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Reduction of programming time and strong symptom control using Image Guided Programming (IGP)

Lange et al., 2021 – University Hospital of Würzburg

https://www.frontiersin.org/articles/10.3389/fneur.2021.785529/full

Lange F, et al. (2021). Reduced Programming Time and Strong Symptom Control Even in Chronic Course Through Imaging-Based DBS Programming. Front. Neurol. 12:785529. doi: 10.3389/fneur.2021.785529

KEY HIGHLIGHTS

Parkinson's disease (n = 10)
Bilateral STN-DBS

Randomized, double-blind, controlled, crossover study

frontiers in Neurology

ORIGINAL RESEARCH
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Reduced Programming Time and Strong Symptom Control Even in Chronic Course Through Imaging-Based DBS Programming

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20 min

56%

- Using IGP, programming optimization lasted less than 20 min, which was significantly shorter (56%) than Clinical Based Programming optimization
- Equivalent long-term improvement in motor outcomes

STN: subthalamic nucleus
DBS: deep brain stimulation
IGP: Image Guided Programming

INTRODUCTION

Traditional DBS programming is a time-consuming and complex task that relies on considerable physician expertise and subjects patients to a long testing procedure

IGP offers a way to streamline this process

Boston Scientific's IGP software displays patient-specific anatomy, combined with precise postoperative lead location and orientation to inform programming and stimulation location relative to the target

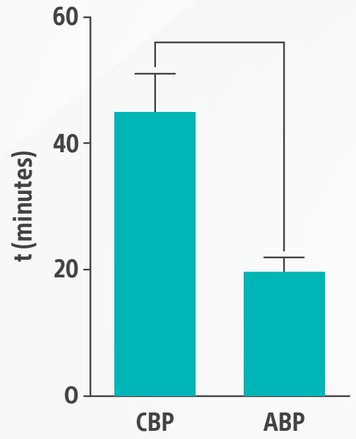
This work represents the Würzburg's group experience using IGP software in an 8-week randomized, double-blind, controlled, crossover study

RESULTS

Data demonstrated efficiency and efficacy

Reduction in Programming time

Time needed for directional monopolar review vs. anatomy-based programming



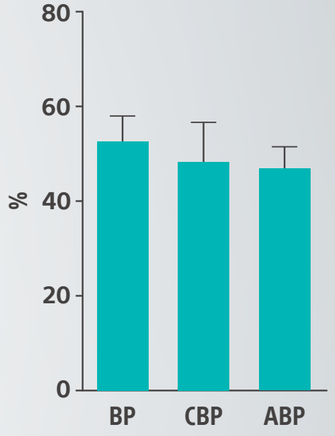
20 min total

56% shorter

The average programming time when using Anatomy-Based (Image-Guided) Programming (ABP) was 19.78 ± 1.85 min, which was significantly shorter (p=0.039) than 45.40 ± 5.79 min using Clinical-Based Programming (CBP)

Motor symptom control and Patient Satisfaction

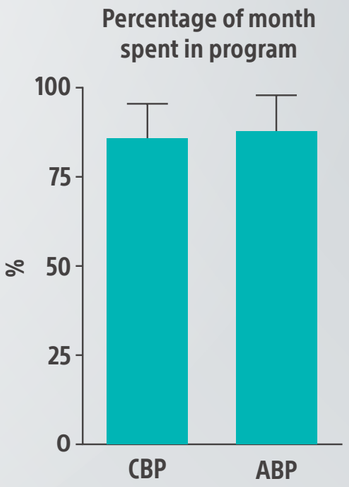
Percentage of improvement relative to MedOFF/StimOFF



47%

The relative reduction in motor symptoms was 47.46% when using ABP, comparable to Baseline Program (BP) and CBP

Percentage of month spent in program



88%

When given a choice to go back to their BP, patients preferred to spend 88.6% of the time on ABP, comparable to CBP (86.1%)

CONCLUSIONS

Image-guided DBS programming in PD patients drastically reduces programming time without compromising symptom control and patient satisfaction in this small feasibility trial.

- First study on the clinical effects of stimulation settings derived using Image Guided Programming in a chronic approach.
- Strong study design demonstrating efficiency and efficacy using Image Guided Programming.
- Overall high satisfaction of patients with settings derived using Image Guided Programming.

PD: Parkinson's disease

Back up information

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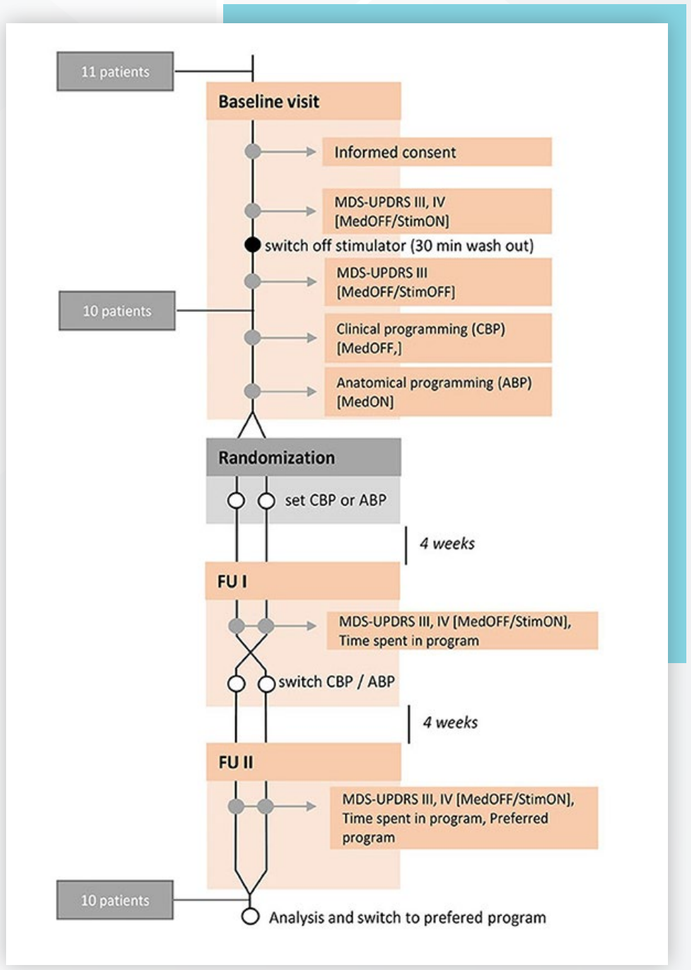
Study Design: Randomized, double-blind, controlled, cross over, 8 weeks



