Opinion

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A Reasonable Pathway to Introduce an Array of Subdural Pharmacodialysis Devices (SPDs) for Currently Intractable Neurological and Psychiatric Disorders

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Opinion

In a series of papers published in the last fifteen years we described our invention, the Subdural Pharmacodialysis Device, SPD (Figure 1), for the safe and effective treatment of intractable neocortical epilepsies, ischemic and hemorrhagic strokes, Alzheimer's disease and possibly even for some types of malignant brain tumors (Ludvig, et al. [1-5]). This work was – as still is – justified by the devastating impact of drug-resistant epilepsies (Jehi [6]), Alzheimer's disease (Serrano-Pozo A, et al. [7]) and other intractable brain disorders on the lives of millions of people all over the world (Figure 2).

Yet, SPD-type devices haven't been introduced into neurosurgical, neurological and psychiatric health care. This author believes the following reasons blocked this medical progress:

1. Most neuroengineers are too busy with their short-term work to spend time on the larger picture of the at least decade-long pathway to the wide arrays of such devices.
2. Most neurologists and psychiatrists are still uncomfortable with the idea of using intracranial drug delivery and neurotoxin-drainage devices in their practice.
3. Most neurosurgeons simply do not have the experience, sometimes even willingness, to implant such devices.
4. Clinical and health center administrators are worrying about the costs and legal aspects of implanting pharmacodialysis devices in the brain, knowing the problematic aspects of the even simpler electrical stimulators.
5. Venture capitalists rarely have the medical knowledge and general modesty to understand that the development of safe and effective neurochemically acting brain implants would need a decade-long work before their use and commercialization.
6. Companies manufacturing neurotherapeutic devices that use electrical stimulation only, like the implantable Deep Brain Stimulation (DBS) device for Parkinson's disease or the implantable Responsive Neurostimulation (RNS) device for drug-resistant focal epilepsies, have vested commercial interests to prevent competition from SPD-like systems. Therefore, any support by these companies for developing SPD-type devices has been – and still is –impossible to obtain, while their frequent representatives in relevant NIH review groups have hardly been helpful for alternative device projects like ours.
7. NIH, the primary organization for funding pioneering neurotechnological research in the United States, has never been interested funding work with intracranial drug-delivery/neurotoxin-drainage implants (e.g., Ludvig, et al. [1,2,4]), though NIH's own neurosurgeons intended to develop similar neurotherapies with less advanced devices (Heiss, et al. [8]). This author's last attempt to initiate clinical trials with an Early Feasibility Study for the antiepileptic version of SPDs (Figure 3) in collaboration with the neurologists and neurosurgeons of the Feinstein Institute for Medical Research, Manhasset, NY, was rejected by NIH in 2019.

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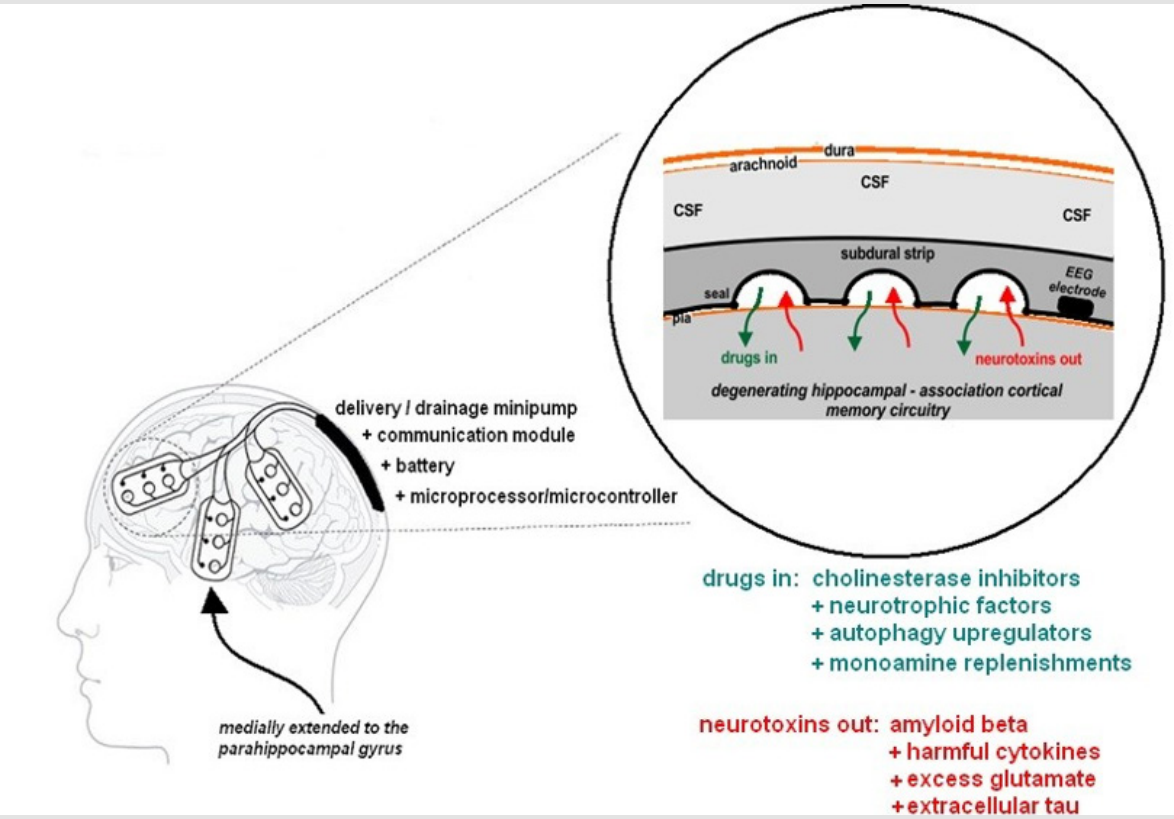

