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Occupational Exposure to Magnetic Field in Transcranial Magnetic Stimulation Treatment

Kjell Hansson Mild and Ole Jacob Møllerløyken

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Abstract

Transcranial magnetic stimulation (TMS) is used both as a diagnostic instrument and for therapy, available only at some psychiatric clinics for treatment of depression and at clinical neurophysiology where TMS is used for diagnosis of nerve damage. The Swedish National Board of Health and Welfare issued a referral edition about the use of repetitive TMS as an alternative treatment for depression. This may lead to a major increase in the application of TMS to treat depression. TMS is based on induction of an electric (E) field inside the brain by application of an external magnetic field with rapid rise and fall time. The E field in the brain has been calculated when different coils were used for the treatment. The reported E fields are of the order of tens to hundreds of volts per meter and the induced current density is estimated at tens of A/m². This field can depolarize neurons or modulate cortical excitability by selecting the appropriate parameters for stimulation and the duration of the treatment session. The mechanisms of action of neurostimulation still remain incompletely understood.

Keywords: staff, EU directive, health risk, precautionary principle

1. Introduction

Transcranial magnetic stimulation (TMS) is used primarily in research and treatments of central nervous diseases, such as recurrent depressions, and has been used for several years. The non-invasive stimulation of the cortical cortex is accomplished through the application of pulsed magnetic fields generated by coils in different arrangements. The effects on major depressive disorder in adults have been reviewed by Perera et al. [1] and the Clinical TMS society, and they state that following the clinical recommendations given in their document it should result in continued safe and effective use of the TMS.

However, it is not yet so widespread, and today in Sweden and Norway, TMS equipment is available only at some psychiatric clinics for treatment of depression and at clinical neurophysiology where TMS is used for diagnosis of nerve damage. The Swedish National Board of Health and Welfare has issued a referral edition about the use of repetitive TMS as an alternative treatment for depression. The method is new, but it has been used with positive effects on persons with medium-to-severe depression. This may lead to a major increase in the application of TMS to treat depression.

However, although TMS have been reviewed several times, the potential exposure to the therapeutic staff has been neglected. The magnetic pulses can be targeted to selected cortical areas through the design and placement of the different coils used.

Occupational exposure limits have been recently revised in Europe and are given in the new EU directive [2] and the ICNIRP guidelines [3]. For the exposure experienced during TMS treatment, the limits are set to avoid stimulation of nerves. Studies by Karlström et al. [4] and Möllerlökken et al. [5] investigated the therapeutic staff exposure to pulsed magnetic fields during TMS/rTMS treatments in relation to the occupational exposure limits given and found that these limits may be exceeded close to the coil and safety measures are needed. In this paper, we will look closer into this exposure.

2. Different coil design

The magnetic pulses can be targeted to selected cortical areas through the design and placement of the different coils used. Lu and Ueno [6] have recently reviewed different coil configurations and how the induced electric field in the brain is distributed. **Figure 1** from their publication shows some of the most common designs. Most commonly used is a pair of coils arranged in the form of the figure-8. The pulsed magnetic field will induce electric currents in the cerebral tissue, and the effect will be strongest in the areas close to the coil. The treatment is non-invasive and therefore to prefer compared to electro-convulsion therapy.

2.1. Measurement

Figure 2 shows a typical position of a patient receiving treatment with a figure-8 coil positioned with a fixed position on the head.

The current in the coils can reach some kA in strength and the waveform is sinusoidal with frequency around some kHz. The magnetic flux density generated by TMS equipment can reach the order of 1 Tesla. Since the duration is only about 0.05–0.4 ms, this give rise to a time derivative of the field of the order of tens of kT/s. This then induce an electric field in the tissue that can reach the threshold for localized axonal depolarization of more than 100 V/m. For further information on this, we refer the reader to Deng et al. [7], Bottauscio et al. [8] and Lu and Ueno [6]. Since the limit for occupational exposure for the frequencies used in TMS is around

