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Focused Ultrasound and the Brain

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Why is high-intensity focused ultrasound being explored to treat the brain?

For a number of brain disorders focused ultrasound (FUS) will represent a treatment that is either superior to best current therapy, or fulfils an unmet clinical need. The driving factor is a validation of the technology. It doesn't take an enormous leap of faith to appreciate that if you can treat something deep in the brain in an awake patient, through the intact scalp and skull with extreme precision and accuracy, if that technology works for the brain it will also work more easily for things outside the brain in more forgiving locations, such as breast or liver tumours.

It is a new field, and it is very important to increase awareness. Everyone is interested in how the brain works, and concerned about brain disorders, such as stroke, Alzheimer's disease or brain tumours and other disorders related to the brain, even though they may not numerically or epidemiologically be the largest disease category. These are certainly the ones that garner most attention from the general population. We are working on increasing awareness and validating the technology in addition to providing better outcomes at lower cost.

What are the most promising applications for the brain, and how soon could these be implemented into clinical practice?

The full spectrum of what we're looking at pretty much has equal priority in terms of ultimate importance, including movement disorders, such as essential tremor, Parkinson's disease and dystonia; epilepsy, brain tumours and psychiatric disorders, such as obsessive compulsive disorder and depression. They are all important, but in terms of rolling out technologies that can be rapidly adopted, the movement disorders are good, because the patients enter the MRI machine, and come out a couple of hours later and we know the result. We don't have to wait a period of time like you have to for either epilepsy or psychiatric disorders. The movement disorders are like the tip of the spear: essential tremor was a predicate for treating Parkinson's disease. Parkinson's disease numerically is not very different from essential tremor in terms of how many patients could be treated, but Parkinson's disease has much greater disability. My hope is that in two years' time FUS for essential tremor will have U.S. Food and Drug Administration (FDA) approval, and that treatment will be reiumbursed in the next 3-4 years. It is already available with the CE mark in the UK.

What are the main challenges and barriers to wider use of focused US, especially for brain treatment?

The technology currently is only useful for the central part of the brain, but the engineering is being improved so that it can treat basically the entire volume of the brain, and by the end of 2015 we expect that technical hurdle will be overcome.

The main barrier is the evidence. You have to have the evidence, and we are gathering evidence on safety, efficacy, outcomes and cost. Once we have that evidence, it will lead to regulatory approval, reimbursement, and persuasion of the medical community that FUS is better than current treatments.

The potential benefits of focused US are many (quality of life, longevity, decreased costs, shorter treatment time), but are there any potential drawbacks?

It is a major step forward in treatment of a broad spectrum of brain disorders, but it is not a panacea. There are some drawbacks. For example, treatment of large brain tumours may take a long time, but on the other hand there is no other treatment currently. For some tumours e.g. with 10-20 brain metastases, patients are better served with stereotactic radiosurgery, the Gamma Knife or whole brain radiation therapy.

Focused US can cross the blood brain barrier. What potential new treatments might that facilitate?

There are a couple of mechanisms of action that FUS can be used for. Firstly, to destroy tissue either by heating it or by breaking up the cells. Secondly, delivering drugs with microbubbles to a precise part of the body or brain where needed, to minimise the systemic side-effects. Importantly, there are many drugs that are very effective, but they don't get into the brain because of the blood brain barrier. FUS can reversibly open the blood brain barrier that will allow drugs to get into the brain that are otherwise excluded, and these drugs can be used for treating tumours, be they chemotherapy agents, or in future genes, growth factors or even stem cells – to treat the Parkinson's disease itself not just the symptoms, and even Alzheimer's disease. The first patient to have chemotherapy agents delivered by FUS across the blood brain barrier to treat a brain tumour is expected in Canada in the next few weeks. Immunomodulation is another exciting area: treating tumours with ultrasound unleashes the body's immune response, which is an area of potential.

With brain, where should research be prioritised in your view?

FUS can stimulate or block neural activity, so it can be used to map the brain, to help plan surgery so you avoid eloquent areas of the brain or to confirm the target for doing treatments for movement disorders.

Is the cost of the technology within reach of the average tertiary hospital?

For applications outside the brain, the short answer is yes. The long answer is that in the next couple of years there'll be solid evidence that FUS is not only advantageous in reducing procedural costs, but it will also have a high impact on societal cost, which is important in the new affordable care organisation model where the emphasis is on value-based purchasing.

Who should be using this technology? Are there enough trained physicians who can use the technology?

It depends on the organ. For brain treatment, I personally believe that it should be within the purview of neurosurgery. For uterus treatment, FUS can be carried out by gynaecologists, radiation oncologists or interventional radiologists. For the prostate, by radiation oncologists or urologists.

In the future, I think we will have physicians from a variety of specialities, who are trained, certified and credentialed to use the technology. The training needed is not nearly as challenging as it is to learn to perform minimally invasive or open surgical procedures. So I don't anticipate a shortage.

The Focused Ultrasound Foundation is a very innovative organisation (to quote the website: "tax-exempt, highperformance entrepreneurial service organisation with a global reach." Why is this set-up needed to accelerate adoption of focused US?

The development and adoption of any new therapeutic technology occurs at a glacial pace. For example, the Gamma Knife technology was invented in 1950. The first research device was installed at the Karolinska Institute in 1968, the first unit was commercially available in 1987, and it didn't become mainstream until 1995 – 45 years later. The process of accelerating adoption involves a large number of steps from concept to widespread utilisation, and involves the dynamic interaction of a huge number of organisations that represent the stakeholders or the ecosystem. Is there a way to shorten the process? Every day that goes by translates into unnecessary death and disability and suffering for countless people. It needs to be faster. We needed this new model and it can be used to implement other disruptive technologies.

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