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Operator Safety and Field Focality in Aluminium Shielded Transcranial Magnetic Stimulation

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This paper aims at verifying the effectiveness of the Transcranial Magnetic Stimulation (TMS) treatment when a passive shield is introduced for the nursing staff safety. The analysis is developed through a modeling approach, splitting the solution of the field problem into two successive steps. The Duke anatomical model of the Virtual Family dataset is used to model both the patient head and the operator body. The investigations are performed by considering stimulators equipped with a circular spiral coil or a figure-of-eight shaped (FoE or butterfly) winding. The addition of the shield slightly reduces the induced electric field values, while increasing the field focality in the patient brain (especially with the circular coil), preserving the effectiveness of the treatment, anyway. On the operators' side, the presence of a passive conductive shield significantly reduces the exposure levels.

Index Terms— **Biomedical computing, Biomedical equipment, Electromagnetic shielding, Finite-element method, Magnetic field.**

I. Introduction

Transcranial magnetic stimulation (TMS) is a non-invasive pain-free technique which uses an induced electric field to stimulate the human brain cortex. TMS has been quickly recognized as an efficient tool to both verify the functional integrity of central motor conduction in corticospinal or corticobulbar pathways [1] and treat a large range of neurological and psychiatric conditions [2]. The stimulation is produced by coils [3] placed above the subject's head, where electric current pulses generate an intense time-varying magnetic field and consequently an induced electric field inside the brain, without the need of surface electrodes.

During the treatment, the nursing staff is exposed to magnetic pulses, which could exceed the limits specified in the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines [4] and, in Europe, the indications of the Directive of European Commission [5], [6]. The studies (actually not many) devoted to the nurse operator's safety (e.g. [7], [8]) suggest a minimal distance of the staff from the coil to comply with the ICNIRP limits, but this constraint reduces the manual dexterity of the operator. The use of a conductive shield placed around the coil at the operator side can overcome this problem, as suggested by the authors in [9], [10]. Such a screen reduces the operator exposure, but could affect the induced field in the patient brain. Some authors intentionally include conductive plates near the TMS coil in order to improve the field focality in the patient brain [11] or minimize the surface field induced in the scalp [12], but without considering the operator exposure.

This paper aims at quantifying the effects of passive shields, on the efficiency of the TMS treatment. The analysis is performed inside the patient head, described by the Duke anatomical model of the Virtual Family dataset [13]. The same human model is used to evaluate the exposure conditions experienced by the operator. Two commercial stimulators (i.e. a circular spiral coil and a figure-of-eight shaped coil) have been considered. Both TMS coils have been supplied by a sinusoidal current pulse and analyzed with and without an aluminum shield, 1 mm thick. The shield shape and material have been designed by a Finite Element modeling where the main constraints are the minimization of the electrodynamic effects and the limitation of the device weight and size, in order not to compromise the operator's dexterity.

Without screen, the electric field induced in the operator's arm that holds the stimulator is significant for both stimulators and with the circular spiral coil (which represents the worst case) reaches relatively high values also in other parts of the body (e.g. head, trunk). The presence of the shield introduces a strong reduction factor in the nursing staff exposure, making it easier to comply with the legal requirement in force. The computations also demonstrate how the shield does not affect the TMS effectiveness, but rather it slightly improves the field focality in the patient's brain.

II. Numerical simulations

Exploiting the very limited deviation of the current and field waveforms from a sinusoid (deviations between positive and negative peaks lower than 7%) and the linearity of the electric and magnetic properties of the considered materials, a purely sinusoidal time evolution is assumed for all the field quantities and the computational procedure is implemented in the frequency domain.

In addition, the proper working frequency and the corresponding values of electric conductivity and permittivity make the magnetic field contribution due to the currents induced in human tissues negligible with respect to the one generated by the stimulator and shield. Thanks to this assumption, the computation of the electric field inside the human body is conveniently split into two successive steps [14].

