


RESEARCH ARTICLE

# Subject and Family Perspectives from the Central Thalamic Deep Brain Stimulation Trial for Traumatic Brain Injury: Part II

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## Abstract

This is the second paper in a two-part series describing subject and family perspectives from the CENTURY-S (CENTral Thalamic Deep Brain Stimulation for the Treatment of Traumatic Brain InjURY-Safety) first-in-human invasive neurological device trial to achieve cognitive restoration in moderate to severe traumatic brain injury (msTBI). To participate, subjects were independently assessed to formally establish decision-making capacity to provide voluntary informed consent. Here, we report on post-operative interviews conducted after a successful trial of thalamic stimulation. All five msTBI subjects met a pre-selected primary endpoint of at least a 10% improvement in completion time on Trail-Making-Test Part B, a marker of executive function. We describe narrative responses of subjects and family members, refracted against that success. Interviews following surgery and the stimulation trial revealed the challenge of adaptation to improvements in cognitive function and emotional regulation as well as altered (and restored) relationships and family dynamics. These improvements exposed barriers to social reintegration made relevant by recoveries once thought inconceivable. The study's success sparked concerns about post-trial access to implanted devices, financing of device maintenance, battery replacement, and on-going care. Most subjects and families identified the need for supportive counseling to adapt to the new trajectory of their lives.

**Keywords:** brain injury; deep brain stimulation; cognitive restoration; disability rights; post-trial obligations

## Introduction

This is the second paper<sup>1</sup> in a two-part series describing subject and family perspectives from the CENTURY-S (CENTral Thalamic Deep Brain Stimulation for the Treatment of Traumatic Brain InjURY using the Medtronic PC + S) [UH3 NS095554, NCT 02881151] first-in-human invasive neurological device trial to achieve cognitive restoration in moderate to severe traumatic brain injury (TBI), with subjects who were deemed capable of providing voluntary informed consent. In this follow-up paper, we report on interviews conducted postoperatively after a successful trial of thalamic stimulation which met targeted milestones for improved executive dysfunction in chronic brain injury with at least a 10% improvement in completion time on Trail Making Test-Part B, which evaluates executive function.

## Results of the CENTURY-S Study for Moderate to Severe TBI

In the CENTURY-S study, deep brain stimulation (DBS) electrodes were placed in six participants with moderate to severe TBI (Glasgow Coma Scale Extended GOSE 5–7) to modulate cognitive impairment.

Electrodes were safely implanted bilaterally in the “lateral wing” of the central lateral (CL) nucleus of the thalamus and its projecting fibers transiting the medial part of the dorsal tegmental tract (DTTm). At the end of the 90-day treatment phase, all five subjects who completed the study (excluding one participant who exited the study following a scalp infection requiring device removal) demonstrated faster processing speed on the Trail Making Test-Part B. All exceeded the predetermined efficacy standard of 10% improvement (mean 32% improvement; range 15–52% improvement). These data were consistent with self-reports of improvement in the TBI-Quality of Life (TBI-QoL)-Attention measure (mean 79% improvement). A set of additional performative and qualitative assessment tools demonstrated selective improvements linked to executive function and attention; notably, two subjects gained a point on the GOS-E scale after three months of stimulation.<sup>2</sup>

### Subject and Family Perspectives

Here we report on interviews performed postoperatively after the DBS trial. These interviews revealed the challenge of adaptation to postoperative changes, including improvements in cognitive function, altered (and restored) relationships, and family dynamics. These improvements exposed new barriers to social reintegration made relevant by a recovery thought inconceivable. These changes prompted deep reflection by respondents about life goals once believed to be immutable. The success of the intervention sparked concerns about continued access to implanted devices and the responsibility for the financing of post-trial device maintenance, battery replacement, and ongoing care. Finally, most subjects and families identified the need for supportive counseling to help them adapt to the new trajectory of their lives.

### Methodology

As noted previously,<sup>3</sup> our subjects were drawn from the “Central Thalamic Stimulation for Traumatic Brain Injury” [UH3 NS095554, NCT 02881151], a study designed to assess the safety and efficacy of DBS for patients with moderate to severe brain injury (GOS-E levels 5–7). The CENTURY-S study enrolled six decisionally capacitated research participants. The study enrollment criteria, semi-structured interview methodology, analysis of transcripts, and IRB oversight has been previously described in Part I.<sup>4</sup>

### Demographics

Participant demographics were previously described in Part I. Eight surgical candidates and 10 family members were drawn from 419 potential enrollees who were screened for the CENTURY-S study and referred to us. Six of the eight surgical candidates went to surgery. One of the six subjects had a minor postoperative infection that necessitated explantation of the device. Thus, postoperative interview data are presented here from five subjects and their families.

Five subjects and nine family members were interviewed in the postoperative phase of our study. Interviews of respondents ranged from 47 to 113 minutes, with subjects generally having shorter interviews. Total postoperative word count for subjects was 56,810 (range 5,707-16,386) and for families 67,488 (10,931-16,705).

### Reflections on Study Participation

Previously, we characterized the clinical history of each of the subjects in Part I. What follows are the reflections of the respondents on the success of the study, how the intervention affected personal identity, and the effects of the device.

A common theme among the narratives was the preservation and restoration of personal identity following neuromodulation. The neuroethics literature is rife with science fiction scenarios about

personal identity allegedly hijacked by neuroprosthetics.<sup>5</sup> This is a common and misleading trope. The issue is far more nuanced than these speculations suggest.

The challenge of personal identity is a recurrent theme among survivors of brain injury.<sup>6</sup> Individuals can present in a heterogeneous manner with positive and negative self-narratives.<sup>7</sup> Self-identity may be lost in part or whole and recovered or reemergent.<sup>8</sup> Some narratives center on how patients grapple with the loss of self and work toward a reconstructed identity.<sup>9,10</sup> Other qualitative studies report unexpected self-continuity with the pre-injured self.<sup>11,12</sup>

A related question is how one's sense of self is altered by neuroprosthetics. Katarina Hamberg and Gun-Marie Hariz note participants' need for professional support to balance symptom relief and side effects, which Marya Schechtman argues might be best understood as a threat to personal identity and agency.<sup>13,14</sup> Felicitas Kraemer and Alistair Wardrope debate subjectivity and the relationship between authenticity, autonomy, and legal competence, drawing upon a DBS narrative first published by Kraemer in 2013.<sup>15,16</sup> Sven Nyholm and Elizabeth O'Neill, reflecting on DBS and anorexia nervosa, offer an alternative view on neuromodulation and personal identity and suggest that through its functional (and even transformational) effects, DBS can help actualize a *truer* synchronic self.<sup>17</sup>

Remarkably, respondents in the present study told us that brain injury, not the neuroprosthetic device, disrupted personal identity and that neuromodulation helped restore it. We made this observation previously in a study done with DBS in the minimally conscious state,<sup>18</sup> when the mother of the young man who received neuromodulation remarked that, with the device, he was still "Freedom," his childhood nickname.<sup>19</sup> As reported below, narratives articulating the reemergence of personal identity were voiced by subjects and their families.

Although philosophers like Derek Parfit would distinguish psychological continuity as being equated with personal identity,<sup>20</sup> the narratives suggest that neuromodulation restored the psychological and deeply held notions of the self as understood by the subjects and observed by their family members. Injury fractured personal identity and neuromodulation made the post-injury self more like it was before injury. These data—as opposed to philosophical speculations and contrived examples of space travel as in the case of Parfit's interplanetary "teletransporter"<sup>21</sup>—become dispositive and create an *empirical* social science predicate that needs to be incorporated into the musings of future philosophers.

### Narrative Reports<sup>22,23</sup>

To fully capture themes seen across the interviews, it is necessary to tell the individual stories of subjects and their families. Each narrative uniquely speaks to the study's success, while the collective reveals shared themes that will be summarized.

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DBS was restorative for this subject and her family. The subject reports that the study was successful and that she is seeing progress in her life. She told us, "At least now, I kind of feel like, give it some more time and it could go somewhere. Before, I wasn't going anywhere. At least here—like, it's only been five months. At least here, I'm moving somewhere a little bit. ... I'm not as irritable. I have my days sometimes, but who doesn't?" The subject also reports feeling smart again, having improved memory and less irritation, and less obsessive-compulsive behaviors (e.g., cleaning). Physically, she recovered the ability to spread her toes on the left foot and balance on one leg after implantation.

Her mother was more effusive: the study "has been so miraculous ... I don't ever want it [the device] to be off. It's given her back her life. She has hope. She's going to have a future. She's a new person. She's an intelligent, functional human being. ... In my mind, no, this works. I don't think it should be turned off. Will it have to be turned off? Yes, it does, because we have to prove it, not just for my daughter to fine-tune and finesse how this is going to work long term, but because this is a—I feel like she got penicillin before anybody else in the world ever got penicillin."

Both the subject and her mother reported significant intellectual improvement. After a long hiatus the subject began reading again, noting “That’s a step forward.” At the time of the interview, the subject stated she was on her *fourth* book when she had not read a book since her injury. Her mother stated, “She hasn’t read a book in 18 years, and she’s read six novels. She’s reading. That’s just like, yes. And she retains what she reads, and she talks about it critically, you know? We can have a discussion again.” The subject could now read Harry Potter books and watch the movies without being confused because she could remember the plot. The subject’s mother told us she is sleeping better and “... she can carry on more complex conversations, ... her humor is more sophisticated, ... overall [she is] emotionally calmer.” She also reports that her daughter is more confident and socially adept and can adopt the viewpoints of others. She also reports improvements to memory, calmness, less anger, and more impulse control.

