4th URSI AT-RASC, Gran Canaria, 19-24 May 2024

Approach for assessment and reduction of occupational exposure in transcranial magnetic stimulation treatments

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Abstract

Transcranial Magnetic Stimulation (TMS) treatments have gained widespread acceptance in clinical practice due to their recognized significance in diagnosing and treating of various brain diseases. Nevertheless, to date, the exposure of the operator that performs the treatment remains an open issue in the framework of the occupational exposure evaluation, especially considering their daily close exposure prolonged in time. Therefore, in conjunction with the lack of a technical standard for the device's safe usage, we conducted a numerical assessment of occupational exposure, with a particular emphasis on local exposure analysis and studying methods to possibly mitigate exposure, especially concerning the upper limb.

1. Introduction

TMS has emerged as a pivotal tool in contemporary clinical neuroscience, offering non-invasive insights into the intricacies of brain function and providing therapeutic avenues for various neurological disorders[1], [2]. During the TMS treatments, the stimulating coil placed over the patient's head generates a high-intensity pulsed magnetic field, up to 3 T, that crosses the scalp and, given the conductive properties of the patient's head tissues, it induces an intense electric field (maximum in order of 100 V/m) that alters the brain neuronal activity [3], hence achieving the desired clinical or experimental response. Therefore, the operating principle of TMS is based on neuronal activation, which is elicited by the highly intense electric (E-) field induced into the brain tissue [4]. This variable magnetic field is produced by an intense current that flows inside the windings of the coil. Since the TMS magnetic field spreads in the space around the source, the clinician performing treatments also undertakes an exposure, and this occurs because typically they operate in the vicinity of the patient, intending to improve the stability of the coil and to have full control of the treatment. This means that often the operators hold the coil with their hand while the device is active, which produces a not negligible local exposure in the area of the upper limbs. Therefore, as reported by Rossi *et al.* 2021[5], in parallel to the expansion of TMS clinical utilization of TMS, becomes more and more demanding the need to address the open issue to manage the extent of the exposure for the operators, particularly in the absence of standardized technical guidelines.

In response to this critical gap in knowledge and regulatory frameworks, this work aims to conduct an in-depth study of occupational exposure to TMS devices, analyzing a real condition of exposure through the reproduction of a work scenario, focusing on specific local exposure sites, addressing two aspects: i) an analysis to assess the extent of operator exposure during a typical TMS treatments; ii) a methodology aimed at reducing the exposure of the operator's upper limb, through the identification of potential materials suitable for constructing a shield for the reduction of the exposure.

2. Materials and Method

2.1 The TMS source: features and setup

The modeled source of exposure is the standard double TMS coil (simply called *figure-of-eight* or *fo8*). Precisely, the model reproduced is the Magstim device MAG-9925-00. This fo8 TMS coil consists of copper wires continuously wound to create two connected circular coils (two lobes), each one characterized by a diameter of 90 mm. The supply system is the two-phase generator Magstim Rapid2 which implies a maximum supply current of about 4 kA and a working frequency of 3 kHz. The magnetic flux density (B-field) is at its maximum (1.2 T) approximately under the center of the coil. However, reproducing the real working setup of the device is important to consider the different percentages of maximum stimulator output (%MSO) typically used. In particular, the choice of the %MSO strictly depends on the type of clinical treatments and it could vary in a range of 30% to 80% [6], although, percentages of 80% and above are typically used only in the research contest. Thus, it results in a different extent of exposure for the clinician since the B-field produced by the TMS is linearly dependent on the %MSO.

