The Medical University of South Carolina

WARNING WARNING

The Medical University of South Carolina (MUSC) performed a Deep Brain Stimulation (DBS) operation on Thomas White's left brain on September 28, 2010. This operation was done correctly and it eliminated the tremors in his right hand. On January 25, 2011 they did a second Deep Brain Stimulation (DBS), called a bilateral, operation on his right side. This operation was not done correctly and it caused many problems. The operation did not meet MUSC's qualifications for a DBS operation and it violated all directives that advised against performing of a bilateral operation (two DBS electrodes) for essential tremors. The key to a successful surgery is the precise spot (Vc) to insert the tip of the DBS electrode. A computer program combines x-rays from a C-Scan and a MRI to determine and identify the precise spot called Vc. Studies have determined that a placement error of a little as 2 mm causes an 87% chance that it will not control the tremors. Dr. Revuelta, Director of the Deep Brain Stimulation Program, did not place the DBS electrode in the precise spot (Vc). He wrote in his report "Although we did not identify Vc in the posterior track, we were clearly close to it." Which translates to "I could not find the right spot but I am close"? Dr Revuelta should have removed the DBS electrode, but he did not. The incorrect placement of the DBS electrode caused problems with every "movement" activity in the patient's brain. The DBS electrode is controlled and powered by a pacemaker. The pacemaker supplies a pulsating voltage to the electrode that is programmed to eliminate the tremors and side effects (movement actions). Later the patient had blood on his brain. Dr. Revuelta left the DBS systems turned on. When the blood got deep enough that both tips where covered, arching occurred. This arching ate lesions in the brain area around each DBS electrode tip. The brain lesions caused all the "movement" problems to be permanent. MUSC tried to program the DBS Systems 10 times without obtaining tremor control and eliminating the movement problems. Every session, the MUSC programmers used the wrong program method. They used programming for a unilateral (one DBS) method and should have used the bilateral (two) method. MUSC would not tell the Thomas White what was causing the movement problems so he saw many specialists (doctors) and took many tests to find out what was causing his problems. None could tell him what was causing the problems. But all suspected that the problems where caused by the DBS operation. As a last resort the patient went to the Mayo Clinic. After a few tests and consulting with a two doctors the Thomas White was told that his movement problems were caused by the DBS operation on January 25, 2011. Both of the DBS systems could never be turned on, because of the brain lesions, so the wires and pacemakers were removed. It was too dangerous to remove the electrodes. Part of his problems include: tremors, vision, choking, constipation, urinary, walk, and balance. The patient has to live with these problems the rest of his life. The Medical University of South Carolina and the South Carolina Insurance Reserve Fund refuses to take responsibility for the botched operation and make appropriate compensation. The only way the patient will receive compensation for MUSC destroying his brain is for you, the public, to call or Email David Cole, MUSC's President, at 1-843-792-2211 or coledj @musc.edu and tell him to pay compensation.

Functional Connectivity Targeting for Deep Brain Stimulation in Essential Tremor

ORIGINAL RESEARCH by
J.S. Anderson, H.S. Dhatt, M.A. Ferguson, M. Lopez-Larson, L.E. Schrock. P.A. House, and D. Yurgelun-Todd

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http://www.ajnr.org/content/32/10/1963.full.pdf+html

The lack of direct image guidance is particularly important, given that even minimal variation in lead placement may result in long-term clinical failure or less than satisfactory treatment of essential tremor.

Long-term failure rates for deep brain stimulation in essential tremor have been reported to be 13%–40%, due to a hypothesized physiologic tolerance or suboptimal lead placement.

In 1 study, **even as little as a 2-mm error in placement resulted in only a 17% chance of producing essential tremor control** defined by criteria of 66% improvement in tremors.

TESTING of electrodes

Special Studies

Date Printed: 02/25/11

Name: WHITE, THOMAS ID: 1756561 SEX:M AGE:74

01/25/11 : 04:04pm (RIGHT SIDED DBS SYSTEM)
dbs mer

PROCEDURES:

1. Identification of the Vim and surrounding structures bilaterally by microelectrode recording.
2. Intraoperative micro and macro stimulation of the target area with clinical examination for confirmation of placement for the quadripolar deep brain stimulating electrodes.

CLINICAL INFORMATION:
Indication: ET

74 year old man with treatment refractory ET

Duration: 2_hours _30__min for preparation, recording, on-line analysis, stimulation, and examination.