The subject, who had planned on going to a professional school before her accident decades ago, was grateful for her interest in reading, “You made me like reading, which is amazing. I’m like, I never liked reading!”

And with this newfound ability came a change in goals and expectations. When we first met the subject before surgery, her goal—if the surgery was successful—was to become a Pilates instructor, a life-plan that no longer fit with her newfound abilities. She stated, “That bores me now. It’s too beneath me ... I want something that’s more challenging, that makes me have to think a little. Is that weird? Yeah? I think it’s weird because I don’t think you think enough in Pilates.” She explained that she had changed and that her interests, “It just kind of evolved because it doesn’t interest me anymore. All of a sudden, your mind just isn’t intrigued by it anymore. It’s just kind of moving your body. Because I was injured ... it was just something I did every day, keeping your body moving, which I kind of haven’t been doing lately, and I just wanted to do something more. You know, when your mind just wants to do more and give more, and you want to give back to the community.”

Moving beyond Pilates was motivated by altruism and a desire to use her mind again. She told us, “Not that doing exercise isn’t giving back to people and inspiring people to stay fit and helping. It is. I’m not doubting that. I’m just saying I want to do more, help people more. I want to give more. I feel like I can do more.” And then she offered the most profound understatement we encountered given where she was and how far her capacities had come, “I don’t know. *I just—I want to think.*”

She explained, “Yeah. I’ve always wanted to think. I’m bored. Like reading books and stuff—why? I would have thought that was boring, but I’m using my mind, and it’s interesting. I don’t know why, it just makes me laugh, but it’s amazing to me that I enjoy doing these things. Like, I’m a nerd! What happened to me? Oh, my God! ... You guys made me a nerd!”

When we reminded her that she had been headed to graduate school before her accident, she demurred. She noted that she had “never enjoyed reading ... But I’ve always wanted to use my mind. I wanted to work. I did always want to work and have a career and job. That has never changed, but I never wanted to teach—I never wanted to work in Pilates. I had to modify for a while because I was injured ... But you guys made me into a nerd because I enjoy reading now.”

Although she appreciated this transformation, it had consequences for her peer group and friendships. She explained that “... I went to lunch with my girlfriend, and I told her I liked reading, and she looked at me and said, ‘Why?’ I looked at her and I was like, ‘Because I enjoy it now.’ That’s when I looked at her and just knew our lives were going different ways ... I need a different girlfriend now.” When asked if she needed more “intellectual” friends, she replied, “Exactly. We’re going different ways, my girlfriend and I ... it’s weird. I want smarter friends ... The people I’ve been hanging out with are just like—and just weird. I’m like, where have I been? These people are really not my speed.”

As the subject experienced her evolution cognitively and socially, her mother bore witness as a family member and confidant. She thought her daughter is becoming like she was pre-injury. In a preoperative interview, she told us that she had lost her daughter because she was not the same person. After the surgery, however, when asked if her daughter has reemerged, she answered affirmatively, “Yes. She was coming back. Now I’m going to cry, so give me a minute. I’m not a crier. ... [Truly] her personality changed after the accident. She was irritable, self-centered, narcissistic ... A lot of it was because there were barriers and things, she knew she should be able to do and couldn’t. I totally get the emotional side

of it, but it changed her. Now she's gaining in confidence. She's calmer. She has more insight into other individuals' point of view, which had been totally lacking for 18 years."

When asked whether this is her *old* daughter and whether she had gotten her daughter back, she told us, "I got my daughter back, I got my daughter back. It's a miracle. [Laughs] It's so profound for us. It's a profound change. Now here come the tears. If somebody told me in August, we'd be sitting here having this kind of conversation in January, I never would've believed it. It's beyond my hopes, beyond anticipation. Somebody turned the light back on. [Laughs] Yeah, wait until you talk to her. ... Yeah, she's reemerged. The maturity she's showing—she can stop and think before she acts ..." Simply put, "It's changed everything. It's changed everything ... She can go out and find herself—find a position in the world that she'll really enjoy, find a partner, and see what's possible. I did not think that six months ago."

The subject reports differences in her sense of self when the device is on or off. When it is off, she is apathetic and lacks a sense of responsibility, "Yeah. I don't care when it's off. It's when it's put back on. It's like a split personality." She remarked that, "Yeah. I felt horrible. I'm like, I could give a rat when it's off. I'm like, 'Pfft, I'm going to do whatever I want.'" With the device on, she feels more responsible.

Interestingly, she reports an evolving sense of maturity when the device is on, stating, "I thought I grew up twice." She told us "... After my accident, I did go through this. I thought I grew up ..." And then she reflected, "This is a third time." Her mother concurred.

All of this is encouraging, but not without cost and regret. The subject and her mother have reflected on the subject's behaviors before and after stimulation; although they celebrate the improvements, her mother confessed that it was also "very painful," with the subject regretting her behaviors after injury and mourning lost opportunities. Her mother told us how the subject gained a greater appreciation of how she had, "... behaved during those years, when she was angry, impulsive, and would run away ... Now she realizes [it's me]. It was her ... she's ashamed of that."

Her mother understands her daughter's sense of shame and regret as akin to her pre-injury self reflecting on a post-injury version of herself. She told us, "The new [subject] reflecting upon the old [subject], and that's a mind game—her working through. Now there's a big, big thing. Right now, that's our big challenge: to get her to wrap her head around okay, forget about it. Close that door. That's what happened, but we're here ... These are the facts. These are your abilities."

But there is confusion amidst all the change. The subject looks to her mother for guidance, asking "... tell me what to do." And her mother steps back and tells her, "I can't." These challenges of adaptation were compounded by an inadvertent deactivation of the stimulator. This event was reported by the subject as occurring after entering a store and setting off a metal detector. The subject later dated her symptom recurrence as coinciding with this event, which occurred three weeks prior to the discovery of stimulator deactivation.

Some of the old behaviors that she later came to regret returned during this period without ongoing stimulation. It was a microcosm *in reverse* of the positive changes that occurred postoperatively as she lost capabilities gained with ongoing stimulation. But it was, as her mother observed, "almost worse because this was a rapid, rapid regression. I think, and I'm speculating of course, that she was just counting on herself with the device being on ... because she had rational thoughts and feelings. Then when the device was turned off, rationality went out the window. She became irritable, became impulsive, and became self-centered."

Despite this temporary setback, resetting the device resulted in the return of initial gains. The subject had no regrets about participating in the study and would do so again, stating that "there's got to be hope for me." She felt she has been given "a second chance at life" that others should also get. Thinking about the needs of others, she said, "I think more people need to be offered this ... You need to provide this." Then reflecting on the trial's very restrictive enrollment criteria, she asked, "Why is the window so small? Like the criteria? .... I'm like, no, this works!" There was an urgency in her appeal for wider availability of a technology that helped her move beyond her expectations and promised to be even more beneficial, "I need more time to progress. Yeah, I would do it again. I just need more time. I'm not done healing. ... I still think I'm getting better."

Both the subject and her mother expressed their gratitude. The subject told us, “I’m grateful to all of you, and I don’t know how to say thank you enough. The surgery was great.” Her mother told us, “She wouldn’t have her life if it wasn’t for this trial. She’s [quite thankful] for that.”

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This subject viewed his experience as an accelerated recapitulation of normal maturation via a neuroprosthetic. He told us he is “more as I was before the accident.” He explained that “... before the implant ... [my age] would be early mid-teens. After the implant I would say it’s back to either late teens or [my] actual age ...”

When asked how many years he gained following stimulation, he said, “six or seven.” With neuromodulation, he rapidly retraced prior milestones in his earlier development, making up for lost time. He explained, “The way I understand it is that it kind of reset development ... I was back to being around ... three or six, very impulse driven. I [had] no thought for [the] consequence of the actions. And the stretch after that it was the next stage, and then the next stage. *So, I’ve just kind of re-grown up again.*” (Italics added)

Although he was set back by his brain injury, his developmental recovery progressed expeditiously with the stimulator. His forward motion crossed multiple domains: executive function, emotional, and relational. Cognitively, he is now able to play complex multiplayer video games when many conversations are occurring simultaneously. He is not as good at the games as he was before his injury, but he is much better than before stimulation, which he attributes to being less distracted and having greater focus. He links the improvement, in part, to the stimulation ameliorating chronic headaches.

With increased focus, he can participate in video games with friends even with significant environmental distractions, stating “I’m not sure of the exact time frame of it, but I had been able to play games with my friends again.” Previously, “... it went fairly poorly ... because the way we did it was everyone is kind of talking at once ... vaguely following different conversations and kind of jumping in and out. ... It was on the line between difficult and impossible for me to do.” He could track a single conversation but, “... if there’s another conversation in the background I couldn’t—I would try and follow both at the same time. If there was a third one ... all conversations nearby that were intelligible.” This cognitive exertion prompted a severe headache. “I would try and track [all] at once and it hurt so much to the point actually I just stopped going to spend time with them [his friends] as much.”

