Movement Disorder

THE IMPACT OF THALAMIC STIMULATION ON ACTIVITIES OF DAILY LIVING FOR ESSENTIAL TREMOR

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BACKGROUND
Deep Brain Stimulation (DBS) of the ventro-intermedius nucleus of the thalamus is the treatment of choice for drug-refractory essential tremor (ET). This study evaluated the effectiveness of thalamic stimulation in improving the patient's quality of life through activities of daily living.

METHODS
Sixteen ET patients completed a health questionnaire, the "Tremor Activities of Daily Living Scale" (TADLS) measured by the patient, a 10-item subset of the TADLS measured by the clinician, and the Fahn-Tolosa-Marin tremor rating scale (TRS). Each patient was evaluated with the stimulator on and off with the average evaluation occurring 13 months after surgery. Additionally, improvements on the TADLS were compared to electrode positioning on the axial plane and stimulation parameters.

RESULTS
There was a 44.0% improvement in the patient-rated TADLS, a 45.2% improvement in the clinician-rated TADLS, and a 33.9% improvement in the TRS. The average electrode location was 5.65 mm anterior to the posterior commissure (AC-PC), 13.4 mm lateral from the midline, and 2.0 mm below the AC-PC line. The average stimulation parameters were 2.74 Volts, 160 Hertz, and 119 μsec. There was no correlation between improvements on the TADLS, electrode location, and stimulation parameters. Of the 16 patients, 10 patients would repeat the surgery, two were unsure, and four would not repeat the surgery.

CONCLUSIONS
Tremor is significantly controlled with DBS and activities of daily living are highly correlated with patient satisfaction. The degree of improvement in the four patients who would not repeat the surgery was outweighed by the negative factors associated with the surgery.

KEY WORDS
Essential tremor, quality of life, thalamic stimulation, activities of daily living.

Until recently, thalamotomy of the ventro-intermedius (VIM) nucleus was the treatment of choice to control essential tremor (ET) refractory to medical/pharmacological therapy. However, current studies advocate deep brain stimulation (DBS) of the VIM, which is reversible, elective, adjustable, more effective and with fewer complications [1,6,10,12,14]. Reduction in tremor is well documented [5,11,13] and should correlate with similar improvements in the patient's quality of life after surgery. Several methods have been used to measure quality of life in ET patients with DBS. Hariz et al demonstrated that DBS improved skills associated with the patient's abilities of coordination, calibration, endurance, and accommodation during particular activities of daily living using the occupational therapy tool, AMPS [3]. Troster et al used broad neuropsychological tests, measures of mood state, the Sickness Impact Profile, and a modified PDQ-39 to show short-term improvements in quality of life [15]. Schuurman et al used the Frenchay Activities Index as a primary outcome measure in comparing thalamic stimulation with thalamotomies for severe tremor [12].

It was hypothesized that DBS improves ET patients' quality of life, using the disease-specific Tremor Activities of Daily Living Scale (TADLS) [7]. Lyons et al developed the TADLS based on 30 activities typically difficult for ET patients to perform. Lyons et al reported a 54% improvement in the clinician-rated TADLS, which correlated highly with the patient-rated TADLS and the Fahn-Tolosa-Marin Tremor Rating Scale (TRS) [2]. These tools were

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therefore applied to the first group of patients at UCLA, who had DBS implants for ET and had agreed to participate in the study. The purpose was not only to validate the TADLS, but also to correlate it with the patients' satisfaction with the surgery, electrode placement, and stimulation parameters.

Methods

Patient Population

Twenty-three essential tremor patients with DBS in the VIM nucleus were asked to participate in this study. Sixteen completed the study. Of the seven who did not complete the study, distance from the clinic and the time needed to complete the study were the predominant reasons why they chose not to participate. Twelve patients had stimulators implanted on the dominant side while four patients had bilateral implants. One patient had a thalamotomy contralateral to the implant. Eleven patients had upper extremity tremor, one patient had head tremor, one patient had head and trunkal tremor, and three patients had both upper extremity and head tremor. Mean age was 72.9 years with average disease duration of 22.8 years. The patients in the study were at least 3 months postoperative with the average assessment taking place 13 months after surgery (range: 4.5-22 months). At the time of the evaluation, the patients were not taking any antitremor medications.

