MagVenture News

#11

December 2017

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To reimburse or not to reimburse TMS

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Dr. Peter Chan (number 3 from left), and fellow BrainStim supporters helped bring in almost $5,000 at the annual "Ride Don't Hide" bike ride in Canada which seeks to raise awareness of mental illness.

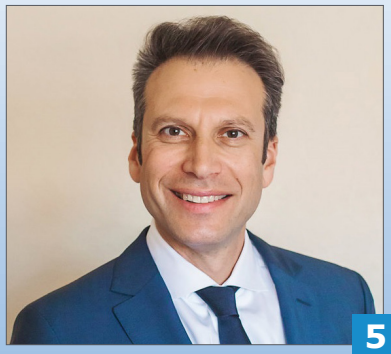
In Canada, both possibilities exist

In Canada, the availability of TMS for the treatment of depression varies considerably from province to province; where some provinces offer full reimbursement for the treatment, others do not.

MagVenture NEWS spoke with two Canadian healthcare practitioners from two different provinces.

The province of British Columbia offered partial public funding but eventually decided to cut it. This decision led a group of healthcare practioners to take matters into their own hands.

Quebec, on the other hand, fully covers TMS for the treatment of depression.



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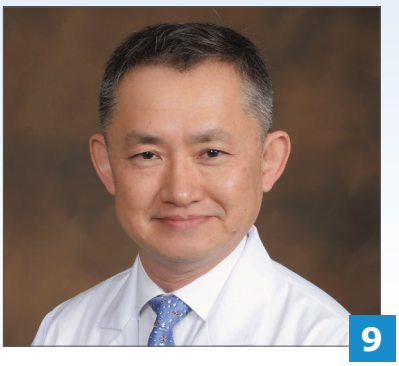

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UNIVERSITY OF CALIFORNIA, USA:
TMS for pain management is a great tool

We are headed in the right direction

Another exciting year for the field of neurostimulation and for MagVenture as well is coming to a close!

When it comes to the clinical use of TMS for depression treatment, the US has currently taken the lead but many other countries are rapidly picking up the pace as well. Even though reimbursement is still not well-established, outside the US, where TMS is covered by most health insurance providers, it has not deterred healthcare providers in Australia, Japan, and several countries in Europe from establishing TMS practices – or adding it to their existing treatment portfolio. We also see more clinical TMS courses offered, TMS societies established and expanded, and even specific TMS conferences and events where TMS professionals can establish and/or strengthen their peer network.
Within research, scientists continue to seek new paths and make advances that will undoubtedly pave the way for not only *how* we treat but also *what* we can treat. Clinicaltrials.gov, for instance, currently lists almost 200 ongoing clinical trials within TMS, including a wide variety of conditions such as depression, Parkinson's disease, schizophrenia, neuropathic pain, addiction, and OCD. In comparison, between 2000-2005, only 34 clinical studies were listed.

The clinical practice is also under constant development; FDA has, for instance, since 2008 revised its "indications for use" label which today suggests using TMS after just one failed medication trial. The initial indication prescribed two failed rounds of medication prior to TMS. Recent literature furthermore identifies rTMS as "the dominant therapy compared to antidepressant medication trials over the life of the patient across the lifespan of adults with MDD, given current costs of treatment. These models support the use of rTMS after a single failed antidepressant medication trial versus further attempts at medication treatment in adults with MDD."[1)]
It certainly is promising that TMS is not only an effective treatment for depression with only few side effects but actually the better choice, when seen from a financial point of view.

Stig Wanding Andersen
CEO, MagVenture

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

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

[1)] Full article at: http://journals.plos.org: "Cost effectiveness analysis comparing repetitive transcranial magnetic stimulation to antidepressant medications..." by Jeffrey Voigt et al.

