS treatment does not seem to be less effective, less well-tolerated, or less safe than the standard, longer rTMS treatment.

Jonathan Downar
Change in HamD-17 Score with treatment

![Change in HamD-17 Score with treatment graph](image-url)

[Image description: Graph showing the change in HamD-17 Score with treatment. The x-axis represents time (baseline, week 1, week 2, week 3, week 4, post-TMS), and the y-axis represents HamD-17 Score. The graph compares the 30 minute 10 Hz protocol (blue line) and the 6 minute iTBS protocol (red line).]

minutes of stimulation rather than 37 minutes, he says.

**Faster localization of stimulation site**

Another area which Jonathan Downar believes will help expand the number of patients who can get access to timely, affordable, and effective rTMS treatment for their depression is to ease the often challenging task of locating the dorsolateral prefrontal cortex (DLPFC), which is the most common stimulation site for rTMS in depression treatment. According to previous studies, this seems to fail in at least 1/3 of the patients.

MRI guidance is more accurate but also much more expensive and time-consuming and worsens the access problem, since performing a timely MRI scan for every patient with depression would strain the resources of even the wealthiest countries in the world, explains Jonathan Downar.

Same accuracy as MRI-guided neuronavigation

A few years ago, a different approach was developed by William Beam and colleagues at the Medical University of South Carolina, the so-called BeamF3 heuristic.

This method was developed as an alternative method for locating the stimulation site, using just three skull measurements to estimate the F3 EEG scalp location. However, until now, it has not been compared to MRI-guided methods.

– We have therefore recently assessed the accuracy of the BeamF3 method in 100 patients who had undergone MRI-guided rTMS to compare the scalp location specified by the MRI versus the BeamF3 approach. To our surprise, they were quite close, and, with a few adjustments, we were able to improve the accuracy even further, up to 3mm, explains Jonathan Downar.

– We suspect that the adjusted BeamF3 approach should be able to achieve equivalent efficacy to MRI-guided methods. However, definitive proof of this would require another large, randomized controlled study, concludes Jonathan Downar.

**Theta Burst Stimulation**

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

TBS protocols have a major advantage over standard rTMS approaches in their reduced administration duration. Conventional rTMS procedures last up to 45 minutes compared to TBS paradigms which require a much shorter time of stimulation.

The standard theta burst pattern consists of three bursts of pulses given at 50 Hz and repeated every 200 ms.

The two most widely used TBS patterns are:

1) Continuous (cTBS) stimulation. Here, a 40 second train of uninterrupted TBS is given on the right dorsolateral prefrontal cortex and typically 600 pulses. This induces a long-term inhibitory effect, much like 1 Hz rTMS.

2) Intermittent stimulation (iTBS). Here, 2 seconds of stimulation on the left dorsolateral prefrontal cortex is followed by an 8 second pause, for example for a total of 190 seconds and typically 600 pulses. This induces long-term potentiation-like effects - also known as an excitatory effect, much like 10 Hz rTMS.
Two years after Vaasa Central Hospital introduced rTMS depression treatment, 95 patients have been treated. The results are promising.

– Most of our patients notice some kind of positive change in their mood after receiving rTMS depression treatment. Some feel a lot better after getting the treatment. They are happier, and the depression symptoms are not noticeable any more. Other patients do not experience such a big difference, but they sleep better, are more active and feel more alert, says TMS nurse Frida Österåker from Vaasa Central Hospital.

Since the treatment was first introduced at the hospital in February 2013, 95 patients between the age of 18 and 85 years old suffering from depression have been treated. Some of the patients have been depressed for a very long time and have, prior to rTMS, tried various treatment methods without success. Others come in for the treatment in an early stage of their depression.

– I have worked with rTMS treatment for about a year now and during that time, I have only met a few patients who have not seen any kind of change after getting the treatment. We have also treated pregnant women who have not wanted any kind of medication, and these rTMS treatments have been very successful, says Frida Österåker.

Popular treatment in Finland
Vaasa Central Hospital is just one of several regional and university hospitals in Finland offering rTMS depression treatment. Private clinics also offer the treatment. At Vaasa Central Hospital, the treatment is getting increasingly popular with patients having to wait for the treatment.