Localization and Stimulation Methodology

(Updated from Mobin et al) [8]. The preoperative VIM target was localized on 1-mm slice thickness fast spin echo and spoiled gradient sequences, in all three conventional planes. The Leksell frame was used and aligned with the A-line connecting the nadir of the inferior orbital rim to a point in front of the tragus (Reid line). This maneuver optimized the chance of having the anteroposterior axis of the frame parallel to the AC-PC line. The intended stereotactic VIM target was characterized by the following measurements: 1) in the anteroposterior plane one-fourth of the intercommissural length in front of the posterior commissure, 2) in the mediolateral plane 11 mm lateral to the wall of the third ventricle, and 3) in the rostrocaudal plane at the level of the AC-PC line. These measurements allow for the fact that a slightly more medial placement in the VIM permitted us to reach predominately the hand and head based on the homunculus of the VIM. Also, more medially, dysarthria can be avoided to some degree, which is usually related to stimulation of the internal capsule. A slightly posterior target gives a slight sensory localization during electrode placement that has been useful in the operation when one is using only electrical stimulation as was done in this series.

Intra-operatively, 2-Hz stimulation was performed with a Radionics 1.8 diameter and 2 mm exposed tip radiofrequency electrode (Radionics, Burlington, MA). The patient was examined to determine the motor threshold for contralateral tongue or face twitching. Stimulation at 50 Hz was used to determine the sensory threshold for paresthesias in the same areas. Ideal placement of the probe was characterized by motor thresholds around 2 V and sensory thresholds greater than 1.5 V, without evidence of dysarthria.

Next, the quadripolar electrode (model 3287; Medtronic) was inserted through the guiding cannula that housed the radiofrequency electrode. The bottom contact (number zero) was placed at the intended stereotactic target. Intraoperative fluoroscopy was used to check for accurate placement and unexpected migration of the electrode during the procedure.

Using a handheld pulse generator with a 100-μs pulse width, patients were then tested for tremor control. Generally, stimulation at 150 Hz, 2-3 V, and 90 μs produced tremor arrest. The criterion for acceptance of electrode placement was complete control of tremor. This was evaluated by asking the patient to drink from an empty glass and perform the usual tasks of neurologic exam testing for tremor. In cases of incomplete response, new tracks were performed. The direction of the new track was dependent on electrical stimulation induced symptoms, such as paresthesias, dizziness, twitches, etc., indicating the proximity of the electrode tip to the structures responsible for the induced symptoms.

Postoperative Adjustments to Stimulation Parameters

In general terms, we have found that 90 μs and 160 Hz are more effective at a given voltage than the usual 60 μs and 130 Hz recommended by Medtronics, probably because of better recruitment of cells within the effective radius of the stimulation. Most patients were initially started at these levels with voltage adjusted to minimize side effects and maximize tremor suppression. All monopolar and bipolar electrode permutations were tested on each patient until the one with the best results was found (optimal tremor suppression, fewest side effects), then voltage was optimized. Voltage was increased until either the tremor was suppressed or side ef-

1 Tremor Activities of Daily Living Scale (TADLS) [7]

Eat*	Tie a necktie
Drink liquids*	Brush teeth
Drink hot liquid	Clip fingernails
Write*	Put glasses on
Eat soup with a spoon	Put a key in the lock
Shave	Use a telephone
Apply lip balm or cosmetics	Take medications or vitamins
Button clothing*	Wash dishes
Use a screwdriver*	Drive
Drive a nail	Use a TV remote control
Thread a needle*	Open mail*
Carry a cup and saucer*	Use a typewriter or computer keyboard
Do a hobby or recreational activity	Eat at a restaurant
Tie shoes*	Degree of embarrassment while eating out
Cook (measuring ingredients)	

Scoring: 0 = normal, performed without difficulty; 1 = able to do, more careful than the average person; 2 = able to do with difficulty; 3 = able to do with errors or requires assistance; 4 = unable to do.

*Rated by both the clinician and the patient.

fects were seen. If side effects were seen before the tremor was suppressed, then pulse width was increased. When the asymptote was encountered, frequency was increased. Considerable time was spent with each patient during multiple visits, if necessary, to find the set of contacts and parameters that "felt best" to the patient.

