

A Comparison of Lead Location, Placement Accuracy, and Clinical Outcomes Following Intraoperative MRI - and MER-guided Pallidal Deep Brain Stimulation for Parkinson's Disease

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Introduction

Deep brain stimulation (DBS) lead placement using intraoperative MRI (iMRI) utilizes real-time intraoperative neuroimaging to guide electrode placement. However, there is limited literature on clinical outcomes with this procedure, especially in comparison with more traditional DBS guided by microelectrode recordings (MER).

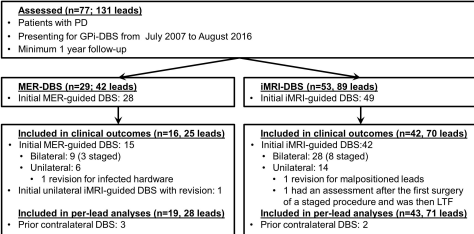
Methods

All patients with PD undergoing GPI-DBS between July 2007 and August 2016 with either MER-guidance or iMRI-based targeting using ClearPoint® (MRI Interventions) were identified and segregated based on surgical procedure. Lead accuracy and adverse events were assessed for all patients. Clinical outcomes were assessed using UPDRS part III motor scores for patients who competed 12 months follow up. For per-patient analyses, we excluded all patients with prior stereotactic procedures; for per-lead analyses, contralateral DBS was permitted. Other measures assessed in this study include levodopa equivalent daily dose and stimulation parameters.

Table 1 - Demographic Information and Outcomes

	All surgeries	MER	iMRI	Statistics
Patients	36	42	49	
Unilateral/Bilateral; %unilateral	21/37; 36.2%	7/9; 43.8%	14/28; 33.3%	c2=0.544, p=0.461
Gender (M/F; %M)	33/25; 56.9%	10/6; 62.5%	23/19; 54.8%	c2=0.283, p=0.595
Age at Surgery (yrs)	65.7 ±1.2 (9.4)	67.8 ±1.6 (6.4)	65.0 ±1.5 (10.3)	t=-1.016, p=0.314
Duration of illness (yrs)	10.2 ±0.5 (6.0)	10.2 ±1.2 (4.7)	10.1 ±0.6 (9.8)	t=0.008, p=0.970
LEDD at baseline (mg)	1422 ±81.5 (621)	1189 ±176 (704)	1511 ±87.9 (567)	t=1.798, p=0.078
LEDD at 1 year (mg)	1109 ±69.3 (528)	1012 ±163 (653)	1146 ±73.3 (475)	F=0.151, p=0.699
(% change)	(20.2 ±4.2 (31.0%))	(21.2 ±8.4 (38.8%))	(19.8 ±4.9 (31.0%))	
Statistics (LEDD)	***F=18.73, p<0.001	**t=2.115, p=0.024	***t=4.486, p<0.001	
UPDRS III at baseline	36.2 ±1.0 (8.0)	35.4 ±1.5 (6.0)	36.5 ±1.3 (8.7)	t=0.455, p=0.651
UPDRS III at 1 yr	22.0 ±1.4 (10.4)	26.5 ±2.8 (11.4)	20.3 ±1.5 (9.5)	(44.1)
(% improvement)	(39.0 ±3.2 (24.3%))	(25.5 ±6.7 (26.9%))	(45.1 ±21.4%))	**F=6.812, p=0.012
Statistics (UPDRS III)	***F=82.15, p<0.001	***t=3.792, p<0.001	***t=11.11, p<0.001	
Leads	99	28	71	
laterality (L/R); %Left	53/46; 53.5%	13/15; 46.4%	40/31; 56.3%	c2=0.793, p=0.373
Contra UPDRS III at baseline	11.7 ±0.4 (3.8)	11.4 ±0.5 (2.9)	11.9 ±0.5 (4.0)	t=-0.668, p=0.507
Contra UPDRS III at 1 yr	6.0 ±0.4 (3.5)	7.1 ±0.7 (3.7)	5.5 ±0.4 (3.3)	(50.3)
(% improvement)	(46.5 ±3.2 (32.3%))	(37.1 ±7.2 (38.3%))	(43.4 (29.0%))	*F=5.433, p=0.022
Statistics (Contra UPDRS III)	***F=143.2, p<0.001	***t=5.692, p<0.001	***t=13.44, p<0.001	
Voltage (V)	3.3 ±0.07 (0.66)	3.4 ±0.12 (0.64)	3.3 ±0.08 (0.67)	t=1.242, p=0.217
PW (µs)	81.2 ±1.6 (18.3)	84.6 ±4.6 (24.0)	79.8 ±1.8 (15.1)	t=1.175, p=0.243
Frequency (Hz)	135.3 ±2.4 (23.7)	135.7 ±5.6 (29.8)	135.1 ±2.5 (21.3)	t=0.107, p=0.915
Data are presented as mean ±SEM (SD)				

Figure 1 - Patient Flowsheet



Results

Patients

77 patients underwent GPI lead placement with a total of 131 DBS leads. Clinical outcome analyses were performed on 58 patients who met inclusion criteria – 16 underwent MER-guided DBS, and 42 underwent iMRI-guided DBS.