Right:

Number of electrodes used in Ben gun array: 2_
Trajectories: 2__
Final DBS lead placement relative to imaged target:

_0_ mm anterior posterior
_0_ mm medial lateral
_0_ mm ABOVE OR BELOW image based original target

MICROELECTRODE RECORDING:

Deep brain intra-operative, single and multi-cellular electrophysiological recording was performed in order to avoid vital brain structures, define the boundaries of the target nuclei for provide optimal deep brain stimulation (DBS) electrode placement, and determine initial parameters of clinical effectiveness.

Recording is performed under sterile OR conditions as part of stereotaxic functional neurosurgery. On each trajectory of the recording electrode in the brain, monitoring began 25 mm above the provisional target, as determined by image fusion of CT and MRI brain scans.

The Alpha Omega MicroGuide Pro physiological navigation system was used to coordinate single and multi unit microelectrode recording and analysis with depth measurements using a computerized clinical micropositioner that advances the electrodes by 0.01 mm increments. Continuous simultaneous measurement and recording was performed with monitoring of signal amplification and filtering. Visual, audio and numeric microelectrode data was displayed and selected portions of the case are recorded by a PC based system. On line signal analysis is performed at various intervals of the trajectory for amplitude and wave frequency distribution using frequency raster, wave form analysis, oscilloscope, and chart recorder functions. Microelectrode impedance monitoring was performed to determine integrity of the entire electrical circuit.

MACRO STIMULATION AND DBS LEAD TESTING:

Mono-polar macro stimulation is performed via the micro-electrode canula at multiple locations within the target nucleus. Poor clinical response or adverse stimulation effects determines the need for a different trajectory to target. In the case of GPi placement, the boundary of the visual tract is located by microrecording of activity induced by strobe light. After final optimal depth of the electrode placement is recorded for the target area (VIM, GPi or STN), the microelectrode assembly is removed and the quadripolar electrode is placed in the micropositioner. The bottom most electrode is then placed at the target depth for DBS lead testing.

Testing of the DBS lead is then performed using the four electrode regions of the quadripolar DBS electrode with test stimulus delivered by Medtronic Stimulation Tester Model 3625. The electrodes are stimulated in combination with a 60-90 microsecond duration pulse, delivered at 90 - 200 Hz, with amplitudes ranging from 0 to 10 volts, with clinical examination of efficacy and evidence of electrical spread outside the target zone producing paresthesiae, visual phosphors, tremor, or corticospinal tract signs. Final DBS lead placement is then determined. Either lack of efficacy, presence of deleterious electrical stimulation or inadequate traversing of the target nucleus may be reason for further stereotaxic trajectories with microelectrode recording, and is documented below.

NOTES:

Track length:

There was robust bursting activity in both tracks, see recordings for exact track length.

Somatotopy:

Posterior: we found arm and leg motor driving in 4 areas throughout the posterior track.

Monopolar thresholds with Macrostimulation through the canula:

Center: 75% efficacy at 2mAmps 2 and 4 mm above target. Transient paresthesias present, no motor or sensory threshold reached at 3 mAmps.

Posterior: lip paresthesias at 0.5 mAmps, permanent at 1 mAmp, could not reach therapeutic amplitudes

Comments:

Although we did not identify Vc in the posterior track, we were clearly close to it, since sensory thresholds were very low when testing. Based on these findings and clear efficacy with wide therapeutic window in the center track we implanted there. Of note, there was significant insertional effect after implanting the DBS lead, so determinations regarding efficacy were limited.

Monopolar thresholds with the DBS lead were as follows:

0. 3 V, motor, 50%
1. 3 V, motor, 15%
2. 3 V, motor, 80%
3. 4 V, motor, 90%

Gonzalo J. Revuelta, DO
Director, Deep Brain Stimulation
Movement Disorders Program

Deep Brain Stimulation (DBS) Frequently Asked Questions

http://www.uwhealth.org/neurosurgery/deep-brain-stimulation-dbs-frequently-asked-questions/12764

Deep Brain Stimulation (DBS)
UW Health neurosurgeons in Madison, Wisconsin, perform deep brain stimulation (DBS) for selected patients with Parkinson's disease, essential tremor, tremor and other movement disorders.

Is deep brain stimulation (DBS) approved by the Food and Drug Administration?

The Federal Food and Drug Administration (FDA) approved deep brain stimulation of the thalamus for the treatment of tremor in 1997.

While DBS has not been approved by the FDA specifically for the treatment of other conditions, such as tremor due to causes other than Parkinson's disease or essential tremor, physicians and surgeons consider DBS for these conditions safe and effective. The same devices approved by the FDA for Parkinson's disease, essential tremor and spinal cord stimulation for pain are used in DBS surgery.