TREMOR AND ADL EVALUATION

The TADLS was used to measure improvements of daily activities in 16 ET patients who had DBS in the VIM nucleus (Table 1). Patients were asked to perform the 30 activities at home on a day with the stimulator turned off. These activities were repeated another day with the stimulator on. The 30 activities were rated on a 0 to 4 scale (0 = normal, 4 = unable to do). These activities included items such as eating, drinking, threading a needle, and tying their shoes. Each patient completed a health questionnaire, which included the question, "If you could do it all over again, would you have deep brain stimulation surgery?" This question was the only measurement of patient satisfaction associated with the surgery.

Each patient was seen by the clinician and scored on a 10-item subset of the TADLS. The ten items used were tasks that were relatively simple to perform in front of the clinician as designated by Lyons et al. The clinician was not blinded to the patient's on or off status. Patients waited at least thirty minutes after turning their stimulator off before attempting any of the ten items. Tremor was also quantified with the Fahn-Tolosa-Marin TRS. Comparisons between on and off scores for the TRS included only the measures that could be quantified by the clinician. Therefore, the patient-reported questions were not included in the final analysis.

Similarities between the total scores for the patient-rated TADLS, the clinician-rated TADLS, and the TRS were analyzed with Spearman rank order correlation (r_s). Wilcoxon signed rank test measured the significant difference between on and off total scores ($p < 0.01$).

ELECTRODE LOCATION AND STIMULATION PARAMETERS

Linear correlation between stimulation parameters, electrode placement, and clinician-rated TADLS was analyzed. Variation in electrode placement was defined as the distance on the axial plane from the planned location, where the Y-axis was one-fourth the AC-PC distance, anterior to the posterior commissure, and the X-axis was 13 mm from the midline, assuming the third ventricle was 4 mm across.

Results

IMPROVEMENTS ON THE TADLS AND TRS

Patients reported a 44.0% improvement between on and off scores for the TADLS (59.8 off, 33.5 on). On average, they completed 28 of the 30 items available. The clinician measured a 45.2% improvement on the 10-item subset of the TADLS (19.6 off, 10.8 on). Clinician ratings and patient ratings were highly correlated for both on and off states (r_s = 0.91). Patient improvements on the TADLS are individually defined in Table 2. Total scores for the TRS showed a 33.9% improvement (32.7 off, 21.6 on). TRS scores were highly correlated with the patient-rated TADLS ($r_s = 0.80$ on, $r_s = 0.78$ off) and the clinician-rated TADLS ($r_s = 0.88$ on, $r_s = 0.86$ off).

ELECTRODE LOCATION AND STIMULATION PARAMETERS

The electrode was located 5.65 ± 1.76 mm anterior to the posterior commissure (average AC-PC line was 24.7 ± 1.66 mm) and 13.4 ± 1.46 mm lateral from the midline. MRI/CT quality was not adequate in six patients to measure electrode placement on the Z-axis above or below the AC-PC line. The electrode locations on the Z-axis that were well visualized were on average 2.0 ± 2.4 mm below the AC-PC line. The average stimulation parameters were 2.74 ± .99 Volts, 160 ± 28.2 Hertz, and 119 ± 44.0 μs. There was no correlation between electrode location, stimulation parameters, and improvements on

2 Individual TADLS Improvements and Patient Satisfaction with DBS Surgery

Patient	TADLS-On (self report)	TADLS-Off (self report)	Percent Improvement	TADLS-On (clinic)	TADLS-Off (clinic)	Percent Improvement	Repeat Surgery?
1	25	45	44.4	6	16	62.5	Yes
2	92	92	0.0	28	33	15.2	No
3	7	48	85.4	0	21	100.0	Yes
4	1	20	95.0	0	10	100.0	Yes
5	28	79	64.6	10	23	56.5	Yes
6	78	88	11.4	33	36	8.3	No
7	13	32	59.4	5	10	50.0	Unsure
8	26	28	7.1	5	10	50.0	Yes
9	23	36	36.1	2	11	81.8	Unsure
10	32	72	55.6	8	20	60.0	Yes
11	57	87	34.5	23	25	8.0	No
12	23	21	−9.5	7	10	30.0	No
13	1	48	97.9	2	17	88.2	Yes
14	30	60	50.0	8	11	27.3	Yes
15	27	104	74.0	6	23	73.9	Yes
16	73	97	24.7	29	38	23.7	Yes

the TADLS. Electrode locations and stimulation parameters are individually listed in Table 3.