2.2 The exposure scenario: analysis and considerations

Following this aim, the authors focused the attention on the posture of the operator, to reproduce the condition in which

the treatment is performed with the coil held with the hand of the clinician (Figure 1). The operator is here represented by a human male model Jeduk, member of the Virtual Population (ViP)[7], [8] available in the Sim4Life V7.0.0.7995 software [9], used in this study for computational analysis. Jeduk is a Korean young adult male model (33-year-old, 1.62 m, 64.5 kg), that presents a set of 1186 tissues at high resolution. Nerves, muscles, veins, and arteries are separated, and his segmentation is based on the high-resolution cryosection images obtained from the Visible Korean Project (https://vkh3.kisti.re.kr/?q=node/24). The model supports the Poser function for changes in body posture and thus allowing to perform a real condition of operation in which the medical staff grips the handle of the TMS coil.
For the assessment of the exposure a dosimetric analysis was performed using the Quasi-Static Low-frequency Solver included in the simulation software Sim4Life, with the aim to evaluate the induced E field inside the human body model.

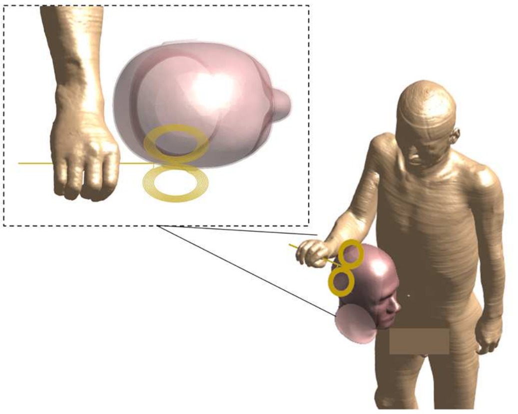

Figure 1. Exposure condition. The clinician represented by the human male model Jeduk is depicted in the act of holding the figure-of-eight coil with the hand during a TMS treatment.

The data of induced E-field have been post-processed and the compliance with ICNIRP 2010 guidelines [10] was assessed by comparing the evaluated 99th percentile of the induced E-field with the recommended limits (i.e., Basic Restrictions-BRs) at a specific working frequency (3 kHz in our cases). These guidelines suggest a limit of induced E-field of 1.13 V/m (peak), at our working frequency and for occupational exposure. In parallel, comprehensive literature research to identify a method or approach for the reduction of the extent of the exposure is carried out, based on the individuation of materials with good shielding capabilities to the low frequency magnetic field. The research was performed using standard scientific database as Scopus, Science Direct, IEEE Xplore, and PubMed. Additionally, the authors considered important that the materials may include certain characteristics like light weight, possible available in commercial use, low cost, and ductility. The materials collected represent a starting point for future in-depth study, currently ongoing.

3. Results

The 99th percentile of the induced E-field inside the body tissues of the clinician considering different percentages of maximum stimulator output, is first evaluated. To obtain a comprehensive analysis of the exposure, the 99th percentiles of the induced E-field in the whole-body of the clinician and in a local portion of his upper limb, are reported separately (Table 1).

Table 1. 99th percentile of induced E-field as a function of %MSO

	30%	*50%*	*80%*	*100%*
Whole-body	0.18	0.30	0.49	0.61
Hand district	1.21	2.02	3.22	4.03

As can be seen, in the case in which we evaluate the induced E-field considering the whole-body, in all the conditions the 99th percentile does not exceed the limit of 1.13 V/m (peak). Nevertheless, if we focus our attention only on the district of the hand and forearm (named *Hand district* in Table 1), on the contrary, in all the conditions of exposure, the 99th percentile of the induced E-field exceeds the suggested limits. This result could be confirmed by observing the map of the induced E-field on the clinician body (Figure 2).

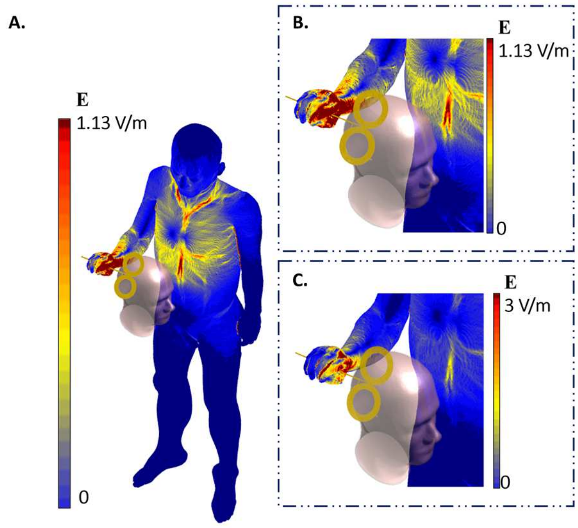

Figure 2. (A) Whole-body maps of the induced E-field at maximum MSO on the clinician's body during TMS treatments; the focus is on the hand region (B) colormap at the ICNIRP limit, (C) colormap adjusted to a higher E-field, to highlight its extent in the hand.