Medtronic

For Healthcare Professionals

About Deep Brain Stimulation for Movement Disorders

http://professional.medtronic.com/pt/neuro/dbs-md/edu/about/#.U4B-FyjdUyX

Proven Safety Profile (for PD and Essential Tremor)

Improvements in MRI imaging, stereotactic equipment and software have all helped advance DBS Therapy since it was first approved by the FDA in 1997.

DBS Therapy is safely performed bilaterally[1] (Parkinson's disease only)

Qualifications for Deep Brain Stimulation Surgery

http://essentialtremor.org/treatments/surgical-treatments/
Potential candidates for surgical procedures are ET patients who do not experience satisfactory tremor control with medications, and **who have disabling tremor that affects their ability to perform activities of daily living such as eating, writing, drinking, dressing, working, or enjoying their hobbies.**

http://www.medtronicdbs.com/essential-tremor/about/what-is-dbs/index.htm
You may be a candidate for this therapy if you have essential tremor not adequately controlled by medications **and the tremor is keeping you from what you need to do.**

http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=279&ncdver=1&NCAId=21&NcaName=Deep+Brain+Stimulation+for+Parkinson%2527s+Disease&IsPopup=y&bc=AAAAAAAACAAAAA%3D%3D&
For thalamic VIM DBS to be considered reasonable and necessary, patients must meet all of the following criteria:

> **Marked disabling tremor of at least level 3 or 4 on the Fahn-Tolosa-Marin Clinical Tremor Rating Scale (or equivalent scale) in the extremity intended for treatment, causing significant limitation in daily activities despite optimal medical therapy.**

http://www.mountsinai.org/patient-care/service-areas/neurosurgery/areas-of-care/center-for-neuromodulation/conditions-we-treat/essential-tremor
Qualifications for Deep Brain Stimulation

> In general, however, the treatment is most successful in patients who have:
> Not responded to traditional therapies or medications
> Have severe side effects to medication
> **Have an advanced form of ET that is impairing**

http://www.muschealth.com/neurosciences/about/movementdisorders/forms/4%20Movement%20Disorders%20Program%20DBS%20expedited%20referral%20form%2012%2007%2011.pdf
MUSC Medical Center

> To be a surgical candidate for tremor or dystonia, **these conditions need to be disabling** and medically refractory.

Listed above are only five of the many sources that state the qualifications for DBS surgery for essential tremor. All of them state the qualifications are "conditions that are disabling or impairing" even the MUSC Medical Center.

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Prior to my first DBS surgery, on Sept 28, 2010, I was thoroughly checked out to make sure tremors were severe enough and that I met all the other criteria. At that time my tremor in my right hand was about a 3 inch swing and my left hand had about a 2 inch swing, conditions were disabling and impairing.

I first was examined by Dr. Athar, a neurologist, 0n April 23, 2010. She tried me out on three different medicines and none done anything to stop my tremors. Then she said that I passed her step of the qualifications for DBS surgery and she referred me to Dr. Wagner.

On July 19, 2010 I was seen by Dr. Wagner PhD a Clinical Neuro-psychologist. In his report he wrote "The patient was ambulatory with a steady gait. He had a fine action tremor right greater than left. He had some minor tremor in his head and mouth. In a cognitive testing, the MMSE was replicated and he continued to score 30/30 which is no change from 2007. On the RBANS, he scored in the low average range with some difficulty for sustained concentration. Executive function was within normal limits. Perceptual function was above the average. Delayed recall was low average. Fine motor dexterity was impaired right greater that left. Impression: 1. Essential tremor. 2. Age- associated memory loss. 3. No neuropsychiatric contraindications to proceed with DBS therapy. Discussion: The patient has a history of essential tremor now about 30 years in duration. He has not responded to multiple medication trails. He is unable to do many of the hobbies that he normally has enjoyed in the past because of the tremor including working on cars and boats. There are no neuropsychiatric contraindications for him to move forward with DBs therapy for the tremor."

I was examined by Dr. Takacs, MD, Neuro Surgeon, on September 18, 2010, and He wrote in his report "I think he would be a good candidate for VIM stimulation bilaterally and we would begin with placing a left- sided stimulator to control his right-sided tremor."

They performed surgery by placing a left- sided stimulator (DBS) to control his right-sided tremor on September 28, 2010. After the operation my right hand tremor was gone (steady) and the tremor in my left hand was minor – about one inch swing.

