Directional deep brain stimulation

Conventional deep brain stimulation systems use ring-shaped electrodes, which generate an approximately spherical electrical field. In these systems, programming of polarity and stimulation pulse parameters allows only limited control of the shape of the volume of tissue activated. Two acute intraoperative studies have proven the feasibility of horizontal current steering by using novel lead designs, such as segmented or multicontact electrodes. Directed stimulation using these electrodes resulted in increased stimulation thresholds for side effects as compared to standard spherical stimulation [1].

Several new electrode designs have been proposed allowing to shape the electrical field perpendicular to the lead. Industry and clinicians hoped that “directional DBS” (dDBS) would reduce the risk of stimulation-induced adverse effects and optimize the clinical benefit of DBS, but this hypothetical concept could only be tested after first technical solutions became available for clinical use. Prototypes varied from electrodes with up to 40 small circular contacts of about 0.8 mm, which were evenly distributed over the last 5 to 6 mm of the electrode, and more simple models which split up the conventional ring contacts in 3 to 4 segments spanning 90° or about 120 [2].

In 2014, two studies were published, which corroborated the principal hypothesis of dDBS, that current steering in the horizontal plane could modify the current threshold for beneficial and adverse effects, depending on whether current was injected towards or away from the underlying anatomical structures. Both studies used a similar acute, intraoperative design by evaluating current thresholds for stimulation induced clinical effects (e.g., rigidity reduction, dysarthria, or muscle contraction) comparing omnidirectional stimulation (simulated ring mode) against dDBS. This testing was performed intraoperatively by temporarily implanting a directional lead into the subthalamic nucleus, which was later exchanged for a conventional DBS electrode, because no dDBS system had regulatory approval at that time. The electrodes tested in these intraoperative studies had either 32 small circular contacts or segmented ring contacts [3] [4] and both designs resulted in comparable clinical steering effects. The electrode design with multiple small circular contacts proposed by the company Sapiens did not reach market level due to imponderabilities in the manufacturing process and control of stimulation by the associated pulse generator. In this context, it is important to note that lead and pulse generator form a functional unit and the way that stimulation is technically achieved (e.g., current vs voltage control or multiple independent current control) will have an impact on how reliably a computer-simulated field shape for particular polarity settings will be reflected in the “real” implant situation, where tissue properties interact with the technical capabilities of the system in an unpredictable way [5].

The objective of a study was to investigate whether directional deep brain stimulation (DBS) of the subthalamic nucleus in Parkinson's disease (PD) offers increased therapeutic windows, side-effect thresholds, and clinical benefit.

In 10 patients, 20 monopolar reviews were conducted in a prospective, randomized, double-blind design to identify the best stimulation directions and compare them to conventional circular DBS regarding side-effect thresholds, motor improvement, and therapeutic window. In addition, circular

and best-directional DBS were directly compared in a short-term crossover. Motor outcome was also assessed after an open-label follow-up of 3 to 6 months.

Stimulation in the individual best direction resulted in significantly larger therapeutic windows, higher side-effect thresholds, and more improvement in hand rotation than circular DBS. Rigidity and finger tapping did not respond differentially to the stimulation conditions. There was no difference in motor efficacy or stimulation amplitudes between directional and circular DBS in the short-term crossover. Follow-up evaluations 3 to 6 months after implantation revealed improvements in motor outcome and medication reduction comparable to other DBS studies with a majority of patients remaining with a directional setting.

Directional DBS can increase side-effect thresholds while achieving clinical benefit comparable to conventional DBS. Whether directional DBS improves long-term clinical outcome needs to be investigated in the future [6].

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