Figure 2 shows that the hand is more exposed than the other districts of the body to a higher B-field, owing to its vicinity to the source. This is in line with previous studies [11]–[13] finding that the exposure of the clinician's hand during

TMS treatments, in several cases may exceed the limit suggested by ICNIRP guidelines.
To this regard, authors considered that the local exposure of the clinician deserves particular attention. Thus, we considered the adoption of a shielding material to try to reduce the induced E-field inside the human tissues. To obtain this goal, we collected several papers [14]–[17] dealing with materials that might be useful for our purposes. Precisely, the literature review produced a total of twelve possible materials that match our goals. These materials are of both conductive and magnetic types, e.g. aluminum with polyurethane foam filling [18] and silicone rubber composite with ferrite and nickel powders[14], respectively. For both categories, considering several aspects, such as the encumbrance, weight, softness, ductility, thickness and the other mentioned above, some of the obtained materials were excluded, obtaining a final subset of four materials: three of them are ferromagnetic and one conductive.
Specifically, the following materials are finally selected:

Table 2. List of detected materials

Materials	Type	Reference
Ferrite	ferromagnetic	A. De Leo *et al.* 2014 [17]
Soft magnetic strips of amorphous $Fe_{80}Nb_6B_{14}$ alloy	ferromagnetic	G. Haneczok *et al.* 2009[19]
Silicone rubber composite with 80% $NiFe_2O_4$	ferromagnetic	A. R. Caramitu *et al* 2023 [14]
Aluminum screen and polyurethane foam filling	conductive	M. L. O. Bottauscio *et al.* 2016 [18]

The initial choice for preliminary analysis focuses on ferrite. This selection is motivated by its relevance in prior studies, as evidenced by other authors who have specifically tested it for TMS device shielding [20]. Additionally, ferrite is preferred for its notable shielding effectiveness attributed to its high magnetic permeability, with μ_r=88 at 1 kHz [20].
Further insights are still in progress.

4. Discussion and Conclusions

The occupational exposure condition here reproduced regards the clinician performing the TMS treatments while holding the handle of the coil with the hand. The figure-of-eight coil, as evaluated in accordance with the ICNIRP guidelines for whole-body analysis, does not appear to induce an E-field exceeding the suggested limits. However, a more focused examination of local exposure conditions, specifically in the hand and forearm region, revealed that even at the lowest practical level of feeding (30% MSO), the suggested limits are surpassed. As a matter of fact, the ICNIRP guidelines to date do not explicitly incorporate considerations for localized exposure when defining BR limits, which instead are thought only for the total-body exposure analysis. Nevertheless, we consider that the result found still earns attention.
To address this, we recommend exploring methods or approaches based on the use of proper materials with shielding properties. In conclusion, our findings underscore the importance of employing computational methods in exposure assessments within healthcare workplaces, since these methods are essential for identifying potential gaps in knowledge and can guide the development of new protocols for assessing exposure to devices like TMS, which currently lack in standardization. The pursuit of enhanced safety measures and a comprehensive understanding of exposure dynamics will contribute to the overall well-being of healthcare professionals. Further, these results may contribute to enhancing the use of TMS by the operators and promote the responsible and effective application of this important technology within the clinical scenery.

5. Acknowledgments

This work was developed within the Research *Startup Project type 2*, titled: “Dosimetric analysis of electromagnetic field exposure scenarios in occupational environments: equipment design and method development for risk reduction”, funded by Sapienza University of Rome. Prot n° AR223188B46BA574 published with deliberation S.A. 263/2023 of 10.1.2023.

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