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First, an electromagnetic field problem is solved in a sufficiently large domain, filled by air, which includes only the TMS coil and the conductive shield. The coils are modelled in a realistic way using bricks to represent both the spiral conductors and their connections, in order to avoid inaccurate predictions of the field distribution [15]. To this purpose, the commercial software Opera (Electromagnetic FEA Simulation Software by Cobham Technical Services, Kidlington, U.K.) provides the magnetic flux density distributions in the regions where the patient and the operator are placed. The electromagnetic field solution reduces to the application of the Biot-Savart law when the coil is unshielded.

The magnetic field distributions become the inputs for an electric field problem developed in terms of electric vector potential [9] and defined only in the human models of patient and operator. A home-made software, severely tested and largely applied to electromagnetic dosimetry analysis [16], has been adopted to solve this problem.

The posable version of the Duke anatomical model belonging to the Virtual Family data set [13], describes both the patient head (voxel side 2 mm) and the operator body (voxel side 4 mm). The dielectric properties of each tissue have been assigned, at the frequencies of interest, according to the database developed by the IT'IS Foundation [17].

In order to evaluate the effectiveness of the TMS coils on the patient treatment, the amplitude of the induced electric field has been estimated in three brain tissues: grey matter (identified by GM, involving 67954 voxels), white matter (WM, with 63308 voxels), and cerebellum (CB, with 19797 voxels), as shown in Fig. 1. The 99th percentile of the electric field amplitude has been evaluated, separately for each material, in the volume that includes the three tissues. This choice avoids that possible hot spots, due to local computational inaccuracies, could misrepresent the results. A quantitative estimate of the focality of the induced electric field E (capability to concentrate the electric field in a small volume) is the percentage of the tissue volume (denoted by V_{50}) where the E amplitude is equal or exceeds the 50% of a reference value E_{ref}, following the proposal in [2]. According to this definition, the higher the field concentration, the lower index V_{50}.

III. Patient analysis

The analysis has been developed considering a circular spiral and a figure-of-eight shaped (also called FoE or butterfly) coil composed of a couple of spiral conductors. The circular stimulator is a Magpro R30 by Medtronic (Pittsburg, USA) with a probe MC125, having 130 mm outer diameter. The device is supplied by a 3.5 kHz sinusoidal current having a peak value of 5.6 kA. The FoE coil is a Magstim device (Whidland, U.K.) supplied by a 2.5 kHz, 5.0 kA (peak value) sinusoidal current.

The shielding solution in both cases makes use of 1 mm thick aluminum sheets, suitably shaped, to reduce the shield size and facilitate the positioning operations. Ferromagnetic screens have been discarded, since preliminary computations showed large saturation levels in the magnetic material, which could be mitigated only by enlarging the shield thickness, at the cost of an unacceptable increase of the device weight. The schemes of the stimulators, together with their shields, are shown in Fig. 2.

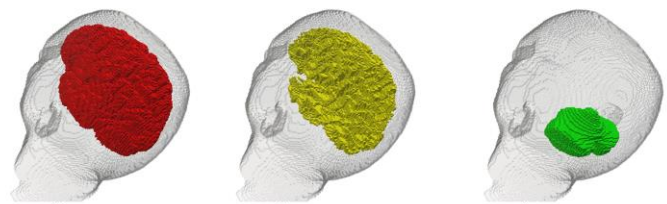

Fig. 1. Brain tissues under analysis: a) grey matter, b) white matter, c) cerebellum.

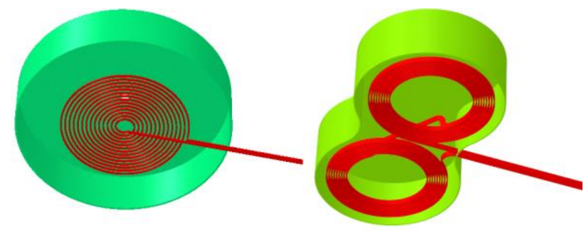

Fig. 2. Stimulator configurations including coil (red) and shield (green): a) circular coil, b) figure-of-eight shaped coil.