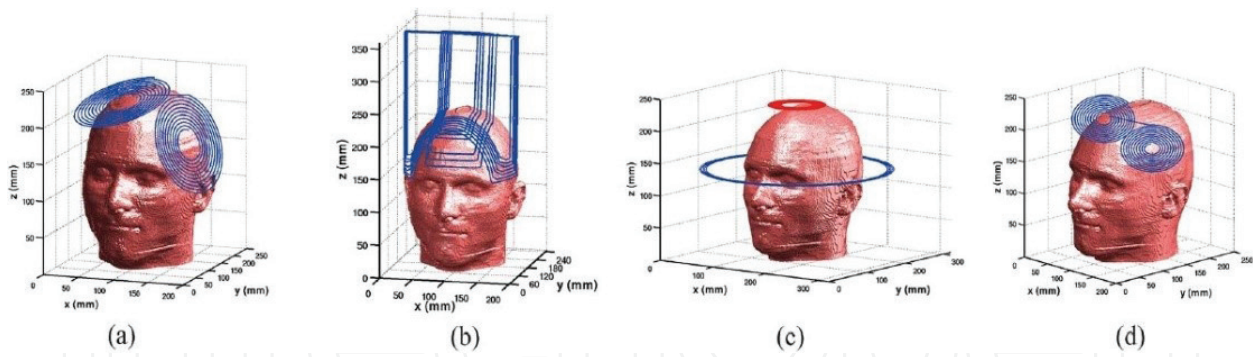


Figure 1. Realistic head model with coils. (a) Double cone coil, (b) H-coil, (c) HCA coil, and (d) Figure-8 coil. Reproduced from Lu and Ueno [6] with permission.



Figure 2. Position of a “patient” received TMS treatment with a figure-8 coil. The schematic drawing shows the induced electric field in tissue. Photo: Kjell Hansson Mild, drawing courtesy of Shoogo Ueno, Tokyo.

1 V/m, it is not surprising that staff can be at risk for overexposure if working too close to the coil when in use. This is something they often need to be because either the coil moves out of position or the patient needs assistance. In addition, many of the coils are designed so that the trigger-button for the pulse is placed on the coil itself. This button is used in the beginning of the treatment sequence to establish what power is needed to place the coil in the correct position. Such work makes it impossible for the operator to not be in close contact with the coil and therefore in risk of overexposure.

We have measured the magnetic field from some TMS machines. We used a system with an electrically shielded circular coil with 2.5 cm radius, calibrated. The induced voltage was

registered with a Tektronix TDS 1012 digital storage oscilloscope. With this equipment, we pick up the time derivate of the magnetic field, dB/dt . An example of the single pulse can be seen in **Figure 3**. **Figure 4** gives an example of the series of pulses delivered in treatment sessions.

The system we have looked at is: MagVenture rTMS system with a magnetic coil type Cool-B65 (MagVenture A/S, Inc., USA). The Cool-B65 coil is a figure-8 coil with partially overlapping coils, and a MegPro unit with a magnetic coil transducer model, and MC-B70 (Medtronic Synectics AB, P.O. Box 265, SE-177 25 Järfälla, Sweden; <http://www.synectics.se>).

At some distance, depending on power setting and coil design, the distance from the coil where the action levels of the EU directive are exceeded is from some decimeter to almost a full meter. For the MagVenture system, the limit distance was 0.4 m and for the MegPro 0.7 m.

In the EU guideline [9] for how to implement the new EU directive measurements and discussion about the TMS exposure to staff are given. They found that at a typical hand position

