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A Non-Invasive Handheld Assistive Device to Accommodate Essential Tremor: A Pilot Study

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Abstract

Background—We explored whether a non-invasive, handheld device using Active Cancellation of Tremor (ACT) technology could stabilize tremor-induced motion of a spoon in individuals with essential tremor (ET).

Methods—Fifteen ET subjects (9M/6F) performed 3 tasks with the ACT device turned on and off. Tremor severity was rated with the Fahn-Tolosa-Marin Tremor Rating Scale (TRS). Subjective improvement was rated by subjects with the Clinical Global Impression Scale (CGI-S). Tremor amplitude was measured using device-embedded accelerometers in 11 subjects.

Results—TRS scores improved with ACT on (versus off) in all 3 tasks: holding (1.00 ± 0.76 vs. 0.27 ± 0.70 , $p=0.016$), eating (1.47 ± 1.06 vs. 0.13 ± 0.64 , $p=0.001$) and transferring (1.33 ± 0.82 vs. 0.27 ± 0.59 , $p=0.001$). CGI-S improved with eating and transferring, but not the holding task. Accelerometer measurements demonstrated 71-76% reduction in tremor with ACT device on.

Conclusions—This non-invasive, handheld ACT device can reduce tremor amplitude and severity for eating and transferring tasks in individuals with ET.

Keywords

Essential tremor; treatment; non-invasive device

INTRODUCTION

Essential tremor (ET) causes upper limb action tremors that may interfere with daily tasks such as eating¹. Medications for ET are variably effective and sometimes limited by side effects². Surgical treatments are effective, but typically reserved for more severe tremor^{2, 3}. Improved therapies are needed for individuals who do not respond to medications, but do not want to consider surgery.

We developed a non-invasive, handheld device using Active Cancellation of Tremor (ACT) technology to stabilize an eating utensil, such as a spoon. The ACT system senses tremor direction and moves the spoon in the opposite direction to stabilize it (Supplemental Figure

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1a). The device weighs about 100 grams, with dimensions similar to an electric toothbrush (40 x 50 x 175 mm). Its rechargeable battery lasts for more than 90 minutes of continuous use.

In this pilot study, we explored whether the ACT device could stabilize a spoon held by ET subjects. We hypothesized that the device would steady the spoon during holding, eating and transferring tasks.

METHODS

Subjects

Consecutive subjects meeting diagnostic criteria for ET⁴ with at least a “2” on the feeding or drinking item of the Fahn-Tolosa-Marin Tremor Rating Scale (TRS)⁵ were recruited from the University of Michigan Movement Disorders Clinic. Subjects could have undergone deep brain stimulation (DBS) surgery, but had to meet inclusion criteria with the stimulation turned off and have their stimulation turned off for testing. The study was approved by the Institutional Review Board for Human Research at the University of Michigan.

ACT Prototype

The ACT Device comprises four key subsystems: the spoon, the motion-generating platform, the controller/sensor, and the power supply. The spoon attaches to the motion-generating platform and can be removed, cleaned, or replaced. The motion-generating platform uses two DC motors connected with mechanical yokes that couple vertical and horizontal motion of the spoon. The sensor/controller subsystem uses a tri-axial accelerometer embedded in the spoon base to sense the direction of tremor in the x (horizontal) and y (vertical) directions (Supplemental Figure 1a), and directs the motors to move the spoon in the opposite direction. Power is supplied by a rechargeable battery in the handle. For this trial, the prototype was connected to data acquisition hardware (100 Hz sampling rate, 12 bit accuracy) and a laptop computer running a data acquisition program (written in LabView, version 2010, National Instruments Corporation, Austin, TX, see Supplemental Figure 1b).

Clinical Testing

Overall tremor severity was evaluated in each subject using the TRS⁵ while off medication. The study involved three tasks (holding, eating, and transferring objects) with the ACT device using the dominant hand, except in 2 subjects whose dominant hand tremor was so severe with DBS turned off that the ACT device was ineffective. The non-dominant hand was used for these 2 subjects.

For the *holding* task, subjects held the device midway between the table and their mouth. We rated tremor severity for the spoon tip, adapted from the TRS upper limb tremor item. For the *eating* task, subjects filled the spoon with foam blocks and lifted the spoon to their lips. Tremor severity rating for this task was adapted from the TRS feeding item. For the *transferring* task, subjects transferred a spoonful of foam blocks into an empty cup 75 cm away. Tremor severity rating for this task was adapted from the TRS pouring item.