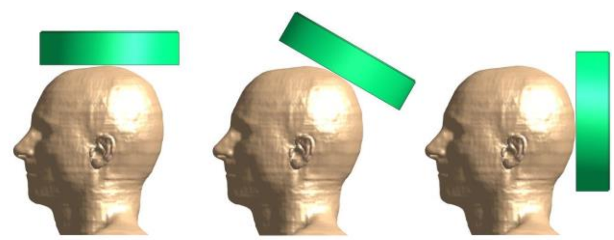

Fig. 3. TMS positions: a) #1; b) #2; c) #3.

Three positions of the stimulator have been taken into consideration, as presented in Fig. 3. In the first position (denoted as #1) the coil is placed over the head top, with its axis perpendicular to ground; in the second position (#2) the coil is placed over the parietal region, with a tilt angle of 30°; in the last position (#3) the coil is behind the head, with the axis parallel to ground. In all cases, the minimal distance between the TMS device and the patient head is about 1 mm.

For each stimulator, the focality estimate has been evaluated by assuming as reference value (E_{ref}) the maximum among the values of the 99th percentile of E (E_{M99}) obtained considering each combination of the three tissues and the three coil positions (for a total of 9 combinations). Two different values of E_{ref} have been adopted for unshielded and shielded configurations.

The distribution of the electric field (peak value) generated by the circular coil on the brain surface is presented in Fig. 4 for all coil positions with and without shield. Table I shows the quantities E_{M99} and V_{50} with E_{ref} = 205.6 V/m and E_{ref} = 179.1 V/m for unshielded and shielded coils, respectively. These values are always reached inside the grey matter with the coil in position #3.

Figure 5 presents the distribution of the peak value of E on the brain surface for all analyzed cases involving the butterfly coil, while Table II shows the corresponding values of E_{M99} and V_{50}. The reference values are 126.7 V/m and 98.0 V/m for the

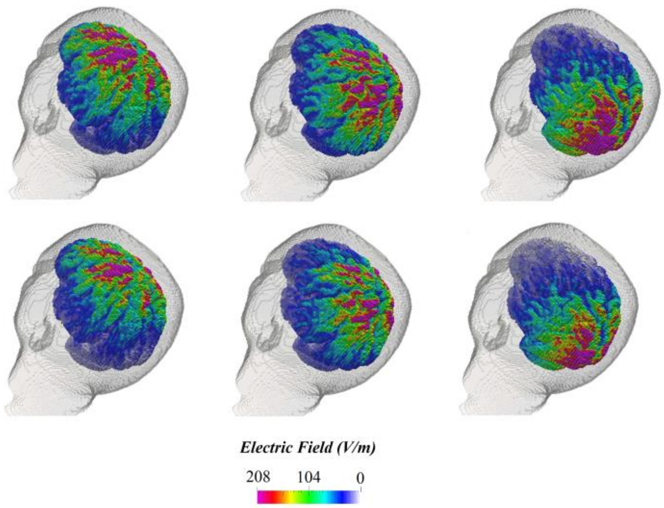

Fig. 4. Electric field distribution (peak value) induced by the circular coil. First column: position #1. Second column: position #2. Third column: position #3. Top: without shield. Bottom: with shield.