PATIENT SATISFACTION

Regarding the patients' satisfaction related to surgery and willingness to have it repeated, 10 would repeat the surgery, two were unsure, and four would not repeat the surgery. The 10 patients who would elect to repeat the surgery (seven unilateral, three bilateral) reported a 58.4% improvement in the TADLS, the clinician measured a 60.8% improvement, and the TRS indicated a 43.5% improvement. The two patients who were unsure if they would repeat the surgery were not included in the analysis

3 Electrode Location and Stimulation Parameters

Patient	CT/MR	R/L	ACPC	Y (PC)	ML	±ACPC	Voltage, V	Frequency, Hz	Pulse Width, μsec	Electrode
1	MRI	L	25.0	7.0	15.0	−3.0	1.4	185	120	3+ 2− 1+ 0+
	MRI	R	25.0	7.0	13.0	−4.5	1.1	160	120	3+ 2+ 1+ 0−
2	MRI	L	26.0	6.0	14.0	0.0	3.0	185	180	3+ 1− 0+
	MRI	R	26.0	8.0	16.0	0.0	3.5	160	150	2+ 1−
3	MRI	L	25.0	5.0	14.0	−2.0	3.0	170	210	2+ 0−
	MRI	R	25.0	3.0	13.0	0.0	2.5	160	60	2− C+***
4	CT	L	21.0	5.0	14.0	−4.0	2.5	160	120	3+ 0−
	MRI	R	22.0	9.0	15.0	4.0	5.0	185	60	1− 2− C+
5	CT	L	24.0	7.0	14.0	N/A*	2.2	130	150	3+ 2−
6	MRI	L	24.0	3.0	16.0	−5.0	4.7	185	120	3+ 2− 1+
7	CT	L	25.0	3.0	14.0	N/A	3.2	170	120	2− C+
8	MRI	L	23.0	5.0	12.0	N/A	2.2	130	210	3+ 0−
9	MRI	L	24.0	6.0	13.0	N/A	1.4	160	90	1− 0− C+
10	MRI	L	23.0	6.0	12.0	N/A	2.0	160	90	2+ 0−
11	CT	L	26.0	8.0	11.0	N/A	3.5	160	90	3+ 2+ 1− 0−
12	MRI	L	24.0	3.0	12.0	−2.0	3.0	160	60	2− 1+
13	MRI	L	26.0	5.0	11.0	−3.0	3.0	160	90	2− 1−
14	MRI	L	27.0	5.0	13.0	−3.0	3.0	185	120	3+ 2− 1− 0+
15	MRI	R	28.0	6.0	12.0	−4.0	2.6	160	90	1+ 0−
16	MRI	L	24.0	6.0	13.0	−2.0	2.0	60	120	3+ 2+ 1− 0−

Definitions of Headings: ACPC = Distance between the anterior commissure and the posterior commissure; Y(PC) = Electrode location on the Y-axis, measured anteriorly from the posterior commissure; ML = Electrode location on the X-axis, measured from the midline; ±ACPC = Electrode tip location on the Z-axis, measured above or below the AC-PC line; Electrode = Numbers indicate which contact is being stimulated and positive and negative indicate polarity; *N/A = The location of the electrode on the Z-axis could not be accurately visualized; ***C+ = The casing of the pulse generator had a positive polarity.

(two unilateral, one with thalamotomy). The four patients who would not elect to repeat the surgery (three unilateral, one bilateral) reported a 13.2% improvement, the clinician measured a 12.5% improvement, and the TRS indicated a 17.0% improvement. The degree of tremor control was significantly correlated with patient satisfaction.

ADVERSE EFFECTS

Patient-reported adverse effects among the four dissatisfied patients included deterioration of tremor control ($n = 3$), progression of the disease ($n = 1$), and side effects of thalamic stimulation such as paresthesia ($n = 2$), dysarthria ($n = 1$), diplopia ($n = 1$), and dysequilibrium ($n = 1$). Among the other 12 patients, adverse effects were infrequent but included deterioration of control, dysarthria (bilateral stimulation), and paresthesias. After evaluation, two patients' stimulators were reprogrammed to reduce the dysarthria and diplopia. One patient had deterioration of tremor control with a shift from distal tremor to proximal tremor and underwent repositioning of the electrode in the VIM without avail. The three patients with deterioration of tremor control were treated with a stimulation holiday without subsequent improvement. Deterioration of tremor control was not correlated with the position of the electrode.