This changed with stimulation: “... since the device was implanted ... I’ve been joining them on calls and playing ... two different games ... at the same time and ... in my third game ... [am] following along and having a good time and no headaches, so that has been a massive plus ...”

His father corroborated that his son could play video games again because the visual stimulation does not give him headaches. He noted that, “... games ... where [there is] lots of visual flashes ... used to be very difficult for him [and] ... give him a headache and just make him very, very tired ... After his injury he just had to stop doing that. And the times when he’d even try to do it, you know, he told me on multiple occasions ... it still makes him tired, it still gives him headaches. ... And it doesn’t seem to be causing him the same physical problem, manifestations of problems, that it did before. And I think, really, I think it is because of the device.”

His mother attributed his improvements to greater attentional focus, “I think the fact that he’s able to play League of Legends means the concentration and focus are better ... that was just way too overstimulating for him before ... I associate that with focus and concentration.” With stimulation he can multitask, “... before the device was there, I think that would’ve just been extremely exhausting and giving him a headache that if he’s playing a game with his friends and having another video playing at the same time that was something he could not have been able to do for any period of time, but he’s doing that now.” His father added, “The headache and the exhaustion that it would cost him before is definitely reduced.”

The subject explained “... I’ve been able to track four regularly and five [activities] ... I’m able to kind of switch my attention between things quicker without getting a headache from it and ... keep track of

both at the same time, to talk about one topic with one person, switching briefly to, like, say something, like, 'Oh, yeah—no, I wanted to put the groceries over there,' and then [go] back to the first conversation and ... follow where it was and keep track of where we were. That was not possible before the stimulator. That would be an instant headache for me ..." This has enabled him to "... turn from the computer, and talk to someone, talk to someone else on the computer, be on a phone call ... quote, unquote, multitasking."

More focused and less fatigued with intellectual exertion, his father noted, "He's reading more ... when the device is on ... when the device is off, I think he's just so tired, he has trouble just focusing ... before the device was implanted trying to read would give him headaches. So, I think that's improved."

These newfound abilities have improved college performance. His father stated, "He was taking college classes this last fall and I think that it went definitely better for him with the device working than last year when he was taking classes without the device." With his success, "I think he definitely was feeling better about his classes ... this past fall, made it seem like a lot of times he was actually enjoying it more." His mother added that he seemed to "... do well with his time management to a good degree and he seemed to maintain his interest ..." The subject told us he took less time to write school papers. He would share a draft with his parents, and they would say, "... yeah, it looks fine, looks good to me, whereas before I would take, three or four different passes and just slowly get at something comprehensible ..."

These cognitive changes have improved family interactions. In addition to better grades, he reports fewer problems with speaking and writing, resulting in improved communication with his family about school and daily life. Conversations are more efficient and "... go a little faster. I can trust that they understood the correct thing when I say something. Although sometimes I still ... jumble my words ... that's gone down a lot." Before "... I would say 'oh, man, it's so cold today. I'm feeling really, like, 'spicy.' ... a random word is in there incorrectly and they would have to correct me on it. And lately I have not had that happening ..." More fundamentally, "I've been able to express myself a bit better ..."

His mother noted he can now keep pace with conversations, "... before he had the device ... he knew he wanted to say something, but he also needed a moment to formulate what he was gonna say and he needed to know the pause was there before he could formulate so that what he was saying was relevant ... [and] wasn't about what people said 10 minutes ago." She explained that keeping track of dialogue was a challenge, but he has developed the necessary quickness to formulate timely responses.

His father observed that, with the stimulator, his son can "... be more proactive about participating in the conversation." Previously, "... his mind just kind of zeroed in and that's kind of what he focused on. Even though when things had moved on, he was still kind of fixed on what he wanted to say." He would "get tense and kind of grit his teeth and sometimes just feel like he's being excluded, even though nobody is intentionally excluding him ... I can still see that he can get frustrated, but he expresses it less and I think he's more proactive ... letting us know that he has something he wants to say." He continued that "with the device he's much more able to assess whether, [he] really has to say it or ... just accept the fact that the conversation has moved on."

His mother noted that he is less perseverative and more flexible. Before the stimulator, "... he'd get a song in his head, and he'd have to hum it out loud for other people to hear before he could move on ... he'd get an impulse and he'd need to follow through with it ... He's better able to hold them back. And it used to be that he would even tell me, 'I have to follow through with this in some way or ... my headache gets worse,' and he hasn't been reporting that since the implant." She added that "... he is able to verbally inject himself into the conversation better. Sometimes he still needs a little extra time and sometimes he still isn't entirely clear yet to himself about what he wants to say ... but I think he is quicker about being able to engage in the conversation ... he still might need more time to formulate what he really wants to say ... He's not kind of waiting for the opportunity, but he's more willing to engage when the opportunity is there."

Within the context of family dynamics, the subject can now sit centrally in his home and stay focused, without a headache, despite the distractions. He explained that "... [at] dinnertime people get their food, they're eating here, and if I want to be on the computer there's a conversation in the background ... And that used to be very headache inducing. Now it's not. I can again kind of keep track of the conversation

without getting a headache. And when a big family conversation is going on and different people bring different ideas to the conversation, I can follow along with it and participate in it.” Although he does not have unlimited endurance for these types of conversations, his tolerance has increased.

Additionally, the subject reports improved emotional control, self-regulation, and ethical deliberation. He contrasted his current self-restraint with an episode that occurred after his injury. At a support group for impulse control, “... there was someone walking by. I was on the edge of the aisle. And I considered, I could, try and trip them ... And had to fight in my head and that I did ... and then I had a massive headache ... afterward because of that little impulse fight.” Now he reports, “I’m able to have more kind of control over my own impulses ... Since the implant I have not really had them ... not had anything on the same scale and made me feel nearly as guilty as the thing I mentioned. So, it’s been easier to stay a good person.”

His parents corroborated this, “I think it’s just easier for him to have the self-control ... he still loses energy by the end of the day, even when it’s still on, but ... it’s easier for him to plan a meal ... whereas when the device is off, he’s just, like, ‘forget it, I can’t.’”

They also report that he is less “short-tempered” and frustrated and attribute his emotional regulation to cognitive improvement. His father told us, “I would say his demeanor is better when the device is on. I think that ... in large part because as he’s sleeping better, he feels better and engaged better. He’s less susceptible to noise and distraction and other things that cause him headaches, but I do notice when the device is off, he’s much more short-tempered, likely to be frustrated when, things aren’t quite the way he wants them to be.”

His mother agrees, “... in general he’s better able to take things in stride ...” Before “... it was common for him to get very frustrated when ... there wouldn’t be a pause in the conversation where he wanted to interject something ... there would be an outburst ... either walk away or ... make an angry statement or interjection. It would be for something that normal people with normal nervous systems could usually manage. And he’s better able to manage that now ... there’s been a noticeable difference ...”

These improvements have lowered tension in the home because “... he’s not getting angry about it in the same way. And so, we’re less in need of ... engaging his emotional state ... which makes it a little more comfortable to be around him. We don’t have to be as ... guarded ... it’s easier to joke with him ... whereas before he might be just indignant that we didn’t understand [him] the first time around.”

The efficacy of the device seems to correlate with sleep hygiene. His mother told us, “... there’s a lot of variation depending on whether he’s slept well the night before.” His father reports that, “... when he’s able to maintain a good sleep schedule that—he [is] definitely better, but when he has trouble sleeping ... he can dip lower when he’s unable to maintain his sleep schedule.” With improved sleep, the subject is less preoccupied by his actions post-injury and previous impulses. “I’m not sure if it’s directly the stimulator, but because it’s helped me get more sleep and be more rested in my sleep ... I spend less time remembering past mistakes just to feel guilty over them and regret them ...” His parents report that he has more energy and can maintain a sleep schedule. This has allowed him to “... participate in normal life without it really being a struggle because he’s so tired he can’t focus ... the fact that he was focusing better during the day I think improved his sleep to a certain degree at night.”

In the aggregate, the subject is “... happier more of the time.” His father reports, “I think he’s happier when it’s on ... so that may be just energy. I don’t know if there’s any other direct effect from the device on his demeanor, but I think maybe just being able to participate in the conversation ...”

The subject’s physical well-being has improved with stimulation, which is the foundation for his emotional and cognitive gains. He reports the reduction in headaches as “... by far ... the biggest and best benefit that has affected things because now ... it just helps me enjoy things more.”

Despite these significant improvements, his recovery remains a work in progress. His parents believe that he is not back to his pre-injury energy, although they believe he is less fatigued. The subject notes that, although he gets fatigued during the day, he has more stamina. By late afternoon, he is “... closer to 80% power as opposed to 60% power or 50% power.” This helps him control his emotions, because, in his own words, “If I’m tired just all emotions are the Energizer Bunny out of power ...” His mother adds “... he [is] not back to pre-injury ... that was never truly the expectation, but ... he’s much more able to think



about his future rather than just trying to get through the present. And I think that's a great positive place for him to be."

When asked whether stimulation changed his son's identity, his father told us, "I would say that he's the same person. It's just I think his mental energy level and just overall demeanor improved when the device is on." He mother elaborated that although these improvements wane over the day with fatigue, he is a "More energetic post-injury version of himself ... personality-wise he's—in my opinion—the same. He has the same interests. He gets excited or not excited about the same things. He is still a kind person either way ... so those things that I would consider personality I think are the same ..." The stimulator made it "... easier for him to have the self-control in order to be the person he wants to be and knows he can be. So, it's easier for him to follow through on being responsible for things that he knows he's responsible for ..."