Without and more testing of my left hand Dr. Takacs wanted to do DBS surgery for my left hand. I told him that the tremors of my left hand were not bad enough for a DBS operation. He told me that I would need it later in time and it would be best to do it now. I thought he knew best so I agreed to the operation. There is no record of this discussion.

This operation did not meet the requirements listed above for the second operation. The second DBS surgery was performed on January 25, 2011.

PL

During the Jan 25, 2010 operation the DBS electrode was incorrectly placed (knowingly) producing the following symptoms/problems:

Lethargic (lack of energy) – I replaced my heart medication, stop taking propranolol, corrected my sleep apnea problems, started taking weekly testosterone shot, change my diet, do exercise, and all test slightly improved my lack of energy, but I still feel tired all the time and I have not felt good all day since the second DBS operation on Jan 25, 2010.

Walking – My walking got worse and worse after the second operation until I was dragging my left leg with each step and had to use a cane to keep from falling because of my balance. Due to everything that I have done to improve all my problems, dragging my left leg has improved to where I drag it a lot less.

Balance – My balance was so bad that I was falling all the way down about five to eight times a month and losing my balance many times per hour. Since taking the medication Azilect I don't fall all the way down any more but I still lose my balance many times an hour.

Speech – My speech is much improved.

Drooling -- My drooling is much improved.

Vision (double and blurred) – I have had two cataract operations and this corrected my double vision. Since Jan 25, 2010 I have had new glasses made 4 or 5 time. But my vision is improved but it is not 100% correct.

Stooped posture – I still have this but not as bad.

Sometimes hard to think – I still have this.

"Spacy" at times -- I still have this.

Dysarthria – As long as I take the medication Azilect this problem has been corrected.

Muscle weakness – I still have this.

Constipation – My stomach does not like milk. I drink milk to lessen this problem but it sometimes causes an upset stomach.

Choking -- Since the operation I have developed an excessive buildup of mucus with the normal level at the bottom of my lungs. Sometimes the level is higher and then just a little bit more and I get a chocking sensation and I can't breathe. I have felt that I was going to drown on my on spit and sometimes when I take a bite of food and it blocks my breathing. I now take Nexium and it lessens the buildup and I have less choking.

Trouble Urinating – Starting going home from the operation I have had a problem urinating. I take Cialis and it makes it better. But I have to stand up to urinate and I have to hold on to a wall bar because of my balance problem. If I sit down to have a bowel movement, afterwards I have to stand up to urinate.

Tremors – My first DBS operation fixed the tremors of my right hand. Afterwards I had zero tremors to do the second DBS operation. Since then I have the all my problems. Later I could not turn on both of the DBS systems so I had the pace makers and wires removed. Now I have debilitating tremors of my left hand.

Movement delay – eye sees something, brain decides what action to take, but there is a delay in the hand taking action. – This has not changed

.

The symptoms/problems were extracted from their records. Later they were made permanent.

STATEMENT MEDICAL MALPRATICE Summary:

May 16, 2014

For Thomas R White and the January 25, 2011 operation

1. Dr. Istvan Takacs MD (DBS Neurosurgeon) performed a Bilateral "Right" Deep Brain Stimulation (DBS) operation on me on January 25, 2010. He was responsible for the operation and to oversee the insertion of the DBS Electrode and its associated wires. I have recently found out that a bilateral DBS stimulation should not have been used. HE did not keep up with the latest directives and policies about the problems of Bilateral DBS use and advise not to use Bilateral DBS on a person (Me) with "Limb" essential tremor problems. I have "Limb" essential tremors (Arms and hands). Unilateral (one) Deep Brain Stimulation (DBS) is used to treat "Limb" essential tremors. Bilateral (two) DBS's is not recommended for "Limb" essential tremor patients because it creates many side effects. Bilateral DBS's is used to treat patients with "Midline" (head, voice, tongue, and trunk) essential tremor. But the side effects have to be tolerated or reduced with bipolar programing. Some expert opinions are for and against Bilateral DBS for essential tremors. But all agree if Bilateral DBS for limb essential tremors you can expect severe side-effects and you have to consider:

1. Using Bilateral DBS and having Sevier side-effects and some control of the severe tremors.

2. Not using Bilateral DBS and having little control of the severe tremors.

I should have been informed of **this and they should have let me choose which method I wanted.**

I did not have severe tremors of my left hand (Right DBS).

