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Open letter on intervention regimes and adverse events in focused ultrasound for neuromodulation

Dear Editor,

Focused ultrasound is a promising technology for neuromodulation with significant potential to advance our understanding and treatment of the human brain. It spans a wide spectrum of intervention regimes from low to high intensities. Ensuring participant and patient safety is a central part of developing this field responsibly across the intensity spectrum.

Recently, a case report described a serious adverse event during a clinical trial applying intermediate-to high-intensity, low-frequency focused ultrasound for the treatment of substance use disorder [1]. We commend the authors for sharing their observations with the broader community - open reporting of adverse events is crucial for protecting participants and for maintaining public trust in this emerging technology.

This report has prompted important discussion in the field, including the commentaries authored by Profs Kim Butts Pauly and Elsa Fouragnan [2,3]. With this writing, we, the undersigned (see Table 1), and the ITRUSST safety group express our full support for their statements. The context and recommendations they provide reflect the shared position of a broad community of experts in focused ultrasound and neuromodulation.

Focused ultrasound can be applied at low-, intermediate-, and high-intensities in terms of its effect. Each regime has distinct utilities and safety profiles.

- At the high-intensity end, the goal is to induce irreversible structural change, as in transcranial thermoablation.
- In the intermediate range, which is less clearly defined, effects may exceed the normal physiological range of healthy brain function but remain reversible. An example in the domain of focused ultrasound is microbubble-mediated blood-brain barrier opening under stable cavitation.
- At the low-intensity end, effects remain within the normal physiological range, as when using transcranial ultrasound stimulation to modulate spiking probability via mechanosensitive ion channels.

A recent consensus statement proposed low-intensity exposure levels below which transcranial ultrasound stimulation is not associated with significant risk [4].

The reported study used acoustic feedback to monitor cavitation activity and to adjust or halt the transmission of power. Direct feedback control, both thermal and acoustic, has proven robust and reliable in high-intensity focused ultrasound thermoablation and microbubble-mediated blood–brain barrier opening [5–7]. However, in the absence of injected microbubbles, the suitability of using cavitation detection to titrate energy or prevent injury in low-frequency ultrasound treatment has yet to be established [3,8].

The methodology described in the current case report seems to have inadvertently invited cavitation, a biophysical effect beyond the normal physiological range. Cavitation is a stochastic process whose likelihood increases with higher pressures and lower ultrasound frequencies. At 220 and 230 kHz, upper-bound thresholds for thermally significant cavitation have been estimated at approximately 1.8–2.1 MPa (mechanical index, MI = 3.8 to 4.4; [9,10]), although isolated cavitation events likely begin at lower pressures. The team that published the case report has previously reported reaching pressures of approximately 1.6 MPa and 1.9 MPa in their trials, corresponding to transcranial MI (MI_{tc}) values at 220 kHz of 3.4 and 4.0 [11,12]. There are significant uncertainties associated with these pressure and MI estimates, particularly given potential skull reflections. Taken together, considering both exposure and effect, the intervention generally operated in an intermediate regime, near the transition to high-intensity. For the affected patient, where cavitation led to irreversible tissue changes, the intervention was unequivocally within the high-intensity regime.

In consultation with the community, the manufacturer kindly shared key technical information on the device settings used in this trial. For brevity, we include below the elements most relevant to estimating in-situ pressure; their full contribution is provided in the Supplementary Information.

> *"Estimated Pressure Levels in Clinical Setting - The typical parameters are 220 kHz, an emitted power of 80 W - 100 W with a pulse pattern of 100 ms and 27 % duty cycle spread between 8 sub-targets (3.3 % for each specific spot). The estimated pressure at the target is influenced by multiple variables such as the acoustic properties of the skull's layered bone structure (skull density ratio), skull and scalp inhomogeneity, tissue properties, electronic beam steering, etc. This theoretically leads to an estimated root-mean-square (RMS) pressure of 1.5 - 2.5 MPa. The manufacturer's experience with over 30,000 procedures, suggests that true pressure levels are 60 - 70 % of this theoretical value - leading to an estimated RMS pressure of 0.9 - 1.7 MPa."*

These RMS pressure estimates provided by the manufacturer correspond to peak negative pressures of approximately 2.1–3.5 MPa and MI_{tc} of 4.5-7.5 for the theoretical in situ range and to 1.3–2.4 MPa and MI_{tc} of 2.7-5.1 for the estimated true in situ pressure range.

The findings of the case report help advance our understanding of cavitation risk and safety of transcranial ultrasound in general. However, importantly, since the reported intervention did not operate in the low-intensity regime, either in effect or exposure, it does not change the safety assessment of transcranial studies conducted with low intensity exposures ($MI_{tc} < 1.9$). For reference, at 220kHz an MI=1.9 corresponds to a peak negative pressure of 0.89 MPa and an RMS pressure of 0.63

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(*continued on next page*)

Table 1 (*continued*)

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MPa. For such studies, analytical and numerical approaches can be used to ensure sufficiently low exposure levels [4], taking into account uncertainties in derived estimates. When pressure and frequency are chosen such that $MI_{tc} < 1.9$ [4], there is no significant risk of cavitation. Additional direct feedback can also be leveraged when signals remain within the physiological range, for example using acoustic radiation force displacement imaging [13–15]. Demonstrating operation within this regime benefits from reporting key acoustic parameters as outlined in recent recommendations [16]. These data were not originally made available in the case report [1]. Providing such information, along with patient-specific data including treatment imaging and acoustic feedback signals - as reported in other clinical studies using the same device [17] - would greatly assist the community in interpreting these findings and guiding future studies. We look forward to forthcoming analyses or simulations by those involved in the case report, as well as to prospective investigations that may further clarify the boundaries between low-, intermediate-, and high-intensity regimes.

Focused ultrasound neuromodulation holds great promise for advancing brain research and clinical care. We are at a pivotal moment - one that offers the opportunity to make a lasting difference for human health and well-being. We highlight the importance of continued collaboration and detailed reporting to ensure that this technology continues to develop safely, for the benefit of patients and the public.

CRediT authorship contribution statement

Miriam C. Klein-Flugge: Writing – original draft, Writing – review & editing. **Raag D. Airan:** Writing – review & editing. **David Attali:** Writing – review & editing. **Jean-Francois Aubry:** Writing – review & editing. **Ellen J. Bubrick:** Writing – review & editing. **Charles F. Caskey:** Writing – review & editing. **Robin O. Cleveland:** Writing – review & editing. **Elsa F. Fouragnan:** Writing – review & editing. **Ryan M. Jones:** Writing – review & editing. **Tatiana D. Khokhlova:** Writing – review & editing. **Jan Kubanek:** Writing – review & editing. **Harriet Lea-Banks:** Writing – review & editing. **Wynn Legon:** Writing – review & editing. **Nathan McDannold:** Writing – review & editing. **Keith R. Murphy:** Writing – review & editing. **Takahiro Osada:** Writing – review & editing. **Kim Butts Pauly:** Writing – review & editing. **Samuel Pichardo:** Writing – review & editing. **Jérôme Sallet:** Writing – review & editing. **Lei Sun:** Writing – review & editing. **Bradley E. Treeby:** Writing – review & editing. **Hairong Zheng:** Writing – review & editing. **Eleanor Martin:** Writing – review & editing, Writing – original draft. **Lennart Verhagen:** Writing – original draft, Writing – review & editing.

Declaration of generative AI use

Generative AI was not used in the preparation of this letter.

Declaration of competing interest

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Appendix A. Supplementary data

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