In sum, the subject and his parents viewed the study a success. The subject reports, "It's what I hoped for, and I got the benefits I was praying for from it." He looks forward to more evolved devices that "... minimize the negatives I have from it." Nonetheless, he was "quite happy" with "the way they [the research team] used it." His father stated, "I think [he] ... definitely benefitted, I think, in terms of how it's worked for him. I think it certainly has been beneficial."

In contrast, his mother noted "there's expectations and there's hopes, right? ... my hope was that his exhaustion would largely go away, and I don't think that that's the case, but I think it's become more manageable ... what I hoped for didn't quite match what happened."

However, she reflected that "I think that the changes in him have been more subtle than I expected or hoped for. And as we're reminiscing here, looking back ... I'm recognizing more changes than I had kind of consciously noticed because they were in part gradual, and they were also a little more subtle than I had probably expected. I did expect some positive change just based on what I had read already about previous subjects. And so, I probably wasn't as neutral in my expectations ..."

The subject was less equivocal and calls the device a "blessing." He told us, "One of the things, you never know [is] what you have 'til it's gone. The ability to keep your focus and ignore the other things that aren't important to focus is very, very important to a lot of things in life." He elaborated, "You never know what a blessing it is until you get it the second time ... if you don't have it for a while it's, like, why'd you take it from me. Where's it been all my life? Give it to me. Give it back."

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This narrative is notable as it reflects the experience of the oldest participant and draws upon the reports of his adult child and partner. All reported that the subject improved but less than they had hoped for, with the subject perceiving less benefit than family members. These perceptions contrast with objective evidence that the participant's improvement was the greatest of all study participants, with a 52% increase in processing speed on Trails B, a result that is especially noteworthy given his age and history of multiple TBIs. This discordance in perception points to the need to contextualize narrative reports against objective data and appreciate that numbers alone only tell part of the story; psychology lurks behind the physiology.<sup>24,25</sup>

The subject thought that the effects of the device were "subtle." He reports minimal improvement in losing/forgetting things and better focus watching TV. Despite what he perceived as minimal effects, he was, "... glad I went ahead and did it, even though I haven't seen a lot of improvement." He compared his experience to another participant, reported in the media, who "... had a lot of improvement" noting that "I haven't really noticed that thus far. So that's a little discouraging ..." However, he felt that the study was successful because, "I came out of it no worse than I went into it."

In contrast to his father's impressions, the subject's son was more positive, "He really has made an extreme change in some ... areas in a short amount of time. And it's hard to not attribute that to this." Both he and the subject's partner believe the subject has more cognitive energy and is less fatigued and that his ability to concentrate is a "little better." He also reports that his father is more motivated and self-confident: "I felt like when it was on, that belief that he could do it, and more than belief, it's like I think he

knows he could do it, but he doesn't want to do it. But I feel like lately he wants to have the best life he can."

The subject's partner reported she could infer when the device was off, as his energy level decreased: "I wasn't positive it was off during the blind part of the study ... I guessed it was off. And it turns out that it was. And he felt like it was off. He didn't feel like he was quite as sharp or had as much energy." In contrast, when stimulated, he was "... able to kind of work something through on the computer" and had enhanced drive.

However, the effects of stimulation were less obvious to the subject. He reported a slight difference when the device was off, "I was hoping it was off when they turned it off and it was. And that made me realize that it must have some effect." In retrospect, he appreciated that "I felt it was different because I was really struggling when it was off ... it was working because I felt a little bit better, prior to them turning it off."

The subject's partner told us of the difficulty discerning the emotional effects of stimulation, "It's just so hard to tell what the difference is between them, the mental and the emotional." On the one hand, there is improvement in relationality as perceived by the subject's son and partner. On the other hand are the negative perceptions experienced by the subject.

The subject's son experienced improved interactions with his father. Although he previously did not trust his father to make decisions—including the one to participate in the study—he noted that the device has increased his father's decisional capacity and impulse control. He told us, that his father's ability "... to look at a situation, evaluate something accurately is like 100 percent better, I mean honestly. I don't know how to put a number on it ..." He elaborated that before stimulation, "I didn't trust him to make decisions ... [Now] He is listening better, he's thinking better, and ... he's making better decisions."

The subject's son also felt that the subject "... is thinking more realistically ... when he talks to me, he's acknowledging of his loss and ... what he likes and doesn't like." His son suggested that the subject is now more realistic about his abilities, appreciating that it was not safe for him to drive, "... it was one thing he had to accept. And I think he couldn't accept that a year ago." He added "... he's more aware of situations with himself and others. He's definitely much more empathetic to me ... I can feel his empathy again instead of just hearing him try to be empathetic." This was an example of a return to his pre-injury self. His father's frankness has improved their relationship, allowing a more "honest discussion about life and about my relationship and about his too."

He also observed that his father has developed more insight into his relationship with his partner, "I do feel like ... because of this implant ... he is able to distinguish the truth of the situation more ... before he kind of wanted what he wanted and he would do anything to get it, and he would say whatever he needed to say to get other people to believe it. But lately I feel like he's been much more realistic with his own faults ... since the implant, it's that he feels more aware of his situation, he feels more able to fix the situation. He can see all sides a little more clearly." His son was gratified that his father seems less in need of attention and external affirmation, telling us that "he's not as much focused on wanting to tell his story. He's more focused on wanting to be happy, which is great."

The subject, in contrast, reported that the device had negative effects on his emotions: "I do know that they turned up the device, originally, and I think it got to a point that I got really emotional, and my teeth were chattering." Although he had hoped that his frustration and irritability would decrease, he found that his irritability "... comes and goes. I get really irritable for days at a time, where I don't even like myself and [my partner] probably would concur. I would say that's the same. Maybe a little better than it was." The subject's partner and son reported that the subject experienced paranoia during the titration phase but after the device was adjusted, he experienced less impulsivity and has since been more open. His partner noted that "... once we got through that piece of it, emotionally I feel like in some ways he's been able to be a little bit more transparent."

The narrative is further complicated by the triangulation of respondent expectations and perceptions. The subject's partner is relieved that her fears about how the subject might react to a lack of an effect were not realized. Before surgery, she and the subject spoke about when "... [positive] things don't happen, then what's going to happen? You know, is he going to crash and burn? I don't feel like he has. I don't feel like he has crashed and burned the way our concerns were." But the subject was disappointed that he was

not more energetic with stimulation, “If I just had all the energy I used to have ... my life would be so much better ...”

The subject’s partner sought to discern the effect of his affect on his functional status. She told us that “... the challenge for me is that I don’t know where to separate the emotional fatigue and the mental fatigue. Like the going to the bed in the afternoons for a nap, is it because he is mentally fatigued and needs to shut his brain down? Or is he emotionally fatigued and overwhelmed because he’s gotten frustrated ... And it’s hard to separate and know what’s what.” Similarly, the subject’s son reported that although the subject is “... acknowledging things a little better,” he is “extremely emotional ... [and] has been since the injury ... he’s very insecure and he’s very needy, extremely needy.”

The subject also reported difficulty in disaggregating the emotional and the functional and highlighted increased depression and lack of motivation: “I’ve faced depression my whole life—but it’s really darker, now. It’s really bad. And I’m not sure what I want to do. I’m not motivated.” He added, “I still just get frustrated very easily. A lot of it is because I can’t remember anything, or I can’t do anything. I can’t even go for a ride ... I think I’m in a really bad place. And it’s just the quality of life is not very good. So, I don’t look forward to anything.” Then he pointed to his preoperative experience with depression, noting that his state of mind might not be related to the surgery but to his premorbid condition. He reflected, “... I don’t know if that has anything to do with surgery or not. Just I think it’s how I was feeling, and I think I feel that way, still. And maybe I thought that the surgery would help. I don’t think it hurt. I just don’t know if it helped much, unfortunately, at this point.”

The subject’s son reports that his father’s avoidance of certain tasks does not relate to an inability, but rather stems from his “... mental state. And that was there before. I think now he’s starting to realize that I think he’s willing to go back to the hard work a little more now, and that’s what is changing.” These insights highlight the paradox that with recovery comes the recognition of, and responsibility for, life’s difficulties. Challenges that were previously shrouded in impossibility are now more present because restored abilities put them in reach. This can be daunting. These responses are reminiscent of the experiences of subjects in Helen Mayberg’s DBS trials for refractory depression. Even objective improvement of their depression did not solve life’s challenges. Quite the opposite—the recovery of cognition or mood (in the case of patients with depression) made it necessary to reengage with one’s life and all its unresolved problems.<sup>26</sup>

Despite their complicated journey, the subject’s family neither regretted his participation in the study nor wanted the device removed. The subject’s son had been opposed to the study and hoped to avoid harm, “... But now that he has had it, I’m glad that he did have it. Because I see improvements and he’s OK right now.”

Similarly, the subject’s partner did not “... have any regrets ... even if he’s only gotten, you know, 10 percent better, or 15 percent better, from a cognitive standpoint, I feel like it was worth it ... it gave him hope and I think that that hope and whether it’s a placebo or not in his own brain, it’s helped him. I think emotionally he’s still struggling with the depression piece of it. I think he still wishes he had more energy in that. But there’s still the opportunity to turn it [stimulation] up and maybe things will get better. And so that’s kind of kept him going with that hope. And I think hope’s powerful.”

