

Title: ClearPoint versus frame-based MRI-guided and MRI-verified Deep Brain Stimulation

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We read with interest the paper by Sharma et al on “Clinical outcomes of pallidal deep brain stimulation for dystonia implanted using intraoperative MRI”.⁶

“First do no harm” is a central tenant of medical practice that is especially relevant in functional neurosurgery, where the procedure is supposed to improve quality of life.

The pioneers of stereotactic functional neurosurgery had to rely on ventriculography and stereotactic atlases to guide the initial trajectory and often performed multiple brain passes while collecting physiological and clinical observations in awake patients under local anaesthesia to guide and verify the surgical procedure. The availability of high-quality magnetic resonance imaging (MRI) and commercially available deep brain stimulation (DBS) hardware provides contemporary functional neurosurgeons with an alternative approach. Dedicated stereotactic MRI sequences can be used: 1. to visualise the anatomical target in the specific patient undergoing surgery; 2. to confirm that the DBS lead has reached the intended target; 3. to refine lead location with one additional brain pass if initial lead placement is suboptimal.

A stereotactic, frame-based approach to MRI-guided and MRI-verified deep brain stimulation has several benefits: 1. It dispenses with clinical and physiological observations under local anaesthesia, reducing patient discomfort as well as the cost involved in terms of equipment and personnel. 2. It allows surgery under general anaesthesia, which is especially useful in young children or patients whose symptom severity precludes surgery under local anaesthesia; 3. It focuses on lead location within the visible radiological anatomy, which has been increasingly

recognised as the best predictor of long-term clinical outcome^{1,7}; 4. It avoids the use of sharp probes within the brain; 5. It minimises the number of surgical trajectories through the brain. These last two factors reduce the risk of damaging vessels leading to haemorrhage that can result in neurological deficit or death.⁹ This approach has been shown to deliver clinical results that are equivalent to traditional approaches but with less risk of serious complications.²⁻⁵

We are therefore concerned when an MRI-based approach reports high complication rates, especially when 4 of 30 patients suffer an intracerebral haemorrhage, as reported by Sharma et al.⁶ The discrepancy from other MRI-based approaches might be explained by the surgical technique used in the study.

Instead of using a stereotactic frame to obtain images before and after DBS lead introduction, the ClearPoint system uses “real-time” tracking during introduction of a ceramic stylet and peel away sheath prior to introduction of the DBS lead. Whereas a frame-based approach requires access to an MRI machine for around 20 minutes before and 20 minutes after lead implantation, the ClearPoint system adds considerable cost to an already expensive procedure since it requires highly priced consumables and access to an MRI machine throughout surgery.

The authors argue in favour of a “real-time” approach by suggesting that “postoperative verification risks delayed recognition of procedural complications”. However, this is a moot point since the options of dealing with a deep-seated haematoma are limited once it has been visualised on MRI. Moreover, it is counterproductive if the new method actually increases the

risk of procedural complications. Indeed, bleeds that caused neurological deficit in two patients (and ultimately death in one) “resulted from technical failures related to the introducer peel-away sheath being inserted too deep.”

It is for this reason that we have adopted the modified “KISS” principle in our surgical practice: “Keep It Simple and Safe”. Rather than introducing novel and complex practices to stereotactic functional neurosurgery, we have streamlined the process, removing unnecessary or redundant steps that increase the risk of errors and complications.⁸ Why fuse a non-stereotactic MRI to a stereotactic CT to plan the initial trajectory, risking the introduction of co-registration errors, when a stereotactic MRI avoids this? Why use a cannula when the DBS lead will follow the exact path of a rigid probe after it has been removed from the brain? Why perform microelectrode recording when lead location on MRI is a good predictor of long-term outcome? Why perform an MRI several days after surgery when performing the same investigation with the frame still on allows the surgeon to relocate a sub-optimally placed lead immediately?

The authors are to be congratulated for their in-depth reporting of adverse events and feedback to the company of potential pitfalls when using their equipment. They have emphasised that most of the complications occurred early in their series and are related to adoption of a novel surgical strategy into a busy surgical practice. However, if moving away from frame-based surgery to adopt this more expensive and complex technique was a challenge for such experienced and distinguished functional neurosurgeons, it will certainly test others.

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