Subjects performed each task at baseline with the ACT device turned off while data and ratings were recorded for fifteen second durations. Subjects then performed each task with the device turned on and off, though the order was randomized. In these trials, both subject and neurologist were blinded and not told whether the device was turned on or off. After each task, subjects rated the amount of improvement using a Clinical Global Impression Scale (CGI-S). This is a 7 point scale quantifying the subject's impression of whether their ability to perform the task changed. Scoring was as follows: 1= Very much improved, minimal symptoms; 2=Much improved; 3=Minimally improved; 4=no change; 5=Minimally worse; 6=Much worse; 7=Very much worse; severe exacerbation of symptoms.

Signal Processing

Accelerometer data in both directions of motion cancellation (horizontal x and vertical y) were used to determine tremor motion. Acceleration data as a function of time (Supplemental Figure 2a) was post-processed with a bandpass filter, resolving the signal into the frequency domain using Fourier transformation. The bandpass filter (1st order, cutoff frequencies of 2 and 25 Hz) removed high frequency noise. The filter also attenuated low frequency gravitational effects, assuming that the patients' intentional motion occurred well below the 2 Hz cutoff frequency. Gravitational artifacts for more pronounced hand rotations may have contributed to error on the horizontal axes. While this error is assumed to be small because the hand is mostly horizontal, the acceleration signals serve as estimates for the true segmental motion. The Fast Fourier Transform (FFT) allows the dominant frequency of vibration and magnitude of acceleration to be identified (Supplemental Figure 2b). Through double integration of the acceleration at the dominant frequency with respect to time, the amplitude of the tremor was determined. Overall magnitude of tremor motion was determined by taking the Euclidean norm of the accelerometer readings in the two directions of motion cancellation. The resulting accelerometer data is depicted as a waveform by plotting acceleration against time (Supplemental Figure 2a). This methodology was validated in the vertical plane of motion using a high-speed camera (120 fps) that recorded vertical motion of the spoon. Image processing (MATLAB, version R2010a, MathWorks, Inc., Natick, MA) yielded the vertical absolute position over time, confirming the vertical tremor amplitude determined from the accelerometer.

Using the described signal extraction method, the peak amplitude of the spoon's displacement was then recorded for each test. While tremor frequencies can vary across a range between 2-15 Hz, higher tremor amplitudes correlate with lower frequencies⁶. In the example shown in Supplemental Figure 2b, the peak amplitude of tremor occurred at 5 Hz.

Statistical Analysis

Change in TRS score and CGI-S ratings for each task with the ACT device turned on and off were compared using the Mann-Whitney test. A p-value of less than 0.05 was considered significant. The change in TRS item for each task was calculated by taking the difference of the TRS item from the blinded tests (device turned on or off) and the baseline. For each of the three tasks, the percent tremor reduction was extracted from the post-processed accelerometer data.

RESULTS

Table 1 showed the baseline characteristics of the 15 subjects. Change in TRS scores significantly improved on all three tasks with the device turned on (Table 2). CGI-S scores improved significantly with eating and transferring, but not holding. (See Supplemental video).

Eleven subjects (9M/2F; mean age 70.5 ± 5.7 years; mean disease duration 30 ± 19 years) had accelerometer and video motion data that could be analyzed; four subjects had excessive signal noise discovered during post-processing that prevented their use. Accelerometer recordings of these 11 subjects showed improvement in tremor amplitude for all tasks (Table 3, Supplemental Figure 2a), including the holding task. With the ACT device turned off, a strong acceleration peak at the subject's dominant tremor frequency was noticed, which was greatly reduced with the ACT device turned on (Supplemental Figure 2b).

DISCUSSION

This small, pilot study tested a non-invasive, handheld device using ACT technology to stabilize a spoon held by ET subjects. The device significantly reduced spoon tremor with eating and transferring tasks based on clinical ratings as well accelerometer data. Furthermore, subjects reported improved tremor for eating and transferring tasks with the ACT device turned on, using the CGI-S.

Subjects and the evaluating neurologist were not told whether the device was on or off. The device prototype also does not emit a sound or cause a palpable sensation that can be detected by the user when turned on. Despite this, true blinding may have been difficult to achieve in a study like this. The potential to unblind was greatest during the eating and transferring tasks, because they used foam blocks to represent food, which provided evidence of stabilization. However, with the device turned on, subjects did not notice improvement in the holding task (based on CGI-S) despite the fact that both TRS and accelerometer measurements showed considerable improvement. This suggests that at least during this task, subjects were blinded as to whether the device was on or off.

