Brain pacemakers without side effects

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For Parkinson's disease (PD) patients whose symptoms cannot be controlled by medication, 'Deep brain stimulation' (DBS) may be the only hope. While DBS is generally considered to be safe, side effects related to the stimulation may occur in some cases, including numbness or tingling sensations, muscle tightness, speech or balance problems and unwanted mood changes. The IMPACT project has set out to counter these side-effects by bringing DBS to the next level.

The IMPACT (Improving the lives of Parkinson's disease patients while reducing side effects through tailored deep brain stimulation) team initiated its work with one premise: the main problem with current DBS practice lies in the fact that physicians do not have the tools needed to provide personalised treatment. Stimulation outside the intended target region occurs in 15 to 30 % of DBS patients and leads to side effects and less effective therapy delivery.

The EUR 5 million IMPACT project has spent the past four years trying to develop a 'direct-feedback, image-based expert tuning tool to improve the positioning and programming (tuning) of "Steering brain stimulation" (SBS) implants in a patient-specific manner'. In other words, instead of targeting a larger average area, the new software will help the clinician to place the stimulation field exactly where it should be, taking into account the specifics of each patient's brain anatomy.

One month ahead of the project's end, Hubert Martens, Director of Product Development at Medtronic and coordinator of the project, discusses the physician tool developed by his team. This new tool

combines pre- and post-operative imaging data (MRI, X-ray), high-resolution electrical recordings of the patient's brain activity and bio-statistical data about DBS target areas. Prototypes are already under clinical evaluation.

What are the main shortcomings of current DBS systems?

DBS is a great therapy, but less precise delivery of stimulation may elicit unwanted side effects. Improved precision is required. In essence, the optimisation of the therapy after surgery is a trial-and-error process. There are currently no tools that guide the clinician to the most optimal position in a time-efficient manner.

How does the technology you developed contribute to solving these problems?

In IMPACT, we have focused on the usage of imaging, advanced modelling and analysis to precisely identify areas of the brain which need to be stimulated for an optimal effect, as well as areas to be avoided because they are closely related to certain side effects. We integrated that information into algorithms and an intuitive tool which is able to help guide programming decisions by a physician managing the therapy for DBS patients.

What are the other features of your technology that, according to you, provide real added value for experts and patients?

We have created an intuitive workflow. A lot of energy was spent on optimising the usability of the product to make sure that physicians—in

light of their busy schedules—can use it in an easy and optimal manner. In general, technically complicated products and user interfaces are not very successful and fail to have an actual impact on clinical practice.

Advanced visualisation and integration with other modalities, for instance the analysis of physiological sensing data, provide a comprehensive view of function and anatomy that helps support programming decisions.

What were the main difficulties which you faced during the project and how did you overcome them?

It really was a challenge to keep geographically remote partners aligned over the duration of a multi-year project. To keep everyone on track, we organised regular consortium meetings to discuss progress, align our plans and have these linked to appealing scientific meetings, so that the partners enjoyed participating and to contribute to the bigger picture.

In addition, a programme manager dedicated to IMPACT, made sure that there was regular communication between consortium meetings and that relevant information on progress/deliverables/plans was shared and available to all.

What other diseases did you focus on, apart from PD?

Most focus was actually on PD, in order to demonstrate the feasibility of the concept. But some research was indeed conducted on essential tremor, dystonia and obsessive-compulsive disorder.

The project is getting close to its end. Does its success meet your initial expectations?

Yes, it does. It has been very rewarding to work together with top-notch clinical and technical partners on this project. It has really allowed us to push the envelope of technology and clinically validate our ideas.

When do you think patients can expect your technology to reach the market?

The IMPACT technology is on our product roadmap. The existing IMPACT prototypes are currently undergoing clinical evaluation as part of the IMPACT programme. The outcome of this initial study will drive our further plans in terms of additional steps needed to further develop and commercialise this technology. These steps will drive the timeline.

More information: Project website: www.csr-impact.eu/

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