Canada: To reimburse or not to reimburse

In Canada, the availability of TMS for the treatment of depression varies considerably from province to province where some provinces offer full reimbursement for the treatment while others do not. MagVenture NEWS spoke with two Canadian healthcare practitioners from two different provinces. One province offered partial public funding which was then cut, forcing him to take a drastic step. The other province fully covers TMS for the treatment of depression.

Dr. Stephen Wiseman (no 2 from left), Dr. Peter Chan (no 3 from left), Dr. Ian Forbes (no 4 from left) and fellow BrainStim supporters helped bring in almost $5,000 at the annual bike ride Ride Don't Hide which seeks to raise awareness of mental illness.

Dr. Peter Chan of British Columbia is the long-time chief of the ECT program at Vancouver General Hospital and was therefore very familiar with the field of neurostimulation for the treatment of depression when he discovered TMS.

After founding a non-profit TMS clinic in Vancouver BC, Dr. Peter Chan also co-founded the private TMS practice BrainStim Healthcare.

To Dr. Chan, TMS offered some clear advantages. More specifically, he saw "a new form of neurostimulation that did not require general anesthesia and did not have some of the cognitive impairment risks associated with ECT but still showed significant effects," he explains on his reasons for taking the next big step: Founding a non-profit TMS clinic at Vancouver General Hospital.

Co-pay clinic model

The clinic, which opened in 2009, was intended for people with major depressive disorder who couldn't afford to pay for the full treatment themselves. It was based on a "co-pay" model where the client would pay $750, while the Health Authority provided the space and equipment for the clinic and covered the remaining salary for the TMS nurse who administered the treatment.

Over 100 patients treated

Even though resources were quite limited, with only 4 hours available per day, the clinic treated over 100 patients over the next 7 years. The results are currently being analyzed with a view towards publication, but according to Dr. Chan, "it is comparable to results published of naturalistic outcomes of TMS for major depression. Generally, the outcomes are 50-60% response rates in these naturalistic studies."

In 2016, the Health Technology assessment branch of the government in British Colombia decided that TMS was not cost-effective enough to fund, much to the disappointment of Dr. Chan: "This [decision] differs from other provinces such as Quebec and Saskatchewan which have TMS fee codes that psychiatrists can bill. It is also counter to the direction to the province of Alberta, which is actively looking at promoting TMS for clinical populations, and the United States, where Medicare and a variety of HMO's [health maintenance organizations] will reimburse providers for administering TMS."

The decision to cut the funding not only affected Dr. Chan's TMS clinic at Vancouver General Hospital, which was subsequently forced to close for clinical TMS treatments, but also the hospital-based TMS clinic in Victoria, BC. The Vancouver General Hospital, however, still has an ongoing randomized, sham-controlled trial for PTSD in non-combat civilians, and the target recruitment for 30 participants is nearing completion.

The right thing to do

As a direct result of this, a group of TMS psychiatrists from the TMS clinic at Vancouver General Hospital decided to establish BrainStim Healthcare. "We had already seen the benefits of TMS

for our clients, many of whom were treatment refractory and had suffered for years. Establishing a private TMS practice is new to all of us founders, but we felt it was the right thing to offer TMS in a comfortable office setting for those people," says Dr. Chan.

19 minute treatment helped lower the cost

The practice is based entirely on private pay and currently the only clinic in BC to offer standard-protocol TMS. The FDA-cleared protocol, which was previously 37.5 minutes per treatment session, has recently been shortened to 19 minutes, which has allowed Dr. Chan and his colleagues to lower the treatment costs, to the benefit of the patients. Presentations at professional groups, advertising, and simple word of mouth have all helped Dr. Chan and his colleagues to be successful in recruiting clients throughout the province.

Reducing the stigma of mental illness

Another important part of Dr. Chan's work is spreading the awareness of depression and to reduce the stigma surrounding mental illness. "We have a firm belief that treating depression isn't just about one form of treatment such as TMS, but should also involve other modalities such as exercise and social contact," says Dr. Chan.