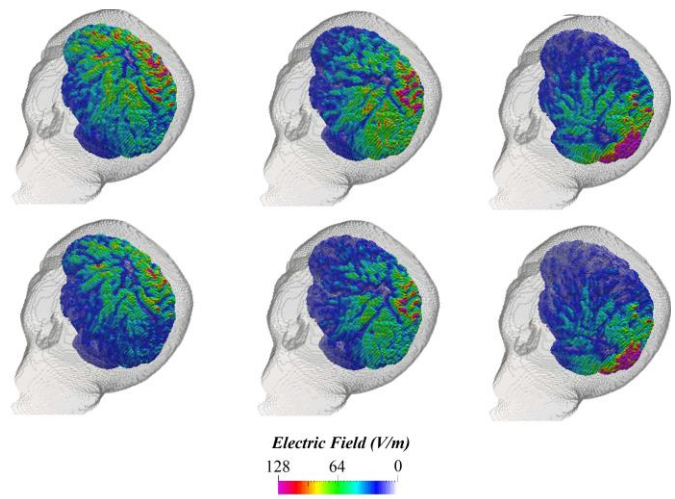

Fig. 5. Electric field distribution (peak value) induced by the figure-of-eight shaped coil. First column: position #1. Second column: position #2. Third column: position #3. Top: without shield. Bottom: with shield.

TABLE I
CIRCULAR COIL

Position	Tissue	Shield	E_{M99} (V/m)	V_{50} (%)
#1	GM	unshielded	191.8	5.75
		shielded	161.8	4.79
	WM	unshielded	183.0	7.21
		shielded	156.8	5.99
#2	GM	unshielded	185.5	5.23
		shielded	157.2	4.42
	WM	unshielded	167.3	5.46
		shielded	141.9	4.72
#3	GM	unshielded	205.6	8.45
		shielded	179.1	7.56
	WM	unshielded	188.7	7.50
		shielded	165.1	6.65
	CB	unshielded	132.0	4.14
		shielded	106.1	2.77

CB is not significantly excited in positions #1 and #2, thus is not reported in the table for these positions.

TABLE II
BUTTERFLY COIL

Position	Tissue	Shield	E_{M99} (V/m)	V_{50} (%)
#1	GM	unshielded	82.6	2,73
		shielded	64.1	2,62
	WM	unshielded	67.5	1,40
		shielded	52.3	1,42
#2	GM	unshielded	81.1	2,57
		shielded	62.4	2,40
	WM	unshielded	65.5	1,18
		shielded	50.2	1,09
#3	GM	unshielded	126.7	3,71
		shielded	98.0	3,65
	WM	unshielded	102.4	2,79
		shielded	78.5	2,66
	CB	unshielded	61.3	0,81
		shielded	46.3	0,74

CB is not significantly excited in positions #1 and #2, so is not reported in the table for these positions.

unshielded and shielded coils, respectively, again reached inside the grey matter with the coil in position #3.

The analysis synthesized by Tables I and II and Figs. 4 and 5 first puts in evidence that the shield slightly reduces the electric field amplitude in the brain (max reduction ~16 %), but tests carried out with the nursing staff in a partner hospital have shown that the treatment remains effective, anyway. At any rate, to restore the values of the maximum electric field of the unshielded device, the coil current can be adjusted accordingly.

As highlighted by index V_{50}, the focality increases. The analysis also shows how the butterfly coil provides a more focal treatment but lower induced E values.

IV. OPERATOR ANALYSIS

The posable Duke model has allowed the correct positioning of the operator's right arm, to evaluate a realistic exposure condition. Among the three positions considered up to now, for the sake of brevity the analysis is focused on Positions #3 only, where the stimulator is in front of the operator chest, as depicted in Fig. 6. The distance between the coil center and the operator body axis is about 25 cm. According to preliminary verifications (not reported here), this situation should provide a severe exposure condition for unshielded TMS coils, as already pointed out in [9] for the specific case of circular spiral coils.

The induced electric field (peak value) along the external surface of the body is depicted in Fig. 7 for both stimulators, with and without screen. Regarding the comparison with the limits in force, it must be noted that the European Directive [5] requires checking the compliance of the spatial peak value of the induced electric field in the entire body. On the contrary, in order to reduce the effects of stair-casing errors in voxel-based simulations, ICNIRP suggests considering the 99th percentile of the induced field in each specific tissue [4]. However, the latter choice seems to be not so suitable in case of TMS, where the operator is subjected to a strongly heterogeneous exposure and the computation of the 99th percentile for extended tissues (e.g. skin) could mask real hot-spots. Moreover, when working with

Fig. 6. Model of the operator body with respect to the patient head. One positions (#3) has been considered for both coils, with and without shield.