Comparison between Clinical-Based Programming (CBP) and Anatomical-Based (Image Guided) Programming (ABP)

Inclusion Criteria

- Idiopathic bradykinetic Parkinson's syndrome
- Stable implant (>3 months) of bilateral directional electrodes (Cartesia™) into the STN, connected to a Vercise™ PC or Gevia™ IPG
- Correct lead placement: at least one contact in the dorsolateral part of the STN
- MDS-UPDRS III Improvement of 30% through DBS alone (Δ StimON-MedOFF/StimOFF-MedOFF)

Methods: Groups and Blinding

Patients were randomized (1:1 ratio) into:

- CBP, Clinical Based Programming: following directional monopolar review
- ABP, Anatomy (Image Guided) Based Programming: choosing active contacts based on the visualization of the electrode location and rotation in relation to the STN

NOTE: The Baseline Program (BP), the program active at the baseline visit, could be reactivated by patients in case of severe side effects or loss of clinical efficacy not compensated by increases in amplitude

Patients and treating physicians were unaware of the group assignment

Physicians responsible for activating programs were not involved in clinical assessment

Physicians performing assessments had 5-10 years experience in DBS programming

Methods: Programming activation and measurements

Clinical and Anatomical Programming

CBP: Performed in MedOFF for both hemispheres

1. All levels evaluated in ring mode for effect (relief of rigidity) and side effect thresholds
2. If the best level included directional contacts, the best contact (or combination) was chosen

ABP: Performed in MedON

1. Image Fusion of preop MRI and postop CT
2. Automatic Segmentation STN, S. Nigra, N. Ruber
3. Selection of stimulation facing dorsolateral STN identified using Guide XT

Outcome measurements

Programming Time:

CBP: Time needed for monopolar review

ABP: Time for loading images, printing anatomical plan, and time to adjust settings on the patient

Motor Outcomes: (Baseline, and Follow-Up at 4 and 8 weeks)

Baseline: UPDRS-III: MedOFF/StimOFF & MedOFF/StimON
UPDRS IV for motor complications, side effects

FU 4 & 8: UPDRS-III: MedOFF/StimON
UPDRS IV for motor complications, side effects

Time spent in an individual program

Patients' personal preference for programs (CBP, ABP, BP)

MRI: Magnetic Resonance Imaging
CT: Computed Tomography

INDICATIONS

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

This summary is created by Boston Scientific and is intended to consolidate the paper for educational use only.

US Indication for Use: The Boston Scientific Vercise™ PC, Vercise Gevia™, Vercise Genus™ Deep Brain Stimulation Systems are indicated for use in:

- Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa responsive Parkinson's disease (PD) that are not adequately controlled with medication.
- Bilateral stimulation of the internal globus pallidus (GPi) as an adjunctive therapy in reducing some of the symptoms of advanced levodopa responsive Parkinson's disease (PD) that are not adequately controlled with medication.
- Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

The Boston Scientific Vercise Deep Brain Stimulation System is indicated for use in:

- Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa responsive Parkinson's disease (PD) that are not adequately controlled with medication.

Contraindications, warnings, precautions, side effects: The Deep Brain Stimulation Systems or any of its components, is contraindicated for: Diathermy as either a treatment for a medical condition or as part of a surgical procedure, Electroconvulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS) as the safety of these therapies in patients implanted with the Vercise DBS System has not been established, patients who are unable to operate the system, patients who are poor surgical candidates or who experience unsuccessful test stimulation.
Patients implanted with Boston Scientific Deep Brain Stimulation Systems without ImageReady™ MRI Technology should not be exposed to Magnetic Resonance Imaging (MRI). Patients implanted with Vercise Gevia or Vercise Genus or Vercise DBS Lead-only system (before Stimulator is implanted) with ImageReady MRI Technology are Full Body MR Conditional only when exposed to the MRI environment under the specific conditions defined in ImageReady MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems. Assess patients for the risks of depression and suicide. This assessment should consider both the risk of depression and suicide as well as the potential clinical benefits of DBS therapy. Monitor patients for new or worsening symptoms of depression, suicidal thoughts or behaviors, or changes in mood or impulse control and manage appropriately. Refer to the Instructions for Use provided with the Vercise DBS System or BostonScientific.com for potential adverse effects, warnings, and precautions prior to using this product.
Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

OUS Indications for Use: CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.