Figure 1: Design of the neurocranial drug-delivery/neurotoxin-drainage SPD system for the treatment of Alzheimer's disease. It contains a neurocranially implanted Control Unit and several Subdural Units over the association cortices for drug-delivery and neurotoxin-drainage. Obviously, once the errors of the gene-network – and I emphasize "gene-network" – for this disease will be known, the right CRISPR gene-editors and/or mRNA-nanoparticles can replace the indicated drugs to achieve cure. The unique ability of SPD technology to bypass the Blood-Brain Barrier with such large compounds allows the therapeutic team to perform this powerful procedure. And the SPD communication module is obviously suitable to furnish the proper EEG data for the implanted patient's physician to develop the right AI module for the treatment and upload it to the Control Unit.

Some intractable brain disorders	Worldwide impact
drug-resistant epilepsies	--- now devastate the lives of ~15 million people
malignant brain tumors	--- cause death in ~300,000 people each year
strokes	--- cause death in ~6 million people each year
Alzheimer's disease	--- now forces ~33 million people into institutional care

Figure 2: Worldwide impact of some currently intractable neurological and psychiatric disorders, potential candidates for SPD therapy.

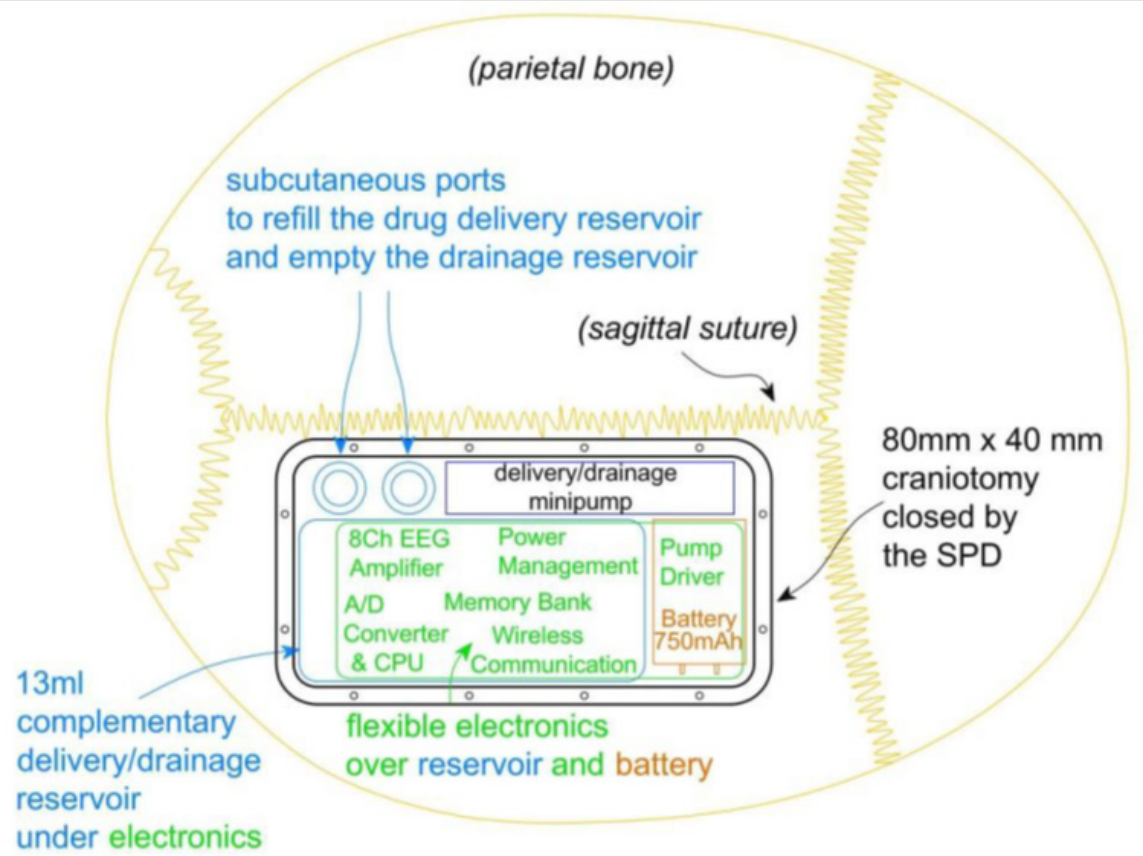

Figure 3: Design of the Control Unit of the SPD implant for the treatment of currently intractable multifocal neocortical epilepsy, as it was presented in the author's NIH grant application in 2019. The Co-Principal Investigator author created this design in collaboration with G-Tech Electronic Research & Development LLC, Cortlandt Manor, NY. The plan was to connect this unit to subdurally placed antiepileptic drug-delivery/inflammatory protein-drainage strips designed by the author to be manufactured by PMT Corporation, Chanhassen, MN. Then the complete system was to be implanted for 2 months in 6 patients selected by Co-Principal Investigator neurologist Ruben I. Kuzniecky, MD, before replacing it with a permanently implanted RNS device by Co-Investigator neurosurgeon Ashesh D. Mehta, MD, PhD, experienced with RNS implantation.

In case the described intellectual environment for SPD-type devices will improve, the following strategy may be used for introducing them for clinical practice: The first device would be for intractable multifocal neocortical epilepsies -- because the most promising data are available for this disease. The second device would be used for subarachnoid hemorrhage treatment, considering the clear need for effective strategies for this devastating disease. And the third device would be for Alzheimer's disease, due to the justification of new thinking about the therapy of this disease after half a century of failures.

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