Discussion

PATIENT SATISFACTION

Patient satisfaction defines the usefulness of a functional surgery such as DBS. It is reasonable not only to assess improvements in activities of daily living, but also address the question of whether patients were globally satisfied with the outcome of DBS surgery. Tremor control and the TADLS were highly correlated with the 10 patients who were satisfied with DBS. The TADLS more closely approximated patient satisfaction than the TRS, yet did not completely address Patient 12 or even Patient 2 who showed modest improvements with the stimulator on (30% and 15%, respectively) and were still dissatisfied with the surgery. These improvements were outweighed by several negative factors associated with the surgery.

Of the four who were not satisfied with DBS, deterioration of tremor control over time was the major complaint for three patients [1,4]. Several patients experienced nearly a 100% reduction in tremor immediately after the surgery. Within a few months they noticed a deterioration of this control, which has not been remedied by adjusting the stimulation parameters. Additionally, these patients were all evaluated for possible repositioning of the electrode. Electrode location was satisfactory in two patients. One patient did have repositioning with no apparent benefit.

The fourth patient (Patient 12) never experienced significant improvements in her tremor after unilateral implantation. Along with Patient 7 who had head tremor, the fourth patient's head and trunkal tremor was never adequately controlled. Neither patient was willing to undergo implantation on the contralateral side, which may have resulted in a more satisfactory outcome [9].

Patient 6 also noticed a progression of her disease after the surgery. She associated this progression with the surgery for two reasons. Whether the stimulator was on or off, the tremor had increased in amplitude compared to her tremor before the surgery (yet stimulation continued to reduce the tremor when compared to her off-status). Secondly, this progression occurred only on the right upper extremity that had been operated. Assuming the disease would progress bilaterally under natural conditions, the patient associated the unilateral disease progression with the DBS. The increase in amplitude in the right upper extremity was validated by pre- and postoperative TRS scores measured by the clinician. Additionally, the tremor in the patient developed from a fine, distal tremor in the right arm to a more gross, proximal tremor.

It is unclear at this time the reasons for deterioration of tremor control over time, and in once case, worsening of tremor. With regards to subacute failure (i.e., progressive decrease of tremor control in the few weeks after initiation of stimulation), it must be related to functional recovery of the tremor cells in the target area. They were not completely functional because of surgical trauma and now will need higher intensity stimulation to be completely blocked. Delayed failure of tremor control after several months of stimulation despite maximization of parameters is a more difficult issue to understand and warrants further study.

The last complaint was the side effects experienced by the patients with the stimulator on. Paresthesia, dysarthria (with bilateral implants), diplopia, and dysequilibrium are common side effects [9,11,12]. They were readily reversible, but were tolerated to maintain a particular level of tremor control. These complications discouraged the four patients from hypothetically repeating the surgery.

CAVEATS AND LIMITATIONS

One additional point that should be addressed is the significant difference between the clinician-rated TADLS and the patient-rated TADLS in a subset of the patients in Table 2. Two variables interfered with TADLS measurements. First, several patients did not complete all of the tasks at home as requested, but completed parts of the survey based on their memory. Thus, their memory and expectations potentially biased the results of the patient-rated TADLS. Secondly, residual effects of the stimulator once it is turned off are not fully understood. Whether the patients were truly at their baseline tremor at home and in the clinic when they had turned off their stimulator is debatable.

Conclusions

Patients considering DBS to control their essential tremor should be aware of all of the ramifications of surgery. Multiple studies have demonstrated the efficacy of DBS in reducing tremor and improving functionality. Yet, patient satisfaction and the reasons why a few patients would not repeat DBS must be acknowledged and explained to potential patients. There was an overall improvement in tremor and activities of daily living, yet a handful of patients would not repeat the surgery for very specific reasons. Once potential patients realize the risk that they might need a second implant with bilateral or head/trunkal tremor, tremor control might deteriorate without avail, or the disease might progress, then patients can make fully informed decisions.

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COMMENTARY

The study presents an interesting evaluation of patient satisfaction after deep brain stimulation in the thalamus. One of the most important contributions of the paper continues to be the four patients who were not satisfied with their outcome. This represents a more realistic assessment of this technology and may temper the widespread enthusiasm for DBS. Bryant et al's technique for intraoperative macrostimulation is well accepted, as is their method of electrode placement.

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The authors report their experience with 16 patients suffering from essential tremor that were reviewed quantitatively on average 13 months after the surgery.