2. During the operation on January 25, 2011 it was Dr. Gonzalo Revuelta's DO (Director DBS Program) responsibility to make sure the electrode and wires were operational and were positioned exactly in the correct position. He committed willful gross negligence when he knew **that he was not placing the electrode in the optimal position and he completed the operation knowing that it was wrong. He should have stopped the operation and removed the Bilateral Right DBS Electrode. By not placing the electrode in the optimal position he performed an unnecessary operation that was against all medical official standards.**

3. The operation on January 25, 2011 caused many problems (symptoms). Here is a list of these problems/ Symptoms:

1. Lethargic
2. Walking
3. Balance
4. Vision
5. Dragging left leg
6. Constipation
7. Speech
8. Choking
8. Drooling
9. Trouble urinating
9. Dysarthria
10. Sometimes hard to think
10. Tremors – both hands
12. Movement delay
13. Stooped posture
14. Spacey at times
15. Muscle weakness

4. Dr. Gonzalo Revuelta's (Director DBS Program) is guilty of failure to provide a proper standard medical care. Dr. Revuelta totally disregarded all my symptoms when he was informed by my family doctor, Dr. John F. Mattei MD, that I was diagnosed as having "Advanced Parkinsonism". Every visit with Dr. Revuelta he noted my symptoms/problems but made no effort to discover what was causing them. I was **repeatedly** told that they (MUSC) could solve the symptoms/problems with one more programming session. I had nine programming sessions and each one worked fine for a few days and then my symptoms/problems returned. They kept saying to wait. MUSC never made any effort to find out what was causing my symptom/problems.

5. I had ten programming sessions and each one worked fine for a few days and then my symptoms/problems returned. Each and every time they failed to follow the latest directives on how to program a Bilateral DBS installation. They should have had the Medtronic "Care of the movement patient with DBS" book (MUSC uses Medtronic products and this is a 50 page guide, revised December 2009, of recommendations for the practice in DBS management). In that book, on page 33 under a section labeled I-4 explains how to program a Bilateral DBS installation with bipolar programming.

***no one used this method of programming**

6. About June 2011 blood was discovered pooling around the tip off one of the DBS Electrodes. When the blood got deep enough to cover both DBS Electrode tips and both DBS Electrodes were turned on arcing occurred. This arcing ate out lesions in my brain around each tip. Failure to prevent the lesions around both DBS Electrodes in my brain caused my symptoms/problems to be permanent.

1. When the blood started MUSC could have turned both DBS Electrodes off preventing the arcing.
2. They could have not installed the "Right" bilateral DBS Electrode.

7. After the operation I went to many doctors and had many tests trying to find out what was causing my problems. No one could tell me what was wrong. As a last resort, to find out what was causing my symptoms, I finally went to the Mayo Clinic in Jacksonville. On November 13, 2011 I saw Dr. Van Gerpen. In his report he wrote **"I am concerned about sequelae from DBS placement (in particular, the natural history suggests that there have been major changes after placement of the right lead). Certainly, there are reports about bilateral DBS being associated with gait dysfunction, dysarthria, etc."** **I was finally told by Dr. Wharen, on November 21, 2011, that the January 25, 2011 DBS operation was causing my symptoms. Certified copies of Dr. Van Gerpen's report and a letter from Dr. Wharen are attached.**

8. **Informed Consent:**
I signed a "Consent" form that said "Although we have discussed the potential likelihood of success, no guarantees or assurances have been made or given by anyone as to the results that may be obtained: bleeding, infection, damage to surrounding tissue." Dr. Takacs talked me into having the operation on the "Right" DBS system (Bilateral DBS). I said my tremors where not too bad on my left hand. But he said that it was best to do it now and that we would have no problems, same as the first time.
Documented Facts: There may also be complications of surgery, such as bleeding within the brain. After surgery, swelling of the brain tissue, mild disorientation, and sleepiness are normal. Once implanted, device related infection, skin erosion and/or system migration may occur. Medtronic DBS Therapy could suddenly cease because of mechanical or electrical problems. Any of these situations may require additional surgery or cause symptoms to return. Medtronic DBS Therapy may cause worsening of some motor symptoms associated with the patient's movement disorder, and may cause speech and language impairments. Stimulation parameters may be adjusted to minimize side effects and attain maximum symptom control. In patients receiving Medtronic DBS Therapy, depression, suicidal ideations and suicide have been reported. Occurrence of "fall" has also been reported. **This was not listed on the consent form that I signed for the operation. I did not sign or consent for an operation that directives and policies said not to perform Bilateral DBS operations for "limb" essential tremors due to serious side effects/problems.**