Long-term safety and efficacy of frameless subthalamic deep brain stimulation in Parkinson's disease

Danilo Genovese[1,2], F. Bove[1,3], L. Rigon[3], T. Tufo[4], A. Izzo[4], P. Calabresi[1,3], A.R. Bentivoglio[1,3], C. Piano[1,3]

[1]Neurology Unit, IRCCS Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy
[2]The Marlene and Paolo Fresco Institute for Parkinson's and Movement Disorders, Department of Neurology, NYU Langone Health, New York, NY, USA
[3]Department of Neuroscience, Università Cattolica del Sacro Cuore, Rome, Italy
[4]Neurosurgery Unit, IRCCS Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy

Background: Bilateral deep brain stimulation (DBS) of the subthalamic nucleus (STN) is standard of care for Parkinson's disease (PD) patients and a correct lead placement is crucial to obtain good clinical outcomes for DBS surgery. The procedure can be performed through the use of a stereotactic frame, whose use is consolidated, or alternatively using a frameless system. Evidence demonstrating the comparable targeting accuracy of frameless technique, along with the advantages for patients and clinicians, is solid, but data reporting long-term clinical outcomes for PD patients are still lacking.

Objectives: The study aims to assess the clinical safety and efficacy of frameless bilateral STN-DBS in PD patients at 5 years from the surgery.

Methods: Consecutive PD patients undergoing bilateral STN-DBS with a frameless system were included in this single-center retrospective study. Clinical features, including the Unified Parkinson's Disease Rating Scale (UPDRS) in its total motor score and axial subscores, and pharmacological regimen were assessed at baseline, 1 year, 3 years and 5 years after surgery. The adverse events related to procedure, stimulation or to the presence of the hardware were systematically collected.

Results: No complications occurred during surgery and perioperative phase, and no unexpected serious adverse event occurred during the entire follow-up period. After 5 years from the surgery there was sustained motor efficacy of STN stimulation: STN-DBS significantly improved the off-stim UPDRS III score at 5 years by 37.6 % ($P < 0.001$), while the dopaminergic medications remained significantly reduced versus baseline ($P = 0.036$).

Conclusions: Our data support the use of frameless system for DBS, as a safe and well-tolerated technique, with long-term clinical benefits comparable with the data available in the frame-based literature.