But most poignantly is the son’s perspective that his father’s pre-injury identity returned. He told us, “You know, I hear him talking on the phone sometimes lately and he sounds like my old dad more often. And you know, his wit and stuff like that, I would say like concentration-wise, effective ability, cognitive ability, maybe like 20 percent when it was on. Like when it was off, I’m not sure. I didn’t see him as much of the time, but I could tell you it was a little bit different ... his self-realization and stuff like that, it’s hard to put a number on it. It’s night and day. I mean it’s so different.”

### P378

Both the subject and his mother thought that the study was a success and that the subject has had cognitive, emotional, and relational improvements post-stimulation. For the subject, the study exceeded his expectations and was “... definitely somewhere between a big success and a huge success.” He told us

if there were to be improvement, it would be in “memory, focus, and attention ... and maybe a few others. Those three things were all improved along with multiple areas of my brain ... from the activation point on, immediately, which I was hoping would happen after a full year. So, what I wanted to happen after a year happened the first day.”

He told us that, “... when the device was first activated. I noticed immediate improvements in memory, processing speed, planning, organization. I mean these are pretty basic functions, mental functions, right? The core function, and that was just the first couple weeks. Then I started to feel these other effects, which I think was the major functions of planning, organization, attention, focus, memory, that stuff kind of intertwining. And the neurons in between those centers connecting and starting to fire, because everything was starting to be interpreted in a different way. I was looking at more angles of a subject so to speak and with more angles came more thoughts on how to interpret the information. So, it’s kind of like going from 180-degree panoramic view to a 360-degree panoramic view.”

The subject was at a loss describing these changes: “... it’s really hard to pinpoint exactly what’s happening because every step of the way my brain is changing—rewiring itself. And while I can’t really pinpoint exactly what’s changing. I can feel it ... in the first two months I mentioned a sense of calm and a complete annihilation of any stress, anxiety, and related feelings. That has not returned anywhere near the same degree as the first two months. But it does seem to be coming back ... I think that is the rewiring of my brain and how that’s affecting me consciously is just a state of calm, at peace, much less anxiety, things like that.”

He analogized his improvement to having an increase in RAM, a computer’s working memory: “The retention of my memories is what I am referring to as the RAM, so as the RAM increases, I can retain more.” A math student before his accident, he observed that during the first two months of stimulation he “... was probably at the point where everything would make sense. Upper division mathematics, like my mind was unlike anything I had ever felt before or after the TBI. It was phenomenal ... the speed at which I answer a math question has improved.” Like other respondents, he also read several books, a goal he had set in our first interview.

His mother told us, “He’s got ... stacks and stacks of books that he’s reading, these he’s read; these he’s reading now; and these he wants to get to ... he’s been doing that and commenting on how much he can read as opposed to before.” The subject was able to be functional at this level because, “... my brain was firing at a whole different level than it is now. I can sit down and read; I just don’t really want to work up the energy.”

The subject thought that all this was “... fantastic ... so after a year I can only imagine where I’ll be ...” He recalled his hopes for the study: “... I just wanted ... to sit and read. Because I spend most of my day doing nothing, so if I could spend most of my day reading that’d be doing something, that’d be great ...” He added that he is now “... past that at this point. I’m just kind of trying to figure out what I’m now capable of, what I can do.”

Without hesitation he attested, “... if I went back in time and had the option to choose I would do it again.” He was struck by the immediacy of the effect, noting that, “... I was expecting after the surgery was to really not notice anything different. And after a year maybe I’ll start to regain some focus and be able to sit and read a book. And I’ll just test every month or so to see if I get there. I mean after the device was activated, I had objective test results in front of me showing immediate improvements in multiple areas ... so my expectations were kind of blown out of the water once the device was turned on.” He analogized that it was “... pretty much a light switch that immediately turned on and then as it remains on it just gets brighter and brighter over a period of time.” He was clear about his view of the procedure: “If I had known that I would be getting the benefits that I’ve gotten so far before I had agreed to the surgery there would have been absolutely no conversation on whether or not I would have joined. It would have just been me showing up, getting my brain cut open, and then walking home ...”

His mother also reports that the study has been a success, and that it has exceeded her expectations, despite her initial hesitancy, “... I was so against it. I mean I tried with all my might to talk him out of it.” But the results were “... better than I expected ... initially, they told us that they probably wouldn’t see any results, possibly up to a year. We saw results almost immediately ... right away. [My son] was blown away by it. That he could have—I can remember, we were in the hotel room, and we—he was talking on

the phone to his brother, and the TV was going, and I was sitting there, probably jabbering in his ear at the same time, and he was like amazed that he could kind of follow all three at one time. That was huge ...”

The subject’s mother feels he has more emotional stability and “... I don’t think his mood swings are as severe, like they were.” Although he had some lability after surgery, she believes it was “... more because the settings were not correct. He was still learning to adjust, and so ...” When he has an outburst, it is more tempered than before surgery and his response afterward more conciliatory and insightful, “... he’ll always come back and apologize ... he always kind of sees it after, he’ll calm himself down ...”

The subject notes that he has less anxiety with stimulation but had one unexpected episode of crying, “... I just started crying, like no idea why. It was just oh, I’m just going to cry now ... just things like that, laughter, sadness, a bunch of emotions just come out of nowhere for no reason, and then they’re gone, and I feel better ...” The subject believes that this was a “good thing” and his “body’s way of releasing emotions that had been trapped.” When stimulation parameters were decreased, the reverse seemed to occur with “... all those emotions to build right back up which was very unpleasant ...”

His mother confirmed that at that time, “He sort of took a downward turn ...” She knew there had been a change in the parameters “because his personality changed so drastically ... that’s kind of when he took a nosedive.” He became irritable, shorter-tempered, and withdrawn, “A lot of how he is before he had this.” These changes were reversed when the stimulator was back on to prior settings.

With these improvements the subject and his mother believe he is more like his pre-injury self, “Oh I’m closer to my older self than I have been in 11 years.” With stimulation he reports he is moving back to his formerly laid-back self, noting that after the injury he had lost his sense of calm, “... I wasn’t an extremely laid-back calm guy, like in high school everyone thought I was the biggest stoner who would always sleep in the back of the class. I never did drugs till after I dropped out of high school. I was just like I’m just the guy in the back of the class who enjoyed a good nap and then would get A’s on the tests, that’s what I did. I was calm, and I was patient. And I’m closer ... I’ve moved in that direction.” He asserted that the accident caused a bigger change in personal identity than the stimulator. Although the stimulator’s initial effects were dramatic, the “... first two months prior to the over stimulation period the device caused a bigger change. Cause it took me back to where I was, honestly that’s how it felt. And then it took me further, so I went from having almost no anxiety or stress and just being really calm to having zero stress or anxiety, having every pathway in my brain firing at what felt like optimum capacity. Everything was quick, fast, smooth, and fluent. The way I felt those first two months was like any—nothing I can describe, it was amazing. But knowing that, that was a result of this technology and seeing where this technology can go is very, very interesting to me.” But these effects paled in comparison with the disruption caused by his injury, “... the accident itself was the bigger change. [The] neurostimulator is probably a fraction of that change, I don’t know if it’s a fourth, or a fifth, or an eighth, or a tenth, or half. I have no idea, but ... the effects compound over time.”

He continued that these changes could be transformative, “And I’d assume in a year or two at this current speed I’ll be a different person.” When pressed whether he would be a different person or more like “the old person before the accident,” he revised his speculation that he would be “... hopefully like before the accident. When I say a different person, I mean for outside people. Other than myself anyone who interacts with me will be interacting with a different person in the sense that they won’t recognize me. But on the inside in my mind and all that, personality wise, the goals, desires, none of those seem to change really. So, it’s kind of like personality, I read it in a book a while back. And it, it described personality as a persona or a mask you wear, like an actor in ancient Greece, right? So, an actor can change their persona or their personality to match their role, but they don’t change. They’re still the same person they’re just acting a little different. Same goals, same desires, just a different persona, that’s kind of what I’m thinking.”

He elaborated that he was the “same person” as before the accident but now “... just wanted to go about things in different ways because things that made sense before no longer made sense.” He cited his, “... perception of the world, how I interpret all the information I see and hear is a little different. How I process information is also different in the sense that I sit back and take my time before giving a response.” Citing his political beliefs, he adds that, “... while I am the same person, I’m now taking

different approaches to subjects and topics that I once thought were more black and white ... politics for example ... prior to the surgery I was closer to hardcore Democrat, left, whatever. After surgery I still want the same things. But how I go about—or how I think we should go about getting them, as in which political platform ... My opinion changed on that ... it's kind of like my soul hasn't changed, just how I can express myself, and how I can interpret the outside world ... And that has allowed me to redevelop old ideas in new ways ...” Operationally, “... the amount of information I can process and retain in a single moment has increased significantly, leading to thoughts that are much more detailed than previously.”

His mother noted that any comparison with the subject's former self was difficult because he was so young when the accident occurred. She told us, “His dad and I were both commenting ... ‘oh my God it's like the old [subject] is back ...’” Whether she got her “old” son back was more complicated, “... I'm going to say no. I don't know if that's even possible, for many reasons. One, he was only 19 years old. Right. So, now he's 30. So, it's really kind of hard to make comparisons.” But overall, she felt that he was *en route* to the person he might have become, had the accident not intervened.

