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CLINICAL ARTICLE

Safety, feasibility, and outcomes of deep brain stimulation in young children excluded from the FDA Humanitarian Device Exemption: analysis of the CHILD-DBS registry

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OBJECTIVE In the US, deep brain stimulation (DBS) is accessible to pediatric patients with dystonia who are 7 years of age and older through an FDA Humanitarian Device Exemption (HDE). The aim of this study was to assess the safety, feasibility, and outcomes of DBS for dystonia in children younger than 7 years of age who are excluded from the FDA HDE.

METHODS Data were collected (February 2015–December 2025) through The Child & Youth Comprehensive Longitudinal Database for DBS, which is a prospective registry of pediatric DBS from 5 tertiary pediatric hospitals in North America. Participants younger than 7 years of age who underwent DBS targeting the globus pallidus internus for the treatment of dystonia were included. Demographics, operative details, and postoperative outcomes and complications were analyzed.

RESULTS Twelve children underwent 14 DBS-related surgeries, with a mean follow-up duration of 2.66 years (range 0.50–10.85 years). The mean age at the time of surgery was 4.72 years (range 2.96–6.83 years), and the mean weight was 16.5 kg (range 9.3–30.8 kg). Half of the children had prior ICU admissions for status dystonicus, and 9 DBS surgeries (64.3%) were performed urgently. Three children had transgression of stereotactic frame pins beyond the inner table of the skull, while 4 other children had wound complications requiring surgical intervention. No patients experienced neurological sequelae, and those requiring explantation of infected hardware were reimplanted successfully once the infections were treated. Overall, there was a mean reduction of 40.1% in the Burke-Fahn-Marsden movement subscale

ABBREVIATIONS BFMDRS = Burke-Fahn-Marsden Dystonia Rating Scale; BFMDRS-D = BFMDRS disability subscale; BFMDRS-M = BFMDRS movement subscale; CHILD-DBS = The Child & Youth Comprehensive Longitudinal Database for DBS; DBS = deep brain stimulation; FGATIR = fast gray matter acquisition T1-weighted inversion recovery; GPi = globus pallidus internus; HDE = Humanitarian Device Exemption; IPG = implantable pulse generator; LOS = length of stay; MER = microelectrode recording; MSSA = methicillin-sensitive *Staphylococcus aureus*; PKAN = pantothenate kinase–associated neurodegeneration; SCA28 = spinocerebellar ataxia type 28.

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at 6 months postoperatively ($p < 0.05$), which persisted to 12 months. Three children died due to underlying conditions > 6 months from their respective surgeries.

CONCLUSIONS DBS had demonstrable benefits in children younger than 7 years of age with severe refractory dystonia, albeit with higher surgical risks compared with older children. Further research is warranted to better inform treatment decisions and regulatory oversight.

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KEYWORDS deep brain stimulation; pediatric neurosurgery; movement disorders; surgical complications; medical device regulation; functional neurosurgery

Dystonia is the most common pediatric movement disorder, characterized by sustained or intermittent abnormal movements and/or postures.[1,2] Children with refractory dystonia might be candidates for deep brain stimulation (DBS) to improve disease control and quality of life, and reverse life-threatening status dystonicus; however, widespread adoption remains limited.[2–8]

In the US, DBS is accessible to children with dystonia through an FDA Humanitarian Device Exemption (HDE).[9] The HDE pathway facilitates access to medical devices for populations that are too small (≤ 8000 affected individuals per year in the US) or too vulnerable to generate high-quality evidence of safety and efficacy. It is based on the premise that probable benefits outweigh the risks based on similar use in other populations.[9,10]

The original 2003 HDE approval for Activa RC neurostimulator (Medtronic) states that the device is indicated for chronic, refractory primary dystonia in patients 7 years of age or older.[11] This age threshold reflects the youngest patients in which evidence was available at the time,[12–14] as well as a precautionary regulatory stance related to technical and anatomical concerns in younger children. This age threshold has been upheld in subsequent reviews up to the current year, given the paucity of efficacy and safety data from younger children.[15] Studies have reported higher DBS-related complication rates in children compared with adults, with younger age ostensibly carrying greater risk.[16–21] In recent years, advances in next-generation sequencing have allowed for earlier recognition of children with genetic dystonias that respond to DBS.[22] Furthermore, emerging evidence supports the role for DBS earlier in the disease process to optimize developmental potential and outcomes.[3,23,24] Collectively, this underscores the need to better understand the role of DBS in young children.