Participating in the annual bike event "Ride Don't Hide", which seeks to raise awareness of mental illness as well as giving charitable donations for the Canadian Mental Health Association, was therefore a perfect activity for Dr. Chan and his Brainstim colleagues (Dr. Forbes and Dr. Wiseman) who happened to share a passion for road biking.

Free healthcare in Quebec

The province of Quebec has taken quite a different approach to healthcare. The Health Insurance Plan covers all services that are medically necessary and

Dr. Simon Patry of University Institute in Mental Health of Quebec uses both ECT and TMS for the treatment of depression. He hopes that TMS will become more accessible in Canada.

rendered by a general physician or a medical specialist. These services also include psychiatric treatments such as TMS for the treatment of depression.

Both ECT and TMS

At the University Institute in Mental Health of Quebec, Dr. Simon Patry administrates both TMS treatment as well as ECT and finds that both treatment options have an entitlement: "They are very different treatments, usually used in very different patient populations. In clinical practice, patients refer-red for ECT are usually much sicker than anyone typically considered for rTMS - they usually have much higher depression rating scores. They often have psychotic symptoms and/or suicidal ideation, and profound melancholic and vegetative symptoms. In short, any condition which requires an emergency intervention or any situation where medication could be contraindicated," he explains.

Stigma of ECT

With TMS also being available, Dr. Patry explains that all patients are told about this treatment option as well. Many of his patients will – when given the choice – choose TMS over ECT. The main reason for this is the adverse-effect profile which is more common and troublesome for patients who receives ECT.

The most common side-effect from ECT is memory loss, which does not occur with TMS. Dr. Patry and the rest of the staff are therefore often faced with problems of availability that leads to a waiting list as they currently only have one TMS device at hand. "This represents a real problem for patients who would benefit from TMS in an emergency situation as well as for those needing maintenance treatment," says Dr. Patry.

> ***TMS is a safe, secure and effective treatment with few secondary effects and no deleterious effects in the brain.***
>
> **Simon Patry**

TMS must become more available

He therefore hopes that TMS becomes much more widely available, not only at the University Institute in Mental Health of Quebec but also nationally. "We need more devices, more centres to provide TMS, and more trained professionals in order to respond to all the demands for people of any age suffering from depression which is one of the most troublesome psychiatric disorders. TMS is a safe, secure and effective treatment with few secondary effects and no deleterious effects in the brain, which we must take into account," he ends, and points to one other significant factor: the cost, which is also at play, with ECT being more expensive than TMS.

Silverlining Psychiatry, USA: TMS will soon become as mundane as pills

Dr. Dmitriy Sivtsov of Silverlining Psychiatry in La Jolla, California, had been running a successful psychiatric practice for 10 years, helping many patients to recover from their mental illnesses such as depression. However, a portion of his patients were not benefiting from the antidepressant medication. Statistically, this is not extraordinary: studies show that approximately half of the patients with depression do not recover fully from antidepressants. It was therefore clear to Dr. Sivtsov that a different approach was needed for these hard-to-treat patients.

"I had already heard of TMS and wanted to try it on those of my patients who were not responding to antidepressants," says Dr. Sivtsov.

Before proceeding with the purchase, he did some thorough research as well as consulting with other psychiatrists. Not only did this convince Dr. Sivtsov that he should start offering TMS at his own practice, he was also given a unique opportunity to learn more about how to set up his own TMS practice as well as how to actually treat patients.

Reimbursement was vital

One particular area of concern to Dr. Sivtsov was reimbursement. With an insurance-based practice and a strong reputation for being successful in getting compensation for his patients, he knew that his ability to ensure reimbursement for his patients was pivotal to his future success as a TMS practitioner.

The paperwork and administration linked to reimbursement is somewhat of a hurdle, but Dr. Sivtsov and his team at Silverlining Psychiatry do manage to get insurance coverage for all their patients. He is certain that once the insurance companies start to see things from a cost/benefit angle, the reimbursement process will be much easier.