– Vaasa Central Hospital invested in the rTMS equipment to improve the hospital’s out-patient clinic. Our aim is to enlarge the supply of treatment and therapy methods so we can more effectively offer treatment to our patients. We get new referrals all the time and since we do not have the resources to treat everybody immediately, we have to put our patients on a waiting list for treatment, says Frida Österåker and stresses that patients in acute need of treatment or patients from one of the hospital’s psychiatric wards jump the queue.

Skeptical and afraid patients
Although rTMS depression treatment is getting more widespread, many patients are still a bit skeptical and afraid before getting their first treatment. They may fear that it will be painful or that they will get a severe headache or get very tired during the treatment.

– Many of our patients also confuse rTMS with ECT, and they think that they will get some kind of electric shock during the treatment.

After the treatment period, most patients say that they have liked coming in for treatment every day, and that the treatment was not at all as scary as they had thought in the beginning, says Frida Österåker.

She points out that many of the patients also get medication and go through psychotherapy. Instead of listening to music or relaxing during treatment, many patients choose to have a therapeutic conversation with Frida Österåker where focus is on acceptance and finding the patient’s own resources in life.

– During the treatment period, I get very close to the patients since I meet

Who pays for the treatment?

In Finland, the public healthcare is financed through taxes and since Vaasa Central Hospital is a public regional hospital, the rTMS depression treatment provided by the hospital is free for the patients.

To get the treatment, the patients must have a doctor’s referral.
them and talk to them every day. It is such a wonderful thing to see our patients beginning to feel better and recover from their depression, says Frida Österåker of her job as the only TMS nurse at Vaasa Central Hospital.

TMS Training Course
Frida Österåker recently participated at a TMS Training Course offered by Maastricht University and MagVenture.

– I really liked the networking part of the course where I got to exchange experiences and knowledge with other people who do the same as me. All the theory I learned I now use as a basic knowledge when I plan and give treatments, says Frida Österåker.

rTMS Depression Treatment Protocol
Vaasa Central Hospital uses the standard approved protocol for depression treatment: 120% MT, 10 Hz, 40 pulses per train, 75 trains, 26 sec inter train interval, 3,000 impulses/session. The treatment spot is the left DLPFC.

Most patients get 15 rTMS sessions to begin with. After 3-4 weeks, the patient comes back to meet a psychiatrist to evaluate the response to the rTMS treatment. If needed, the patient gets 15 more sessions.

A number of the patients also get maintenance treatment over a period of 3-6 months or as long as it is needed. Some get maintenance treatment 5 times a month, others every second month and some every third month.

TMS Courses
TMS courses are offered on a regular basis. The next TMS Training Course at Maastricht University will be offered on May 21-22, 2015.

More information at www.magventure.com

New TMS research coil:
Simultaneous stimulation at a very close proximity

The new, D-shaped coil from MagVenture gives you new possibilities for your research:

Perform simultaneous, focal stimulation of two centers in the brain that are only 2-3 cm apart by using two coils and paired pulses.

The cooling feature allows for repetitive stimulation.

More information about the Cool D-50 at www.magventure.com
How effective is rTMS for treating migraine? An upcoming clinical study in Germany may help answer that question. One of the test centers is Neurologie im Vest, a private practice in Recklinghausen. Dr. Stefanie Dierkes-Möller, founder and owner of the clinic, talks about her expectations of the new study.

The migraine study will include a total of 40 patients who suffer from migraine 8-14 days per month.

Included in the study will also be patients who experience aura which is a perceptual disturbance that affects 10-15% of patients who suffer from migraine.

The aura typically happens approximately 30 minutes before the actual migraine and common symptoms are visual disorders such as flickering or scotomas, which is a blind spot or an obscuration of the visual field. Other symptoms can be paraesthesias, hypaesthesias or paresis, speech disorder, changes of awareness, and change of smell.