#### P410

This narrative is characterized by the hesitancy of the subject to respond definitively or independently to queries about the study, deferring to his parents. A typical response is, “I'm told by like my parents or other people that I'm doing pretty well.” When asked if he is better, he replies, “... that's a very definite potential ... what makes it definite is that people react to the way I am, essentially in a pretty positive manner.”

When asked if he has benefited, he said, “Yeah, I think it went pretty seamlessly, in a positive direction ... I consider it a success because I just feel a lot more elevated, in a sense.” By elevated he meant he was “just happier” and capable of doing schoolwork and other cognitive tasks. He reports being happy “97% of the time.” Before the surgery, “... I wouldn't really do as well or succeed too much of the time on homework assignments or tests, and now whenever I do things, I don't really think about them too much more.” He told us he was “... Plugging along, but I don't really see as many obstacles as I used like before the surgery.” Again, as with others, he is reading more than before and has an improved ability to play the piano, telling us he was, “Either the same or better, so I've definitely gained because of the procedure.”

He reports that he is “definitely more organized since the surgery.” He sets up to do schoolwork and does “... everything that's related to that one homework assignment, that I'm set up to do at my desk, and I essentially complete it, and then, put it away, and [am] onto the next thing.” Nonetheless he equivocates, “I'm not sure it's really different from how I would've ... conducted myself with those kinds of situations beforehand ... I can't really tell the difference in my behavior.”

The subject reports he is “definitely less dependent” on his mother and more reliant upon his phone's calendar to stay organized. His mother reports that the subject is more independent at school and with activities of daily living. Before stimulation, “He would have been just been lost. He wouldn't have even necessarily even noticed that he missed anything until the end of class, and he would have said, ‘Oh, I failed this class, but I don't know why, the teacher is dumb’ or something like that. So, yeah, that's a pretty big change.”

The subject has also taken initiative with household chores. His mother explained that he became less tentative. Before stimulation, she would ask “... ‘could you make pasta’ and he would have come up, in my room—and with the pasta box and said, ‘how much should I make?’ and I would say, ‘oh, you know this much.’ And then he'd go down and then he'd say, ‘the water's boiling should I put it in now?’ ... so, he would kind of ask, along the way, 100 different questions ...” Given his hesitancy, she was surprised to one day find her husband eating pasta that her son had made, “It was just made and rinsed and ready for sauce or whatever.”

She also reports that her son runs errands that previously would have eluded him. She reflected, “... I don't know what that takes [but] it takes follow through, it takes remembering, it also takes where he wouldn't be afraid to do something without asking 100 questions.” His mother attributes this ability to

improved short-term memory. Prior to the surgery, “I would say something and then he would come downstairs and ask me and I said, ‘I just told you that.’ And he would look like he didn’t remember. I haven’t had those types of interactions with him since the surgery ...”

According to his mother, this was emblematic of the subject’s enhanced problem-solving abilities. Instead of being “frustrated with himself and really angry,” the subject would “... find a way to fix a problem rather than just seeing this problem as, so hard, he didn’t even want to, deal with it.”

Central to this improvement was his restored ability to sequence tasks and narratives. With these skills came a more sophisticated and a less perseverative “childish” sense of humor. He regained his ability to recall jokes he had heard before he was injured. His mother told us, “... he stumbled through it, but he told the whole joke perfectly ... he actually even remembered the parts that you need to remember ... those things that ... were important for the joke to be funny without any prodding.”

The subject’s mother also told us of the emotional effects of stimulation. She described her son’s anxiety as tempered by his injury. She believed that his TBI “... sort of acted like a lobotomy and it cut that part out of his brain I think.” Afterward he did not “... suffer from anxiety except for ... if he forgot a test, or if he had one class where he wasn’t doing any homework and he realized he was going to fail the class.” When that happened, “the anxiety came back 1,000 percent, to the point where he’d even say something like ‘this is why I don’t want to live anymore type of thing.’” She reported, “I have not seen one outburst, I think, since the surgery. That’s probably the biggest change emotionally.”

In the aggregate, the subject’s improved cognitive abilities and emotional control have altered his relationships. Whereas before stimulation he needed his mother’s constant hovering and support, she now worries if her ongoing presence could be stunting his independence. She is concerned that “... we sort of stifle his growth because he has everything sort of taken care of here—and doesn’t really have to think too much for himself.”

To foster his independence, his mother has stopped helping him with his homework, “One thing I did do differently this year is I have not helped him at all with his schoolwork ... before, right when he was first recovering from the injury, I was actually sort of almost doing his schoolwork for him and then it gradually went to me just reminding him to do his schoolwork ... but this year I’m not doing anything ... on purpose ... I’m not reading his essays before he turns them in. I’m just kind of letting him do everything.” She acknowledges that this was hard to do but implicitly invoked Perske’s “dignity of risk” (which we alluded to in Part I of this series and elsewhere).<sup>27,28</sup> She “finally let go,” allowing her son’s independent agency to reemerge. Despite the risk, it worked out to her son’s advantage. She reported that her son had forgotten to do an exam on time and that “... before the surgery I think he would’ve taken it really, really hard and then [have been] really frustrated with himself and really angry and he wasn’t at all.” Instead, he asked, “‘What do you think I should do to make sure I don’t do that again?’ which was a pretty big change.”

Moreover, when left to his own devices, he sought help from others. His mother told us, “Another thing he’s done that’s different now ... is he’s gone out of his way to get help. I think he got a grade he wasn’t happy with on an essay and so he made an appointment with his teacher. And he went over what he could be doing better on his essays and stuff like that. And he did that all by himself. He didn’t need any guidance from me or anybody.”

As with many of our respondents, the family reports that the subject’s personal identity reemerged after stimulation. His mother observed him, “... talking to his classmates on a Zoom call,” and felt that “he does seem like the old [subject] before the injury. Like, he’s not hesitant—he has ideas.” She confessed that “... I feel like as long as he’s with us he’s more ... like a child ... and when he’s in his group settings with his students, he’s more like a peer to them.”

There were other occasions when his mother told us that he had become more like his pre-injury self: “... there are definitely some things that make him seem sort of back to normal, like before the accident ... his will to do what he wants.” After his accident he was less self-directed and would, “... take directions from people and didn’t really express his will that much.” After stimulation he is “imposing his will a little bit more” and would push back saying, “... I can’t do it. I have to do something else first.” She reports that his father asked him to do the dishes. In the past he would comply. But now she tells us, “... he’ll (say) ‘I have to finish my homework first and I’ll do them later. He wouldn’t have done that before ... both of us

find it a little annoying, but at the same time we also see it as progress.” As she put it, “... he was expressing himself more [about] what he really wanted to do.” She believes that these behaviors are evidence of his former self, telling us, “He’s still very different from where he was before his injury, although that sort of stubbornness was very, very strong before his injury. So, for that to come back a little bit I guess is a little bit more like he used to be ...”

Reminding us that brain injuries—and emerging therapeutics—affect the whole family, the subject’s mother reported that with her son’s improvement, she has “sort of relaxed a little bit now. Like, I don’t have to worry about him as much ... it’s ok for me to get sick or depressed or—like I couldn’t allow myself that ...”

She expressed both relief and hope, “I do feel a little bit of a relief not having to worry about his school and just thinking that he can take care of it ... I’ve been holding this for 10 years as something I have to do and now, I don’t have to do it ...” Looking ahead she told us, “I guess I can now worry about the future. Like, I never really worried about the future before. It was just more day to day. And now I can worry about the future ... it’s different for sure ... I can plan now ...”

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Overall, subjects and family members viewed study participation favorably. They experienced positive changes from the stimulator and a return to their pre-injury sense of self. The next section describes their suggestions for how to improve studies for future participants.

### Suggestions for Future Studies

Drawing upon their experiences in the clinical trial, respondents had a number of suggestions to support future studies of invasive neurotechnologies. They focused on the need for additional technical support using the device and psychosocial assistance to manage the life-altering changes they experienced as subjects and family members.

#### *Device Modifications and Technical Support*

Respondents reported wanting additional technical assistance managing the deep brain stimulator. One parent was confused by the on–off cycles of the device, especially when the family traveled across several time zones. When reflecting on her interactions with study personnel, she noted that “... 100 percent it was fine ... It was just the device itself ... the only criticism I would have is with the device itself [and] ... just being relaxed about how it works.” (P410) She observed that “... the device itself isn’t super user-friendly,” adding that if her son “... were on his own and weren’t living with us or something it might be really hard for him ...” She hoped that the device would be “... more user friendly ... but that’s just feedback for ... whoever makes the device.” Despite this concern, she reflected, “Everybody has been so accommodating and patient and kind and explained everything really well ... I just think it’s been great—a fantastic experience.”

Another subject reported that the timing on their device was reversed during a blinded study withdrawal period, leading to difficulty sleeping at night. The team resolved this when it was reported. The subject recommended, “Well, make sure to set the device on the time—at the right time.” (P308)

Subjects and family members were also interested in having more control over device settings. One subject wanted it to be turned up, analogizing the device to a higher dose of medicine, “... just another thing she takes every day.” (P201) Her mother agreed, “In my opinion, you might want to ramp it up a tiny bit more. I think she can handle it.”