There is a clear need for this type of non-invasive device in managing tremor. Weighting the limb is a commonly recommended non-invasive way to manage limb tremor⁷, but has little evidence to support it^{8,9}. Tremor suppression orthoses also have been investigated¹⁰⁻¹², which function by physically forcing a person's tremor to cease¹³. Because our device stabilizes tremor while allowing the hand to shake, it has the added benefits of being comfortable and easily adopted by users.

There are other limitations to this small pilot study. Two subjects had severe tremor amplitude with DBS turned off, preventing use of our device, suggesting that the device is most suitable for mild-moderate tremors. We plan another trial to study the tremor amplitude limit at which the ACT device is no longer effective. Additionally, only tremor while using a spoon was evaluated. Improvement with eating was not demonstrated and the acceptability for long-term use remains unknown.

Our results demonstrate the effectiveness of a non-invasive handheld device using ACT technology to stabilize a spoon. The device is lightweight, compact, and could potentially be outfitted with other tools, such as a fork or mascara applicators. It has great potential to help individuals accomplish tasks that would otherwise be frustrating due to tremor.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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AUTHOR ROLES

1. Research project: A. Conception, B. Organization, C. Execution;
2. Statistical Analysis: A. Design, B. Execution, C. Review and Critique;
3. Manuscript: A. Writing of the first draft, B. Review and Critique;

Pathak: 1A, 1B, 1C, 2A, 2B, 2C, 3A, 3B

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Dr. Pathak is the CEO & Founder of Lift Labs Design (his company is commercializing ACT technology for a device that will be released in 2013 and is funded by NIH grant 5R44NS070438), and he is an inventor on two patents for Active Cancellation of Tremor technology.

Dr. Redmond is a consultant for Lift Labs Design.

Mr. Allen is an employee of Lift Labs Design.

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REFERENCES

1. Louis ED. Essential tremor. *Handb Clin Neurol*. 2011; 100:433–448. [PubMed: 21496600]
2. Deuschl G, Raethjen J, Hellriegel H, Elble R. Treatment of patients with essential tremor. *Lancet Neurol*. 2011; 10(2):148–161. [PubMed: 21256454]
3. Umemura A, Jaggi JL, Hurtig HI, et al. Deep brain stimulation for movement disorders: morbidity and mortality in 109 patients. *J Neurosurg*. 2003; 98(4):779–784. [PubMed: 12691402]
4. Deuschl G, Bain P, Brin M. Consensus statement of the Movement Disorder Society on Tremor. *Ad Hoc Scientific Committee. Mov Disord*. 1998; 13(Suppl 3):2–23. [PubMed: 9827589]
5. Fahn, S.; Tolosa, E.; Marin, C. Clinical Rating Scale for Tremor.. In: Jankovic, J.; Tolosa, E., editors. *Parkinson's Disease and Movement Disorders*. 2nd ed.. Williams & Wilkins; Baltimore, MD: 1993. p. 271-280.
6. Calzetti S, Baratti M, Gresty M, Findley L. Frequency/amplitude characteristics of postural tremor of the hands in a population of patients with bilateral essential tremor: implications for the

classification and mechanism of essential tremor. *J Neurol Neurosurg Psychiatry*. 1987; 50(5):561–567. [PubMed: 3585381]

7. O'Connor RJ, Kini MU. Non-pharmacological and non-surgical interventions for tremor: a systematic review. *Parkinsonism Relat Disord*. 2011; 17(7):509–515. [PubMed: 21632272]
8. Hewer RL, Cooper R, Morgan MH. An investigation into the value of treating intention tremor by weighting the affected limb. *Brain*. 1972; 95(3):579–590. [PubMed: 4655283]
9. Morgan MH, Hewer RL, Cooper R. Application of an objective method of assessing intention tremor - a further study on the use of weights to reduce intention tremor. *J Neurol Neurosurg Psychiatry*. 1975; 38(3):259–264. [PubMed: 1151406]
10. Rocon E, Belda-Lois JM, Ruiz AF, Manto M, Moreno JC, Pons JL. Design and validation of a rehabilitation robotic exoskeleton for tremor assessment and suppression. *IEEE Trans Neural Syst Rehabil Eng*. 2007; 15(3):367–378. [PubMed: 17894269]
11. Rocon E, Manto M, Pons J, Camut S, Belda JM. Mechanical suppression of essential tremor. *The Cerebellum*. 2007; 6(1):73–78. [PubMed: 17366268]
12. Rocon, E.; Ruiz, AF.; Pons, JL.; Belda-Lois, JM.; Sánchez-Lacuesta, JJ. Rehabilitation robotics: a wearable exo-skeleton for tremor assessment and suppression.. 2005 IEEE International Conference on Robotics and Automation; Barcelona, Spain. 2005; p. 2271-2276.
13. Rocon, E.; Bueno, L.; Ceres, R.; Calderon, L.; Pons, JL. Theoretical control discussion on tremor suppression via biomechanical loading.. In: Craddock, GM.; McCormack, LP.; Reilly, RB.; Knops, HTP., editors. *Assistive Technology - Shaping the future*. IOS Press; Amsterdam: 2003. p. 827-831.