TMS investment secured with just a few patients

With a handful of patients willing to commit to the TMS treatment, Dr. Sivtsov's investment in a TMS system was already secured. "My patients were all very eager to get started on the treatment, so I was happy to get my MagVita TMS Therapy system delivered in only 3 weeks," he says. The training – provided by MagVenture – was completed quickly, and within a week, the first five patients were getting TMS treatment for their depression.

Dr. Dmitriy Sivtsov of Silverlining Psychiatry in La Jolla has an insurance-based psychiatric practice and has managed to get reimbursement for all his patients.

> ***My patients were all very eager to get started on the treatment, so I was happy to get my MagVita TMS Therapy system delivered in only 3 weeks.***
>
> **Dmitriy Sivtsov**

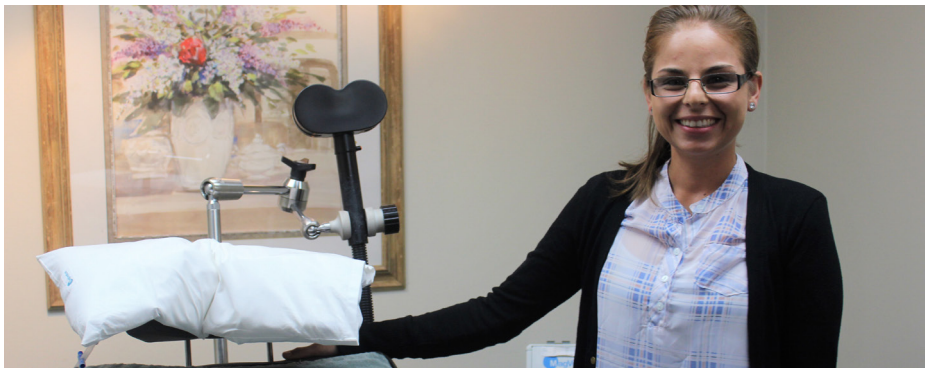
Better sleep comes first

According to Dr. Sivtsov, the first changes his patients notice after starting TMS treatment, are typically of a physical nature such as more energy, and better sleep. One of his patients had, for instance, gone without a decent night's sleep in 20 years – until she tried TMS. The psychological/behavioral changes often start to kick in a little later, he explains. Dr. Sivtsov follows the standard, FDA cleared protocol with treatments 5 times per week for a total of 30 treatments. His treatment room has a TV and some patients enjoy watching their favorite show during their treatment session while others prefer to relax, listen to music, or read.

> ***The depression symptoms improved for all my patients, whereas about two-thirds of them achieved a full remission.***
>
> **Dmitriy Sivtsov**

Full remission for 2/3 of the patients

Since his first five patients started in the fall of 2016, Dr. Sivtsov has taken in several



TMS operator Karla is here seen in the treatment room at Silverlining Psychiatry in La Jolla, California. The room is equipped with a TV where the patients can watch their favorite series while getting treatment.

other TMS patients, and now sees 5-7 patients per day. According to Dr. Sivtsov, "the depression symptoms improved for all my patients, whereas about two-thirds of them achieved a full remission."

TMS goes well in hand with Dr. Sivtsov's approach of "integrative psychiatry", involving several elements such as nutritional supplements, as well as genetic and hormonal testing.

TMS as common as pills

Dr. Sivtsov is still relatively new in the world of neuromodulation but plans to have follow up consultations with all his patients – including those in full remission. He sees great potential in the technology which he believes is "seriously under-saturated but will become as mundane as pills in the near future."

As for future indications, Dr. Sivtsov is hopeful that more will be added soon, and is eagerly awaiting more data from ongoing research, for instance the treatment of addiction, which Silverlining Psychiatry specializes in.

Dr. Dmitriy Sivtsov

Dr. Sivtsov is Dual Board Certified in General Psychiatry and Addiction Medicine. His academic path towards earning his medical degree has led him through several renowned universities including St. Petersburg Medical Academy in Russia, the University of California at San Diego, and Harvard Medical School. He opened Silverlining Psychiatry in 2007.