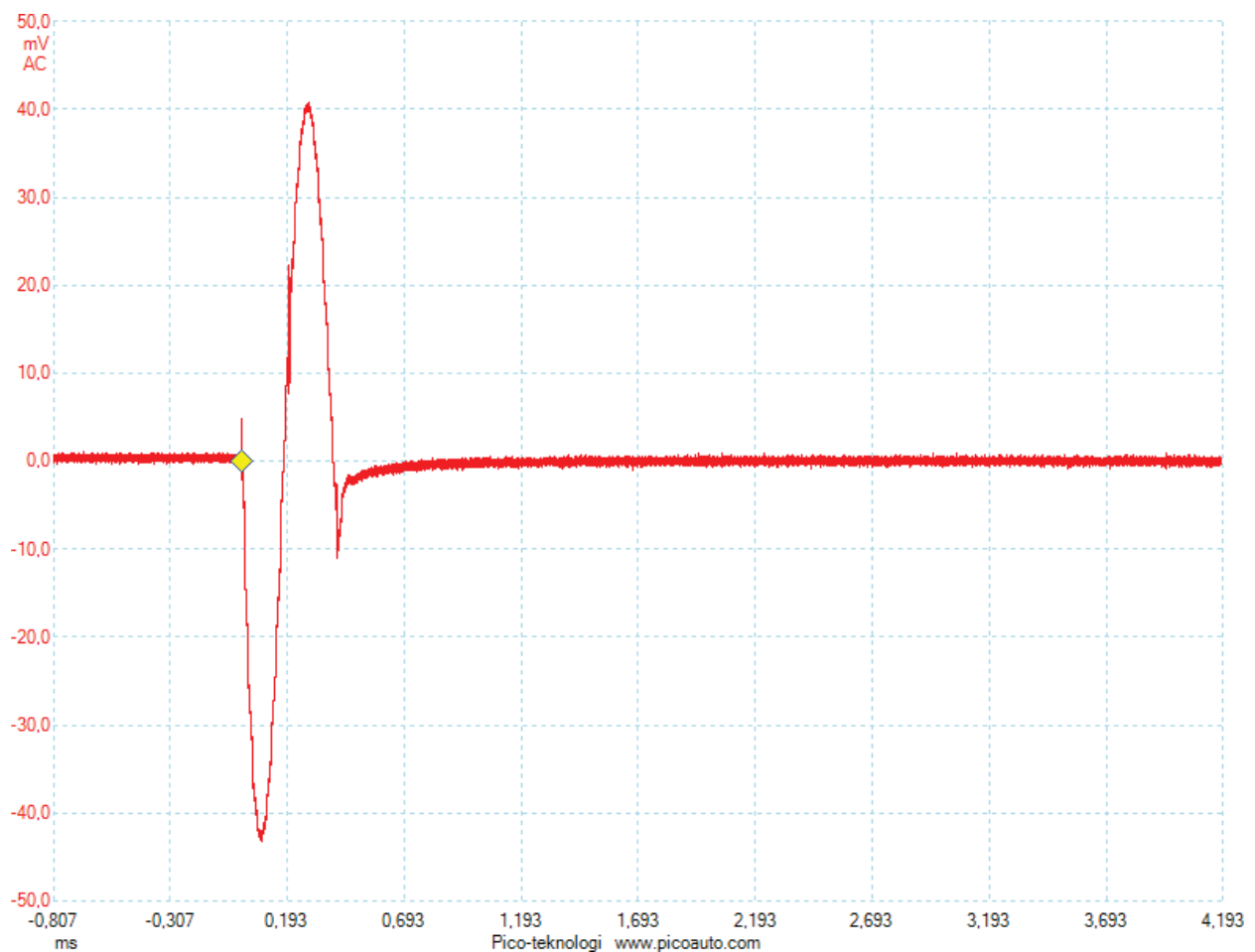


Figure 3. Recording of dB/dt in a single pulse from the MagVenture system. The frequency of the pulse was found to be about 2.5 kHz and practically sinusoidal.