One subject thought that participants should have a role in determining their device’s settings. However, he thought that “... for the majority of patients it would probably be best just to stick them at whatever the model you guys have says and then just leave them there.” (P387) But he questioned whether “... Maybe you can give the patient some leeway and leniency to do as they please with the frequency. But I have no idea if the benefits will change or not. But it does give them some control.”



Some respondents had physical complaints related to the device. One subject reported feeling discomfort from the device and the wires, especially in cold weather. He felt that this was exacerbated by the superficial location of the hardware. He suggested that researchers inform future participants about this, adding, "I would be very surprised if it [this experience] was only me." (P308) His father recalled the subject "... suddenly getting [a] headache because the wires got cold." Another experienced discomfort from the device, "... when I turn my head to the left it feels like it's pulling, I'm not sure if it's the muscle, the tendons, or the actual wire. But I can't take my head all the way to the left and it's very frustrating. It causes ... a soreness down the side of my neck, I don't like it." (P378) One subject felt "a little bit like a cyborg" because he could feel the battery pack "sticking out of my chest a little bit." (P336)

Another parent noted that his son was unhappy about the scar to his scalp following surgery, telling us, "I think it was a bit of a surprise to him, discomfort, and maybe disappointment just in terms of I think where the wire [was] ... and because of the surgery scar ... there's a bump on his head and I know that makes him uncomfortable ... it changed his scalp." (P308) Another subject had unprompted concerns about how the device appears, "I mean the most negative thing is that I'm going bald, and these little horns in my head will probably show up at some point." (P378)

### Psychosocial Support

One of the paradoxes in brain injury recovery is that as individuals regain more function, they are prone to setbacks because of medical complications, psychological distress, or social structures that limit or impede their reentry back into society. Without adequate social support, frustration ensues, undermining forward progress. These setbacks are only possible because of an improvement in self-awareness, heretofore unavailable to the injured brain. For example, it is well appreciated that patients recovering from brain injury can become frustrated by greater insights into their disabilities, even as they are making functional gains and improving on neuropsychological metrics. This progress can lead to negative health behaviors if psychosocial support is not accessible and provided in a timely manner.<sup>29,30,31,32,33,34,35,36,37,38,39</sup>

We anticipate that these challenges may be heightened if recovery occurs suddenly, requiring a concurrent and precipitous reformulation of life goals. As but one example of many, the subject with improved cognitive abilities and new penchant for reading remarked that she needed "smarter friends." (P201) This comment belies the potential social dislocation of recovery following cognitive restoration that must be addressed to support and maximize societal reentry.

The paradox is profound: quality of life is at risk of deterioration *even as functional capability improves*. Without psychological support, regression can occur, as individuals may turn to risky behaviors and substance abuse. When this happens, individuals with the *biological* ability to resume more fully integrated lives may again become marginalized. Conversely, outcomes can be improved with the provision of social services and psychological support.<sup>40,41,42,43</sup>

Our respondents spoke to these compelling needs. Both subjects and family members wished that there had been psychological support embedded in the study to accommodate the life-altering effects of the intervention. In retrospect, it is fair to suggest that investigators should have anticipated this need, but it is important to recall that this was a Phase I study to assess toxicity and safety. We were in a state of equipoise; although we hoped that the intervention would have a therapeutic effect, it was important to be tempered in our expectations. The investigational nature of the study was clearly communicated in the consent process and understood by subjects and family members as noted previously.<sup>44</sup> Had we planned for a more salubrious effect, we risked therapeutic misconception.

But as the objective and subjective data have indicated, efficacy was demonstrated in our small sample across multiple domains. It should be noted that the narratives reflect changes over three months, a short period for an intervention envisioned as a chronic therapy.

Although this was a welcome achievement both scientifically and clinically, the effects on subjects and families were disruptive, albeit in a positive direction. Subjects and their families who were conditioned to the challenges of brain injury now had to reacclimate to lives they never expected after their injury.

This adjustment was further complicated by the accelerated pace of recovery. Progress that would take years, if made at all, occurred in a matter of months. This radically changed the lives of subjects and their families who were more accustomed to stasis than transformation. If the trial brought a new degree of wellness to the subjects, it also challenged them to reimagine old hopes and dreams and recast relationships.

Participating in this study was daunting because its effects were unprecedented. No one had previously used central thalamic stimulation in individuals with moderate to severe brain injury, so there was no established path for our subjects to follow. They had to navigate their future without the guidance of those who had been there before. To borrow a metaphor from Goering and Klein,<sup>45</sup> our subjects and their families were pioneers on an uncharted path without a guide.

Our respondents clearly indicated that they needed support as they encountered a *vita nuova*. One subject told us that it would be helpful to have neuropsychological or psychiatric support during the study, "... I do believe that had there been some kind of neuropsychologist on staff to have these discussions with on a more regular basis for the study, that would have been very beneficial." (P378) He thought, "It would be beneficial for the patient because the patient would be being listened to every single week ... [and] for the doctors 'cause now they're getting a medical interpretation of the psychological aspect of the device."

One mother told us, "... if I was designing this study, I'd like to have more emotional support in place. ... So, more support than just mom and dad." (P201) She recalled that the initial joy of regained capacities was followed by mourning of the many lost years. At the outset, "She [the subject] was bouncing around the house like she's 16 again. 'Hey, mom ... look, I can run. I can walk. I can jump. I can hang from ceiling' ... it was a real waking up of her body and her awareness of, 'my gosh, I really couldn't do this. I forgot I could do this. I forgot what it felt like to do this.'" And then "... it occurred to her what she'd lost. It occurred to her that 'I haven't been able to do this for 18 years' ... [then] depression, anger —'anger over what I couldn't have.' We had to walk through that. We had to talk through these are the things that have gone on."

The subject's mother said she would not change anything about the study except "... a clinician to answer questions for the family or guide them." She added, "We might need to have a psychotherapist who works with traumatic brain-injured individuals and families ... who understands the anger, the irritability, what to watch out for, and when to redirect."

Another subject thought that the team could have been more focused on the emotional impact of the study. He recalled that "... that I did have some depression issues, before, but for whatever reasons I'm definitely having depression issues, now. And I think it's more to do with, I don't know if it's due to the surgery, but I do think it's important that that's tracked ... I think that's important that that's done." He continued, "... But I did want to also mention that I'm very impressed with the team, and the doctors and I think that should be noted ... I felt sometimes like I was a test rat ... I still found a lot of affection for all the doctors ... I did feel their compassion for my situation, and that's really important." (P336)

Similarly, one subject reported her need for psychological support due to the aesthetic consequences of the surgery. She referred to herself as "the freak who had brain surgery," and said she was "... not feeling pretty. I knew that's psychological, too. If you feel pretty ... it's all mental. Looking pretty, feeling pretty ... That's psychological. I totally get it, that it was me. I needed some hair to feel good about myself ... Her mother confessed that, "The most traumatic event for [subject] was her hair. Just amazed me. I would not have guessed, but yes, that was a big deal." (P201)

Other respondents highlighted that the whole family required support. One mother referenced the subject's sibling: "I know that his brother was having a harder time adjusting to this. I mean, his brother is younger and so, to him I think [subject's] injury was in some way traumatic because pre-injury and post-injury for him was suddenly, like ... almost like a different person. And I think he really missed that." (P308).

Another parent suggested connecting families impacted by TBI, "... the only thing I think that might be helpful would be to meet more people like me in my situation. I know there's probably all sorts of groups, parents who have kids who have had brain injury and I just haven't really sought them out. So, if there are groups, knowing about them, and maybe kind of looking into them might be kind of good for

me I think.” (P410) On a related note, one respondent suggested that willing subjects and their families form “... a support group kind of thing ...” Consistent with privacy regulations she told us that “... I am open to anybody ... if they wanted to reach out to me, I am more than willing to speak to anybody.” (P378).

### Investigator and Societal Post-Trial Obligations

Drawing upon the seminal work of Henry S. Richardson on ancillary care obligations, does cognitive restoration impose a “moral entanglement,” obliging the provision of services that maximize the intervention’s benefits and minimize associated harms?<sup>46,47</sup> So improved, they are prompted to reframe life goals and objectives, as changes in their capabilities have made the *status quo* inadequate and perhaps unbearable.<sup>48</sup> How should society respond to and accommodate people who have received cognitive restoration?

Cognitive restoration imposes what might be considered a *positive accommodation* to respond to the subject’s newfound abilities. We often think of accommodations as *negative*, in response to a loss of capacity, like how a wheelchair and a sidewalk cutout provide access to the community for an individual with paraplegia. Here we break new conceptual ground in considering what positive accommodations might be required for individuals with TBI to return to the workplace or resume schooling after cognitive restoration. How can we assist these individuals as they reacclimate?

Although subjects and families were hopeful about the future, they were concerned about the sustainability of the intervention’s benefit. Would it cease to be the miracle that it seemed to be? More pragmatically, they were worried about device maintenance, long-term effects of implantation, and simple battery replacement. Respondents shared their uncertainty about the future, with one family member wondering “... how much support or what’s going to happen with him [the subject] at the end of this study ...” (P336) Another family member worried, “I don’t know what’s going to happen down the road ... I’m always worried about the repercussions of foreign objects in your body ... if you wanted to take that out, what does that entail ... how long is this good for? Does this device stay as it is for the rest of his life? ... what happens down the road if these doctors aren’t around anymore ... Who does he turn to?” (P378) Pointedly, she felt her son was owed “... accessibility. If he needs to contact somebody; if he needs to be in touch with the doctor for anything medical that may come up ...”