More information:
Silverliningpsychiatry.com

Russia: Searching for ways to regain damaged body function in rehabilitation patients

What if it was possible to truly restore lost or damaged body functions in patients with diseases and injuries of the central and peripheral nervous system? That is the main research question occupying Dr. Ekaterina Melnikova at the Moscow Center for Research and Practice in rehabilitation, restorative and sport medicine. She believes the answer may lie in mobilizing a reserve neuronal pool in the brain.

"The global goal of my current and planned research is the development of new, effective rehabilitation technologies aimed at the true restoration of lost or damaged functions, or, at the least, to the greatest possible compensation for the defect that has been formed," says Dr. Ekaterina Melnikova and elaborates:
"I believe that in some cases this can be achieved by mobilizing a reserve neuronal pool in the brain. The search for ways to mobilize this pool of neurons is one of the main tasks of modern neuroscience. The solution of this task will reduce the social burden on society by lowering the number of disabled people while also gaining a more complete restoration of the patients' ability to work. This will again be accompanied by an improvement in their quality of life," says Ekaterina Melnikova of her fascination with the rehabilitation area where she has focused her research for more than 15 years.

Dr. Ekaterina Melnikova has worked with TMS rehabilitation research for more than 15 years. Her goal is to develop new effective rehabilitation techniques to be able to help patients restore damaged or lost body functions.

Rehabilitation is multidisciplinary

"I like the rehabilitation area because it requires that the doctor has extensive knowledge both in the field of modern methods of diagnosis and treatment and that he or she constantly improve her professional level in order to effectively help the patients," says Dr. Melnikova who at the center is engaged in the examination, treatment and rehabilitation of patients with diseases in the central and peripheral nervous system caused by for example strokes or tumors.

Scientifically, she studies the neurophysiological changes taking place during rehabilitation and how they reflect neuroplasticity.

Understanding the neuroplasticity mechanism

"My colleague and I study the effectiveness of TMS in the recovery of patients with peripheral nervous system damage caused by spine diseases. The study includes 120 patients and shows the necessity of using TMS in such patients for the correction of motor stereotype," says Ekaterina Melnikova and continues: "Further processing of the data will allow us to approach the understanding of the complex of neuroplasticity mechanism and be able to propose new rehabilitation techniques," says Dr. Ekaterina Melnikova. In addition to this study, she conducts several other studies using TMS with the overall goal of creating effective

I would like to develop differentiated rehabilitation protocol including the use of TMS, which would significantly improve the results of the rehabilitation treatment.

Ekaterina Melnikova

I think that in the coming years the use of such an effective method as TMS will be developed in the rehabilitation of adults and children.

Ekaterina Melnikova

treatments for the restoration of damaged body functions.

"In all our research, we use different combinations of peripheral and central magnetic stimulation with other physical factors and methods of treatment, or we try to use peripheral or central magnetic stimulation as monotherapy. We estimate a number of factors that can affect the effectiveness of the treatment. We plan to create effective individual protocols for the rehabilitation of patients using magnetic stimulation," says Dr. Melnikova.

More research is needed

Research with TMS and not least the combination of TMS with other rehabilitation technologies such as virtual technologies, which is widely used within rehabilitation today, is needed.
"It is important to conduct more research that will answer the question of whether or not the combined application of magnetic stimulation with other rehabilitation techniques can potentially accelerate and improve the results," says Dr. Melnikova who already has new research planned.

Multicenter study may be on the way

"In the next few years, I would like to initiate a multicenter study in which TMS will be used both for therapeutic and diagnostic purposes. I would like, based on certain parameters of diagnostic TMS and clinical data, to establish variants of realization of neuroplastic properties in patients with diseases and traumas of the central nervous system. On this basis, I would like to develop differentiated rehabilitation protocols including the use of TMS, which would significantly improve the results of the rehabilitation treatment of these patients," says Dr. Ekate-rina Melnikova.

