

MRI Guided Ultrasound Devices See a Future in Parkinson's Disease

GlobalData

On August 20, 2012, InSightec announced it received approval from the Food and Drug Administration (FDA) to begin Phase I clinical trials evaluating the use of its ExAblate Neuro system for the treatment of patients with tremor-dominant Parkinson's Disease (PD). This device is the first clinical system to use magnetic resonance guided focused ultrasound (MRgFUS) through an intact skull, offering non-invasive transcranial treatment without any incisions or ionizing radiation. The ExAblate Neuro system is designed to alleviate the cardinal clinical features of PD through non-invasive deep-lesioning of the brain. While the concept of using focused ultrasound for non-invasive treatment of brain disorders has been recognized for many years, InSightec VP of R&D Eyal Zadicario stated that vast technical barriers had to be overcome to enable this modality to become a reality.

Lesioning has been an accepted technique to treat the symptoms of PD for years; however, InSightec's ExAblate Neuro device offers the first non-invasive lesioning treatment in clinical trials to date. Moreover, this treatment boasts improved accuracy as MR images are used to reconstruct the skull and this data is in turn used to configure the ultrasound beams to properly focus on the targeted lesion. The Phase I clinical trial for ExAblate Neuro will be sponsored in collaboration with the Focused Ultrasound Foundation of Charlottesville, Virginia, where researchers have already treated 15 essential tumor patients successfully. Preclinical studies conducted at the Focused Ultrasound Foundation as well as Arizona State University, UCLA, and Brigham and Women's Hospital indicate that the mechanical effects of ultrasound alone may be sufficient to both excite and suppress neuronal circuits.

PD is caused by the death of nerve cells in the brain, resulting in the ever-increasing impairment of cognitive and motor functions over time. This chronic, degenerative neurological disorder affects at least 1m people in the US and over 5m people worldwide. According to the National Parkinson Foundation, 50,000–60,000 new cases of Parkinson's are diagnosed each year in the US alone, making it the 14th leading cause of death. The number of people suffering from PD is expected to double by 2030, with the greatest growth in the number of cases coming from developing Asian countries, particularly China and India, where the number of elderly people is expected to see the biggest increase. If approved in the US, this device will likely be introduced into other markets quickly to meet this need.

There is no known cure for PD and there are few therapies available for patients suffering from its symptoms. Presently, most treatment options are limited to drug therapy and surgery, including deep brain stimulation and direct lesioning. While each of these approaches has been proven to show some symptomatic improvement, their effectiveness is limited and side effects discouraging. Drug

therapy techniques, even at optimal intervals and dosages of medication, show diminishing effectiveness as the disease progresses and ultimately fail to promote good motor control in late-stage PD. Deep brain stimulation, or neurostimulation, is the most common surgical intervention used; however, this technique is complicated as well as very invasive. Other options include radiofrequency ablation, another invasive technique, as well as radiosurgery, which has adverse side effects related to its use of ionizing radiation. As MRI machines become increasingly available to patients around the world, focused radiation offers a non-invasive means of accessing hard-to-reach areas of the body. It is expected that such techniques will become progressively more accurate and less expensive as technologies improve.

While deep brain stimulation may be on the way out for the treatment of PD, the neurostimulation market was valued at over \$1.8 billion in 2010 across all indications, with Medtronic leading the way with a 54% share of the global market. It is expected that this market will grow at a Compound Annual Growth Rate (CAGR) of 14% to reach \$4.7 billion by 2017 to match the ever-increasing elderly population and consequent rise in disease incidence. With InSightec offering a less-invasive treatment than neurostimulation, it is expected that MRgFUS devices such as ExAblate will take part if not all of the neurostimulation market share for PD indications.

There are many future treatments being developed for PD besides MRgFUS, including gene therapy and the use of stem cells. Gene therapy offers a means of introducing normal genes into people with certain disorders to overcome the effects of defective genes; however, this therapy is not yet available and is in the early stages of research. The use of stem cells to replace damaged cells with healthy, dopamine-producing ones is steadily progressing; however, it will be at least 5–10 years before clinical trials using stem cell therapy to treat PD will be considered. With imaging techniques already advanced enough that they can support MR guided surgery, adoption of the ExAblate Neuro device by physicians is expected to be widespread. As a result of the ineffectiveness and adverse side effects of current treatments for PD along with the long development time before gene and stem cell therapies are feasible, MRgFUS devices are entering a market with a large unmet need and a vast target population.

There are many potential benefits of focused ultrasound treatment as this procedure is non-invasive, the therapeutic effect is immediate, and there is no associated ionizing radiation. Non-invasive procedures greatly reduce the patient's risk for infection, and closed-loop thermal feedback ensures that focused ultrasound damages only the targeted tissue. This one-time procedure does not require subsequent surgery to replace batteries, does not involve implantation of a foreign object in the body, and greatly reduces collateral damage to the brain.

Beyond working to treat indications of PD, additional research using MRgFUS is being conducted for chronic neuropathic pain, targeted drug delivery, uterine fibroids, adenomyosis, and sonothrombolysis for acute ischemic stroke. MRgFUS technology is advantageous as it allows physicians to visualize the body anatomy, plan the procedure, adjust and control the treatment, and monitor the outcome – all

MRI Guided Ultrasound Devices See a Future in Parkinson's Disease

Published on Medical Design Technology (<http://www.mdtmag.com>)

in real time. As technologies develop, this treatment will have applications across multiple clinical disciplines. InSightec is currently testing MRgFUS for multiple indications and will need to push its Neuro product through clinical trials to stay ahead of its competitors as they are slowly expanding their markets to target this population as well.

Source URL (retrieved on 05/04/2015 - 2:04am):

<http://www.mdtmag.com/news/2012/08/mri-guided-ultrasound-devices-see-future-parkinson%E2%80%99s-disease>