TABLE III
OPERATOR EXPOSURE IN POSITION #3

Coil	Shield	E_{MAX} (V/m)	E_{M99} (V/m)	ICNIRP limit (V/m))
Circular	Unshielded	17.7	3.93	1.33
	Shielded	2.85	0.73	1.33
Butterfly	Unshielded	21.4	0.73	1.13
	Shielded	4.86	0.20	1.13

Values here reported are peak values.

virtual human models, the concept of "tissue" depends on the quite arbitrary way in which the biological materials have been grouped. For all these reasons, the results are here presented, in Table III, in terms of both spatial maximum and 99th percentile evaluated over the whole body. The latter is, for all cases, significantly lower than the former, as expected due to the strong heterogeneity in the magnetic fields produced by the TMS devices. As can be seen, the presence of the shield reduces both indexes, even if the absolute spatial maxima still overcome the ICNIRP limits for the two stimulators. This confirms what can be observed in Fig. 7, where the reduction due to the shield is evident. Note that, in case of the shielded butterfly coil, the only remaining hot-spots are localized in the fingers that hold the stimulator. Additional computations (not reported for brevity) have shown that, if the values of the 99th percentile were performed according to ICNIRP (i.e. within each single tissue that composes the adopted human model), a full compliance would be obtained for the two shielded stulators. In the light of Figs. 7b and 7d, working with the arm a bit more extended (and, if possible, with a bit longer handle) might be sufficient to reduce the indexes in Table III below the limits.

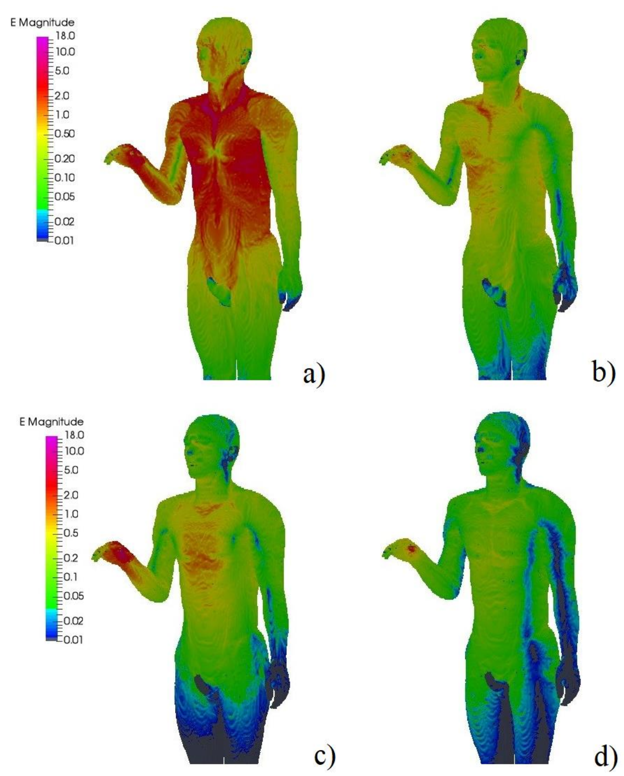

Fig. 7. Peak value of electric field (V/m) induced on the surface of the operator body. a) Circular coil pos. #3 b) Shielded circular coil pos. #3, c) Butterfly coil pos. #3, d) Shielded butterfly coil pos. #3.

V. CONCLUSION

This paper shows how the use of a conductive shield around the TMS coils does not affect the diagnostic and/or therapeutic treatment and, indeed, slightly increases the focality. The screen is always useful to reduce the exposure on the operator body, in particular for the circular spiral coil.

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