Table 1

Baseline characteristics of the cohort

Subject	Age	Gender	Dominant Hand	DBS patient	Disease duration (years)	Positive family history	Medications at time of testing	TRS feeding score	TRS drinking score	TRS total score
1	59	F	R	N	40	Y	Primidone	2	3	37
2	73	M	R	Y	32	Y	propranolol	3	3	47
3	69	M	R	Y	10	Y	propranolol, primidone	3	4	62
4	80	M	R	Y	65	Y	Gabapentin	3	4	69
5	61	M	R	N	50	Y	Atenolol	4	4	67
6	75	M	R	Y	17	Y	Nadolol	3	3	38
7	78	F	L	N	5	N	Primidone	3	2	36
8	66	M	L	N	15	N	Propranolol, primidone	2	3	40
9	68	F	L	N	30	N	Propranolol, topiramate	2	4	53
10	68	F	R	N	35	Y	Propranolol, primidone	3	3	55
11	68	F	R	N	45	Y	Propranolol, primidone	2	2	43
12	64	M	L	N	11	Y	Primidone	1	3	22
13	72	M	R	Y	57	Y	None	4	3	71
14	67	F	R	N	15	N	Topiramate	2	3	41
15	79	M	L	N	8	Y	Primidone, gabapentin	2	3	38
Mean (SD)	69.8 (6.3)	9M/6F	10R/5L	5 DBS	29 (19)	11Y/4N		2.6 (0.9)	3.1 (0.6)	47.9 (14.3)

Table 2

Clinical Results with the Active Cancellation of Tremor (ACT) device turned off and on.

N=15	ACT OFF		ACT ON		
	Mean	SD	Mean	SD	p value
Change (TRS) in holding	0.27	0.70	1.00	0.76	0.016 *
Change (TRS) in eating	0.13	0.64	1.47	1.06	0.001 *
Change (TRS) in transferring	0.27	0.59	1.33	0.82	0.001 *
Holding CGI-S	3.40	0.91	3.00	1.20	0.14
Eating CGI-S	4.00	0.66	2.13	1.41	0.000 *
Transfer CGI-S	3.67	1.45	2.27	1.28	0.013 *

TRS = Fahn-Tolosa-Marin Tremor Rating Scale. A positive change in TRS indicates improvement in tremor

* Indicates a p value <0.05

Table 3

Tremor Amplitude Reduction Based on Accelerometer Measurements

Subject	Tremor amplitude ACT OFF (cm) [*]	Tremor amplitude ACT ON (cm) [*]	% Tremor Reduction				Primary peak freq. ACT OFF (Hz)	Primary peak freq. ACT ON (Hz)	Sec. peak. ACT OFF (Hz)	Sec. peak freq. ACT ON (Hz)
			Combined	Holding	Eating	Transferring				
2	1.2	0.3	70%	77%	67%	66%	5.40	5.20	-	-
3	1.6	0.2	82%	75%	90%	82%	5.90	5.30	-	-
4	2	0.6	65%	63%	65%	67%	5.60	5.50	11.45	-
5	1	0.2	78%	84%	74%	77%	5.04	5.12	10.00	-
6	1.7	0.5	70%	56%	85%	69%	5.00	5.10	-	-
8	1.9	0.4	77%	75%	79%	78%	5.87	5.60	-	-
9	0.8	0.2	80%	77%	82%	82%	5.60	5.45	-	-
10	1.7	0.6	72%	80%	74%	61%	5.40	4.80	-	-
12	1.6	0.3	77%	81%	75%	76%	5.60	5.30	-	-
13	0.5	0.2	41%	30%	50%	42%	4.20	4.40	-	-
15	1.4	0.1	89%	90%	93%	85%	5.90	5.60	12.00	-
Mean	1.4	0.35	73%	72%	76%	71%	5.41	5.22	11.15	-
St. Dev.	0.47	0.16	13%	17%	12%	12%	0.51	0.36	1.03	-

* Tremor amplitude is the average amplitude of the subject during the three tasks. Frequency data is reported for the eating task.