Migraine symptoms help ensure correct diagnosis
Stefanie Dierkes-Möller has found the treatment of migraine patients with aura to be very effective, especially during the actual aura disturbance. – The aura symptoms are usually the same every time and as they are a specific sign of an impending migraine we can make sure that these patients really do suffer from migraine by including them, says Stefanie Dierkes-Möller.

– For example, one member of my staff had symptoms of an aura (scotoma) during work. I treated her using rTMS. As a result of the treatment, the aura stopped immediately and the subsequent headache was less intense than usual. She could continue her work without taking medicine, says Stefanie Dierkes-Möller.

rTMS for migraine could be an effective alternative therapy
– In my work as a neurologist I have found rTMS against migraine to be a successful and effective alternative therapy without side effects. Participating in a clinical study is new, fascinating and enriching for me and will have a lasting impact on my professional development, says Stefanie Dierkes-Möller.

– If this new study confirms that patients suffering from a severe form of migraine can profit from rTMS, it would help prove the effectiveness of this therapy, says Dr. Stefanie Dierkes-Möller about why she has chosen to participate in the study.

CE approval could help further dissemination
Today treatment costs are not covered by health insurance schemes but Stefanie Dierkes-Möller is hopeful that this will change, as a CE certification of the treatment of migraine with rTMS is also being sought.

Stefanie Dierkes-Möller, who has worked with rTMS against migraine as well as depression and anxiety since 2010, believes that an approval by a regulatory body may also help towards a further dissemination of the technique.

The rTMS migraine study

The migraine study will compare rTMS with sham stimulation. The study is suitable for outpatients with 8-14 days of migraine per month and who suffer from migraine ICHD-III-beta, which is the international classification of headache disorders.

3 centers will participate and cover 40 patients in total. 50% will receive actual treatment, 50% will receive sham treatment.

The treatment phase will last 2 weeks with 3 days of treatment per week (6 treatments in total).

Patients will be stimulated with high frequency longitudinal and cross pulls followed by burst stimulation.
New rTMS stimulator gets CE approval

MagVenture has added a new, small and simple rTMS solution to its expanding product line, the MagPro R20.

The MagPro R20 has been CE-approved for the treatment of refractory depression and is especially suited to the needs of psychiatric practices.

Besides the approved protocol for depression treatment, the R20 can also be used for the examination of the physiology of the motor pathways in the central and peripheral nervous system.

MagVenture around the world

In 2015, MagVenture will exhibit at several congresses including:

**March 2-4:**
1st International Brain Stimulation Conference, Singapore

**March 28-31:**
The European Congress of Psychiatry (EPA 2015), Vienna

**May 16-20:**
American Psychiatric Association (APA 2015), Toronto

**June 14-18:**
12th World Congress of Biological Psychiatry, Athens

**October 17-21:**
Annual Meeting of the Society for Neuroscience (SFN), Chicago

**December 1-4:**
European Congress of Neurorehabilitation, Vienna.

MagVenture technical training course

MagVenture offers a technical training course aimed at technical staff at distributors and customers.

Courses and product news

The course will be held at the MagVenture head office near Copenhagen, Denmark. It will combine lectures and hands-on activities and cover a variety of topics including:

- Circuit descriptions
- Troubleshooting
- Module placement
- Safety handling.

**Date:** May 19-20, 2015
**Price:** €250

Further information and registration:
service@magventure.com

TMS course at Maastricht University

MagVenture and Maastricht University will again offer their popular TMS course.

The course, which is led by Professor Alexander Sack, consists of both academic sessions and hands-on training. The participants may also receive individual feedback on intended protocols or procedures.

**Date:** May 21-22, 2015
**Price:** €600

Further information and registration:
www.magventure.com

Neurolite TMS Training Course

MagVenture co-sponsors the Neurolite TMS Training Course in Berne. The course will be held in English and is for MDs and PhDs in Neurology or Psychiatry with or without experience with TMS.

The course consists of a mix of lectures by prominent TMS specialists and hands-on training.

**Date:** June 10-11, 2015
**Price:** CHF 450

Further information and registration:
www.neurolitetraining.ch
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 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.

For further information please contact MagVenture.

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