One subject worried about the device’s settings and if it would be “cycling right.” But her major concern was, “I’m just like, how do I change the battery? That’s the only thing I’ve ever worried about.” (P201) Another subject worried about device maintenance in the event of “battery breaches” or relocating away from the support offered by Stanford. (P308) His parent feared that the device might be removed after the trial’s conclusion, asserting that, “I think he [the subject] definitely would rather not have it removed given how it’s helped him.”

Insurance coverage for experimental devices was a pragmatic and normative concern for respondents. One mother worried about the “prohibitive” costs of battery replacement and suggested “shared responsibility” for maintenance and/or removal of a device between families and researchers. (P410) Another parent reported that it was important for their child “to have the device long term, as well as having medical coverage to support that long term” and stated concerns regarding access, “because in the next couple of years he’s gonna be off of our medical coverage and [his injury] ... delayed his ability to develop his own career.” (P308) Without insurance, this parent worried that the device would be hard to “maintain it even if it is approved [as] a routine device.” But the situation is even more challenging because the device is still investigational and approval “can still be years out.” Plaintively, he told us, “... I’d rather not have him go back to his pre-implant state simply because of bureaucracy around whether somebody will pay for it or not.”

He did not distinguish insurance coverage for experimental versus proven treatments because of the benefit his son has already experienced, “... if he has medical insurance ... it should be covered ... if somebody has a hip transplant, they have ongoing care related to that [and] that should be part of their medical coverage ... I feel that this is the same thing.” He then analogized the device to its cardiac

counterpart, “I guess the closest along that line would be a pacemaker, right? I mean, it’s not just about putting it in. There’s obviously long-term support and maintenance to keep it functioning and working properly and that currently is covered ‘cause it’s approved. In his case the challenge is because it’s not approved ... would it be covered? Forget that it’s showing to be clearly effective for him. I would like to see that even if it’s an exception to be allowed.”

When asked if he thought that his son was entitled to the device before it was approved, he provided a moral cost–benefit analysis: “... from an insurance perspective they’re thinking cost, right, but in terms of his ability to advance and develop [his] career and become a taxpayer I think that would make this worth maintaining for him ... I have to think about for him. I think about it for others as well, right? I mean, obviously things that can help people become contributors in society, in various ways, in many ways justifies the cost of helping them get there ... as opposed to telling somebody, until you’re contributing you shouldn’t get access to these benefits I would rather we try to get them to a state where they are able to participate and contribute. And so, in his case ... I would prefer that from a medical ethics [perspective], given that it clearly is a benefit to him that [the device] be maintained and supported.”

One subject extemporaneously did a cost–benefit analysis of battery replacement, “I hope it’s covered by insurance ... otherwise I don’t understand why the government is not giving me disability insurance or something. Like either cover my medical expenses or cover the disability, pick one.” (P378) He elaborated with actual figures, “With the battery replaced I could make more than disability gives. Disability I think like the high end is \$1,200 a month. And you can’t have more than like \$2,000 in savings unless you go through some obscure process. Then you can have \$99,000 in savings, but I mean \$1,200 a month is the max income that I have seen. It might be higher now. I don’t know, but I mean with 15 bucks an hour at 20 hours a week that’s 300 bucks a week, times four is 1,200 bucks a month. I can do that, that’s not difficult.”

Beyond cost, he recounted the benefits of working: “Plus it kills time, gives me something to do. I’d rather have the job for 20 hours a week than collect ... disability insurance.” When asked about the dignity of work, he replied affirmatively, noting, “yeah, the social aspect is also needed, sitting home alone all day is boring. I mean there are so many reasons to go out and get a job and do something.”

Regarding broader research policy, one parent felt that longitudinal coverage should be considered in federal research funding. He explained that posttrial obligations are “... an ongoing thing with many research teams within NIH.” He added, “... that for these people that [if] it helps that should be factored into their [the NIH’s] overall funding process ... it’s not just about the duration of the study and then suddenly it doesn’t exist anymore ... these are real people and if it helps them ... continuing that for their quality of life, that should be part of their plan.” (P308)

The subject’s mother referenced the ethical obligations specific to an implanted device, “... it’s not a medication that you can just continue and then you guys are gone, right? ... his body is changed forever because of this device, so not supporting it is not the same as not approving a medication and then just not making it available anymore. And I think that that’s worth consideration.” Even though the study’s neurosurgeon volunteered follow-up care aside from battery replacement, she reminded us that the device is “... something that physically changed his body” and its presence is not “simply an inconvenience to him,” even if it’s not turned on.

### Disabilities, Capabilities, and the Law

When we think about brain injury, we think about disability, but our results suggest that we need to reform our thinking and envision a therapy that transforms *disability* to *new abilities*. It is a radical proposition that upends presuppositions about the immutability of brain injury and how society categorizes this population. Our study demonstrates that CT-DBS improves cognition, relationality, emotional control, and a general ability to be in the world.

One subject said it best, “When I’m talking about how I am now compared to how I was, I am still disabled. I’m disabled with old abilities is what I would say, but new abilities, same thing. Yeah, so I’d say I’m disabled with new abilities.” He confessed: he does not know how these abilities will affect his life, “... I haven’t really been able to test out how disabled I am, so I mean I might not be as disabled as I was. I

might be in a place where I can do more than some and less than others.” He modestly concludes, “I think that’s called average ...” (P378) He perceives himself as squarely in the middle, *with liabilities compensated by new capabilities*.

Disability is also a matter of how one is perceived by others. One mother relayed her newfound awareness of how others viewed her son, “I have a friend who I don’t see that often ... she came over to dinner ... and then after the dinner she called me, and she said she wanted to introduce [my son] to one of her friends ... since his injury I’ve never had anybody want to set him up with someone. She was describing this girl and she sounds really cute and really interesting ... so I thought, hum, that’s interesting that someone sees him as wanting to set him up with an able-bodied person, not with someone with disabilities and that was new also. ... since his injury that has never happened. So, to me that sort of opened my eyes. Like, I was thinking, wait, am I seeing him then as somebody who has disabilities and other people are seeing him as somebody who doesn’t have a disability?” (P410)

These passages presage how society should think about disability and new abilities evoked by emerging technologies. Although technological transformation does not eliminate the stigmata of injury, it changes the terrain as new abilities compensate for seemingly immutable disabilities. This possibility should inform our collective response to novel technologies like CT-DBS and other interventions catalyzed by the BRAIN Initiative.

Given the centrality of the Americans with Disabilities Act (ADA)<sup>49</sup> and the UN Convention on the Rights of People with Disabilities,<sup>50</sup> the law becomes a natural locus for recalibrating our understanding of disability in light of positively disruptive neurotechnologies. The ADA and the UN Convention have as their central mandate the societal reintegration of people with disabilities. The ADA requires that reasonable accommodations be made, so people can “live in the most integrated setting appropriate to the needs of the individual.”<sup>51</sup> The success of cognitive restoration changes expectations for community integration and society’s response.

Unlike prior therapeutic efforts, emerging technologies like CT-DBS have the power to foster human flourishing by promoting capabilities as described by Martha Nussbaum<sup>52</sup> and Amartya Sen.<sup>53</sup> Inspired by these narratives, we have invoked their approach to reimagine disability law that considers new capabilities catalyzed by neurotechnology. To that end we have advanced the concept of an *Americans with Abilities Act* (AWAA).<sup>54-55</sup> The AWAA would supplement the rights-based approach of the ADA by realizing novel opportunities for societal integration enabled by technological advance.

The need for an AWAA is a byproduct of scientific success. Paradoxically, our subjects’ improvement brings new challenges. To gain societal reintegration, subjects and their families need to reformulate life goals and find receptive educational and vocational venues to realize newfound capabilities. They require psychosocial and emotional support to sustain their journey. Critically, they need continued access to, and support of, the technology that has transformed their lives and broadened their possibilities. Technological innovation is necessary but not sufficient to fully realize their potential.

Failing to support those who have benefited from scientific progress is an iatrogenic, missed opportunity to realize the fruits of neuroscience. Scientific advance must be accompanied by correlative social change. The lived experience of our subjects and their families make a compelling case for the robust reintegration of the cognitively restored individual into civil society. There is an ethical obligation to complete the task. As we seek to change the biology of the injured brain through neuromodulation, we must also modulate the social context within which this remarkable progress occurs.

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**Competing Interest.** The following authors are listed inventors on a patent application (jointly filed by Weill Cornell Medicine, University of Utah, and Stanford University) describing detailed methods of integrating magnetic resonance imaging, biophysical modeling and electrophysiological methods for localization and placement of deep brain stimulation electrodes in the CL/DTm of the human thalamus as described reference 2, Schiff ND et al.: Nicholas Schiff and Jaimie Henderson.

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22. All interviews are denoted as [P###] when quoting a subject or family member dyad/triad. Names and some content have been redacted to ensure privacy and maintain confidentiality.
23. Subject correlation with Schiff N. et al. (see [note 2](#)); P201 = P1; P336 = P3; P308 = P4; P378 = P5; P410 = P6.

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