Accuracy

Table 2 - ClearPoint Accuracy by Software Version

Software version	# leads (L/R)	L leads	R leads	All leads
1.2-1.3	13 (7/6)	0.81 ±0.07 (0.19)	0.65 ±0.11 (0.28)	0.74 ±0.07 (0.24)
1.4	24 (14/10)	0.72 ±0.09 (0.35)	0.94 ±0.14 (0.40)	0.81 ±0.08 (0.40)
11.5	47 (25/22)	0.56 ±0.06 (0.28)	0.55 ±0.06 (0.29)	0.56 ±0.04 (0.28)
all versions	84 (46/38)	0.65 ±0.04 (0.30)	0.67 ±0.06 (0.36)	0.66 ±0.04 (0.33)

Data are presented as mean ±SEM (SD)

Table 3 - Lead Placement Accuracy

	All leads	MER	iMRI
All patients - tip of the lead			
Leads	127	39	88
x	21.04 ±0.17 (1.89)	20.36 ±0.40 (2.49)	21.34 ±0.16 (1.47)
y	-0.03 ±0.21 (2.42)	-1.06 ±0.52 (3.24)	0.43 ±0.19 (1.78)
z	-4.04 ±0.27 (1.05)	-5.26 ±0.74 (4.65)	-3.50 ±0.19 (1.74)
Patients included in clinical outcomes - therapeutic contacts (cathodes)			
Leads	97	27	70
x	21.36 ±0.15 (1.40)	20.05 ±0.35 (1.32)	21.54 ±0.18 (1.49)
y	2.55 ±0.19 (1.90)	2.99 ±0.32 (1.67)	2.39 ±0.23 (1.96)
z	0.77 ±0.17 (1.63)	-0.48 ±0.32 (1.64)	-0.89 ±0.19 (1.62)

Data are presented as mean ±SEM (SD)

Adverse Events

MER - 5/29 (11.9%): lead infections - 2 (6.9%); malpositioned leads - 3 (10.3%)
iMRI - 11/53 (20.8%): asymptomatic hemorrhage - 3 (5.7%); infections - 4 (7.5%); medical - 2 (3.8%); malpositioned leads - 2 (3.8%)

L-Dopa Equivalent Daily Dosage

Both groups exhibited similar reductions in LEDD (16.8 and 16.9%, respectively).

UPDRS III Motor Scores

The overall improvement in UPDRS-III motor scores was 39.0 ±3.2% (24.3), with greater improvement seen following iMRI-guided DBS (43.3 ±3.3% [21.4] vs. 20.9 ±6.5% [26.9]).

In per-lead analyses, where only the contralateral hemibody was assessed, the overall improvement was 46.5 ±3.2% (32.3), or 50.3 ±3.4% (29.0) and 37.1 ±7.2% (38.3) for iMRI- and MER-guided DBS groups, respectively.

Figure 2

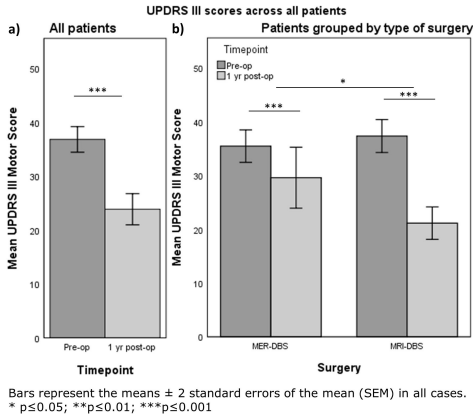
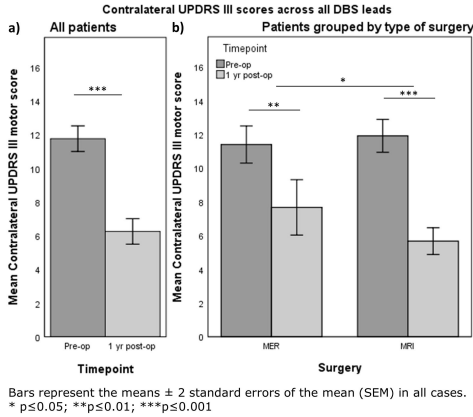


Figure 3



Conclusions

iMRI-guided GPI-DBS in PD patients leads to significant improvement in clinical outcomes, comparable to previously reported results with MER-guided GPI-DBS. When we compared these patients to a historical cohort of patients treated with MER guided GPI-DBS, we observed greater improvement in motor outcomes following iMRI-guided lead placement. These results suggest that iMRI-guided DBS is a safe and effective alternative procedure for selected patients with PD.

References

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Financial Disclosure/Conflict of Interest

Ms. Triche and Drs. Bezchlibnyk, Sharma, Naik, Isbaine, Gale, Cheng, Miocinovic, Buetefisch, and DeLong have nothing to disclose. Dr. Willie is a consultant to Medtronic, MRI Interventions, and NICO Medical. Dr. Boulis is a consultant for Agilis, Voyager, Fortuna Fix, Biomedica, and MRI interventions. Dr. Factor has received honoraria from Neurocrine, Lundbeck, Teva, Avanir, Sunovion, and Adamas, UCB, grants from Ipsen, Medtronic, Teva, US World Meds, Sunovion, Solstice, Vaccinex, Voyager, CHDI Foundation, Michael J. Fox Foundation, and NIH and royalties from Demos, Blackwell Futura, and Uptodate. Dr. Gross is a consultant for Medtronic, St. Jude Medical, and MRI Interventions, and research grants from Medtronic and Boston Scientific.