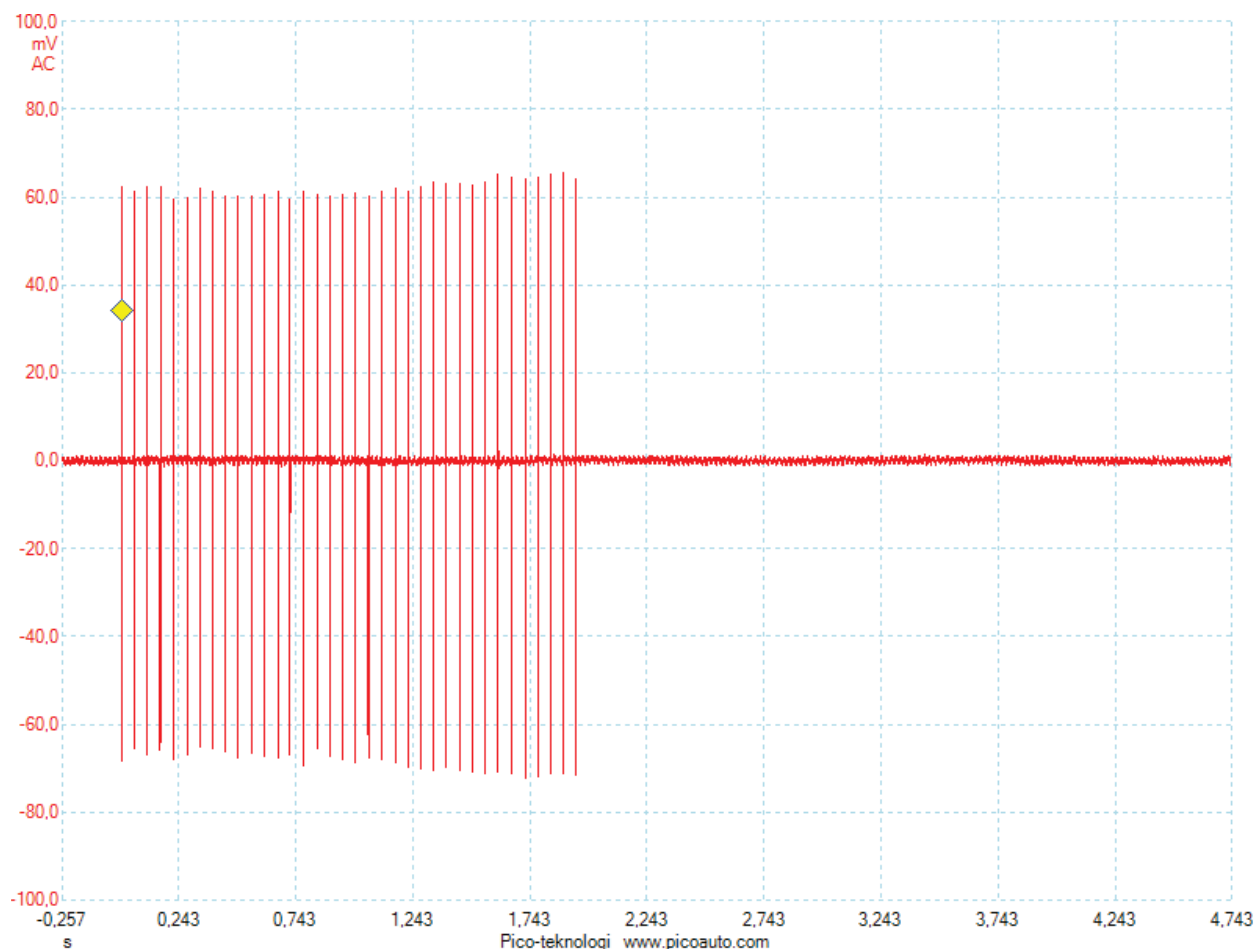


Figure 4. The system can be set to deliver a single pulse or a series pulses. In the rTMS, a pulse train with 20 pulses within some second is repeated with a frequency of some Hz. This is then applied for up to 15 min per session.

holding the hand piece with the coil the magnetic flux density exceed by 5,600% the limit for the limb. The team realized that the clinician was highly likely to exceed the action levels, and therefore a computer model was applied. From the computer calculation of the induced electric field, they found that the exposure limits could be exceeded up to 35,700% with the coil 15 cm from the torso.

2.2. Implants

The magnetic field pulses can exert attractive forces on ferromagnetic objects and repulsive forces on non-ferromagnetic objects. Therefore, it is of importance to screen the patients before treatment for metallic objects, such as cochlear implants, and other implanted objects in the scalp, such as deep brain stimulators and epidural electrode arrays for cortical stimulation. According to a review by Rossi et al. [10], it appears that TMS can be safely applied to patients with implanted stimulators of CNS and PNS when the coil is not in close proximity to the internal pulse generator. However, the information about the safe use in these cases is sparse, and therefore Rossi et al. [10] state that TMS should only be done in patients with implanted stimulators if there are scientifically or medically compelling reasons justifying this.

2.3. Discussion

It was clear from the measurements that the worker's exposure limits for the magnetic field pulses are transgressed at distances of about 0.7 m from the surface of the transducer's coils during normal patient treatment conditions. The coil handle, which is located in the plane of the figure-8 coils, is about 20 cm long, and this results in a short distance between the source of the field and the hand and forearm of the operator. The TMS transducer can in this case be seen as a single dipole with decay as the inverse of the cube of the distance, $1/r^3$. The head and trunk of the operator is at most an arm-length apart from the source, and since the basic restrictions are based on induced current in the head and the trunk for frequencies up to 10 MHz [2, 3], limiting exposures to the head and trunk are necessary. Different designs of TMS devices should be further studied to bring deeper insight in the issue of at what distance the limits in terms of induced electric field on the staff are exceeded from the surface of the transducer's coils during normal patient treatment conditions.

To avoid risks of overexposure to magnetic pulses, a recommendation that is valid for both single coil and figure-8 transducers, the equipment should be used with a mechanical arm holding the transducer in the right position for the patient. The staff operating the TMS equipment need to be educated and trained to operate the equipment in a safe way. EU guideline also states [9] that it is necessary to prohibit pregnant workers and workers with active implanted medical devices (AIMD) from operating the equipment or remaining in the room during treatment. Treatment should not be given to patients fitted with AIMD.

Unnecessary over-exposure to pulsed magnetic fields of this magnitude may cause negative health effects for the therapeutic staff. From the exposure guidelines, it is known that the rationale for limiting exposure is the well-defined biological responses ranging from perception of the fields to annoyance and stimulation of central and peripheral nervous tissue. Our studies were not designed to investigate health effects among the therapeutic staff, this is needed in the future, and neither did we investigate other possible risk factors for health complaints in this working environment, such as indoor climate, noise, and treatment lengths.

In conclusion, staff working with patient treatment with TMS/rTMS can become exposed to magnetic field levels exceeding both EU directive and ICNIRP guidelines; therefore, it is recommended that procedures are developed to avoid unnecessary exposure of staff. Information about the risks associated with the application of the strong magnetic pulses is necessary, and a training programme for the staff would be advisable.

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