The future of TMS within rehabilitation

Dr. Melnikova is passionate about TMS and finding ways to help patients in rehabilitation get a better life after diseases and injuries of the central and peripheral nervous system.

She sees many patients at the Moscow Center for Research and Practice in rehabilitation, restorative and sport medicine, but one case she clearly remembers is a 46-year-old patient with a traumatic spinal cord disease, who regained much of the damaged body function after undergoing treatment at the Moscow Center for Research and Practice.

"This bright case of recovery after a severe spinal cord injury demonstrates the indisputable advantage of including magnetic stimulation in a comprehensive rehabilitation program for such patients," says Dr. Melnikova who believes that the future of TMS in both Russia and the rest of the world is very promising because of the growing interest in neuroscience, both in theoretical and applied aspects.
"Therefore I think that in the coming years the use of such an effective method as TMS will be developed in the rehabilitation of adults and children," predicts Ekaterina Melnikova.

Dr. Ekaterina Melnikova

Dr. Ekaterina Melnikova, MD, is head of the Department for rehabilitation of patients with neurological diseases at the Moscow Center for Research and Practice in rehabilitation, restorative and sport medicine.

She is working to develop TMS protocols within the rehabilitation field (spinal injury and stroke).

She first graduated from the Moscow Medical Academy in 2003, in 2016 received a Doctor of Medicine (MD).

She is the author of 49 articles and 3 chapters in scientific books.

University of California, USA: TMS for pain management is a great tool

TMS for pain management first caught the interest of Professor Albert Leung from University of California – San Diego, more than 10 years ago. Since then, he has led or been involved in several research projects related to pain caused by for instance traumatic brain injury or spinal cord injury, various chronic pain disorders as well as thermal pain, migraine or headaches. The long-term goal is to establish actual TMS treatment protocols for pain.

> ***With the current issues surrounding the opioid epidemic, the adaptation of a well validated non-invasive non-pharmacological treatment for pain management is imminent.***
>
> **Albert Leung**

"I was frustrated by the efficacy and side effects of pharmacological treatment options for my patients. TMS provides a non-invasive means for me to manage their chronic pain conditions without any long-term side effects," says Albert Leung and continues: "Pain is a universal problem which affects a large percentage of the population. With the current issues surrounding the opioid epidemic, the adaptation of a well validated non-invasive non-pharmacological treatment for pain management is imminent."

Magnetic stimulation for chronic pain

Chronic pain is, clearly, an extremely complex condition, and research within the field of applying magnetic stimulation is still relatively limited.

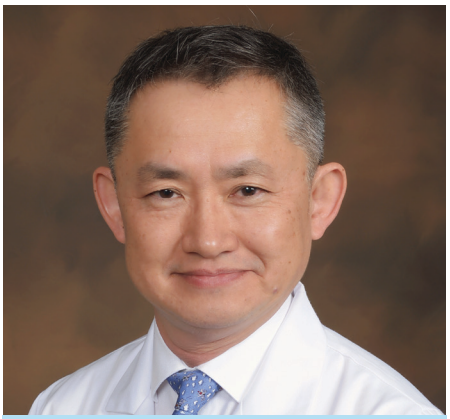
At the VA San Diego Healthcare System, magnetic stimulation is also occasionally used, for instance on patients with myofascial pain who are not responding to so-called trigger point injections therapies. TGI in short, is a procedure in which a needle is injected into the patient's trigger point (or points).

The trigger points can be described as knots of muscle that form when muscles do not relax. This may irritate the surrounding nerves and cause pain, not only in that specific area, but in other parts of the patient's body as well, the latter known as referred pain. Professor Leung found that "the overall results were good but short lasting. Therefore, a workable treatment protocol needs to be developed."

3-4 TMS sessions helped alleviate headache

And more research is, fortunately, on the way: Professor Albert Leung is currently involved in three TMS-related studies. Some of these studies include correlated functional neuroimaging studies for treatment related mechanisms as well. "Based on recent functional imaging studies done at our and other research labs, we come to understand one of the causes for chronic pain/headache is a maladaptive state in the central nervous system. For example, in our most recently published study, we identified that patients with mild traumatic brain injury had diminished supraspinal functional connectivity from their prefrontal cortices. This diminished level of intrinsic cortical pain modulatory function can be one of the major reasons for their persistent headache presentation. Therefore, it will make sense to non-invasively stimulate those brain regions with pain modulatory functions in rectifying this maladaptive state and improving their pain/headache and co-morbid symptoms," says Albert Leung.

"Our most recent studies have focused on the use of rTMS in alleviating mild traumatic brain injury related headache (MTBI-HA), which in my opinion is a form of central neuropathic pain condition as more than 90% of these patients experience persistent, round-the-clock headache after the initial injury. Most migraine patients do not have a history of traumatic brain injury and their headache exacerbations [worsening or flare-up of symptoms, ed.] are intermittent. We completed two studies which demonstrated that even a short period of 3-4 rTMS sessions at either motor or left dorsolateral prefrontal cortex (L-DLPFC) can alleviate MTBI-HA up to one month. The study with L-DLPFC stimulation also demonstrated a transient anti-depressive ben



Professor Albert Leung from the University of California at San Diego is dedicated to conducting research which will ultimately lead to actual rTMS protocols for the treatment of pain.

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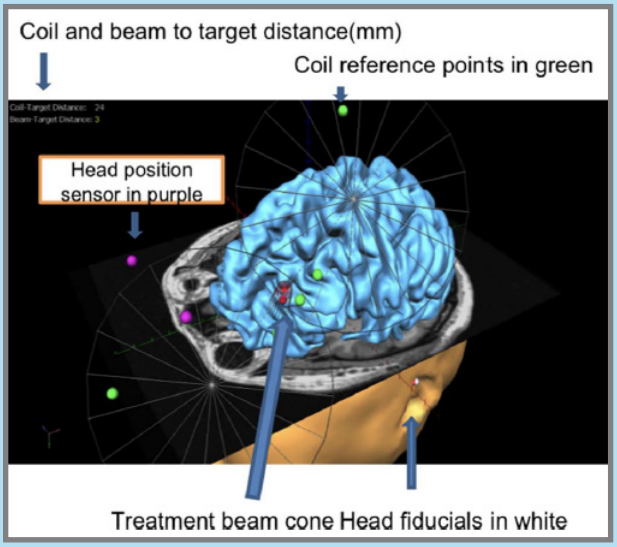
Research using neuronavigated rTMS for MTBI-headache



The image on the left shows a method used by Dr. Leung and fellow researchers to treat MTBI-headache, using a MagPro stimulator and Cool-B65 coil. Distance from coil to actual target in the brain is 24 mm.

Dr. Albert Leung explains: "The target location (coordinates) is based on our prior functional imaging studies. Our lab pioneered this innovative method of target projection based on functional imaging data with neuronavigation guidance to ensure the specificity and reliability of each treatment for each patient."

The purple markers indicate the locations of the head sensors, the green markers indicate the reference locations on the coil, and the red marker indicates the targeted treatment location.

efit. We are about to start a new study assessing the long-term efficacy of rTMS for MTBI-HA up to 3 months," says Professor Leung.

TMS treatment of co-morbid depression and pain

This could prove to be a valuable finding, as pain and depression are known to have a very high co-morbid rate of approximately 50%, according to Professor Leung: "So it will make sense to address both problems at the same time to optimize the treatment outcome for either condition. TMS provides a great tool for doing just that."

TMS for the treatment of pain – FDA cleared?

For Albert Leung, one of the obstacles in moving TMS for pain from a research setting to a clinical adaptation is reimbursement.

An FDA clearance would, obviously, be pivotal in ensuring a wide-spread, public dissemination. First steps have already been taken, stresses Professor Leung: "I am currently working with my colleague in the field to come up with standardized protocols for pain and look forward to working with the industry to seek FDA clearance for the use of TMS in pain treatment," ends Professor Albert Leung.

We completed two studies which demonstrated that even a short period of 3-4 rTMS sessions at either motor or left dorsolateral prefrontal cortex (L-DLPFC) can alleviate MTBI-HA up to one month.

Albert Leung

Professor Albert Leung

Dr. Leung is a Pain Management Specialist as well as Professor of Anesthesiology, dividing his time between the University of California San Diego Health as well as the VA San Diego Healthcare System. He earned his medical degree from the University of Pittsburgh School of Medicine. He has since, among several other academic accomplishments, completed a fellowship in transcranial magnetic stimulation at Harvard School of Medicine.

Albert Leung is board-certified in anesthesiology and pain medicine and has over 20 years' experience in managing chronic pain. He has been published extensively in peer review journals.

More information:
health.ucsd.edu/specialties/pain/Pages/default.aspx

Events and product news

MagVenture establishes new subsidiary in the UK

MagVenture has established a subsidiary in the UK to be able to fully meet our growing number of customers' needs within sales, marketing and support.

Being closer to the UK market ensures that MagVenture can provide the growing number of customers with the internationally recognized high-level support it is known for.

The office is located in Reading (see photo above).

MagVenture already has subsidiaries in the US, Germany and is furthermore represented in over 45 countries through a global network of distributors.

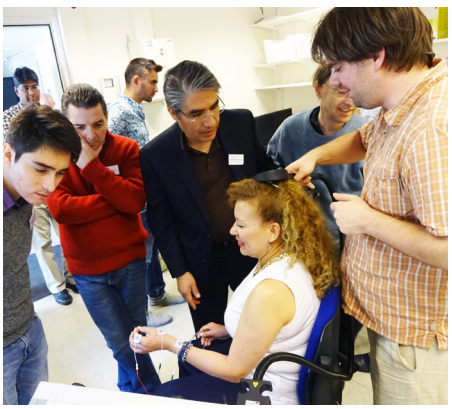
TMS courses around the world

MagVenture provides equipment support to Duke University in North Carolina, USA, which offers training on Transcranial Magnetic Stimulation.
The course is aimed at physicians, nurses, physician assistants and nurse practitioners and include didactics sessions and hands-on training.

Upcoming course dates are:
27-29 January, 2018
28-30 April, 2018
14-16 July, 2018
20-22 October, 2018

The popular Clinical TMS Course originally held only at the Maastricht University is now also, due to popular demand, offered at various European locations at regular intervals.

So far, courses in 2018 are scheduled for the following dates:
14-16 March, 2018 (London)



28-30 May, 2018 (Amsterdam)
13-15 June (Maastricht)

More information at:
www.tmscourse.eu

New FDA clearance cuts treatment time in half

MagVenture has received a 510(k) FDA clearance for "... a range of inter-train intervals from 11 to 26 seconds, rather than the fixed 26 second duration, which will allow a reduction in treatment time from 37.5 minutes to a minimum of 18.8 minutes."

This is good news for healthcare practitioners looking to reduce treatment time for their patients. A MagVita TMS Therapy System with a MagPro R30 or X100 can – thanks to the extremely efficient liquid cooling system and coil –easily handle the reduced inter-train intervals with no risk of overheating.

How to add the 19 minute TMS treatment session to a MagPro stimulator:

1. Recall/load your protocol.
2. In the main menu press "timing".
3. Select Inter-Train-Interval (ITI).
4. Set the ITI to 11 seconds.
5. Press configure.
6. Save the new protocol.

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, the UK 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 R20, R30, R30 with MagOption, X100, and X100 with MagOption are all FDA 510(k) cleared (k160280, k061645, k091940 and k150641).

k150641, k171481: 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.

k160280, 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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