To our knowledge, no prospective studies have been conducted with a focus on children younger than 7 years of age undergoing DBS. Therefore, we aimed to assess the safety, feasibility, and outcomes of DBS for dystonia in children younger than 7 years of age who are excluded from the FDA HDE by analyzing data from a multicenter prospective registry, The Child & Youth Comprehensive Longitudinal Database for DBS (CHILD-DBS). This registry has enrolled more than 130 participants aged < 18 years from Canada and the US.[25]

Methods

Participants

The study was approved by the ethics boards at each participating site. Informed consent was provided by the families of all participants. With the exception of two children who were added retrospectively (patients 11 and 12), all participants were enrolled prospectively between February 2015 and December 2025 in CHILD-DBS,[25] a North American registry that includes 5 tertiary pediatric hospitals: The Hospital for Sick Children (Toronto, Canada), Boston Children's Hospital (Boston, MA), Texas Children's Hospital (Houston, TX), Ann & Robert H. Lurie Children's Hospital of Chicago (Chicago, IL), and Le Centre Hospitalier Universitaire Sainte-Justine (Montréal, Canada).

All participants were referred to a CHILD-DBS center for consideration of DBS surgery to treat severe refractory dystonia. Participants were deemed appropriate to undergo DBS based on review by multidisciplinary movement disorder programs at each site. In general, offering DBS at a younger age (i.e., outside of the FDA HDE) is a decision largely driven by the underlying disease burden and often in the context of refractory status dystonicus or severe and progressive functional impairment that limits quality of life. All participants were < 7 years of age at the time of surgery.

Surgery

DBS surgeries were performed by experienced pediatric neurosurgeons in a standardized fashion under general anesthesia. In brief, all children received prophylactic intravenous antibiotics within 60 minutes prior to skin incision. All participants underwent bilateral implantation of DBS electrodes into the globus pallidus internus (GPi) under frame-based (Leksell, Elekta) stereotactic guidance, using direct anatomical targeting. All children were implanted with directional leads (SenSight, Medtronic) and implantable pulse generators (IPGs; Percept PC, Medtronic). The IPGs were inserted in a subclavicular (chest) or subcostal (abdomen) pocket, depending on body habitus. All participants underwent postoperative imaging to confirm electrode placement.

Data Extraction

Demographic variables include age, weight, and head circumference at surgery, etiology of dystonia, history of hospital admissions due to dystonia, and comorbidities. Skull thickness was measured at the bregma and at each pin site on CT obtained in the stereotactic frame. Surgical variables included the DBS target, use of intraoperative microelectrode recording (MER), laterality of lead placement, the number of procedural stages (single- or dual-stage), IPG location, use of prophylactic antibiotics, urgency of surgery (and indication), and the length of stay

(LOS) from admission to surgery. Urgent surgery was defined as procedures performed within 2 weeks of the decision to proceed with DBS.

Complications

Complications data were collected, including infection, intracranial injury (hemorrhage), electrode malposition, hardware malfunction, dehiscence/seroma, and others. The timing of complications was divided into perioperative, early postoperative (≤ 6 months), and late postoperative (> 6 months) periods. A major wound complication was defined as any wound complication requiring hardware removal, and a minor wound complication was any other wound-related complication not requiring hardware removal.

Clinical Outcomes and Quality of Life

Clinical outcomes were prospectively evaluated at baseline and 6 and 12 months following DBS surgery using the Burke-Fahn-Marsden Dystonia Rating Scale (BFMDRS), a widely used tool for the assessment of dystonia in children and adults.[26] The BFMDRS movement subscale (BFMDRS-M) measures the severity of dystonia in 9 body regions (score range 0–120, higher scores represent greater severity), while the disability subscale (BFMDRS-D) assesses the parent- or self-reported ability to perform daily activities (score range 0–30).[26] The results were presented as raw scores and the percent change from baseline. A clinically significant change was defined as > 20%.[3]

KIDSCREEN-27 questionnaires were answered by caregivers at baseline and 6 and 12 months following DBS surgery and were used to index changes in quality of life. This measure has been validated in children 2–7 years of age with chronic physical illness[27] and encompasses the following 5 dimensions: physical well-being (5 items; score range 5–23, with higher scores representing better quality of life), psychological well-being (7 items, score range 7–35), parent relations and autonomy (7 items, score range 7–35), social support and peers (4 items, score range 4–20), and school environment (4 items, score range 4–20).

Statistical Analysis

Descriptive statistics are presented as means ± standard deviations with ranges. Mixed-effects models were used to assess the effect of time from DBS on raw and percent change scores of the BFMDRS-M, BFMDRS-D, and KIDSCREEN-27, with time as the fixed effect and subject and residual as random effects. All statistical analyses were performed using Prism (version 11.0.2, GraphPad Software), with $p < 0.05$ considered as statistically significant.

Results

Participant Demographics

Between February 2015 and December 2025, 12 participants (6 male and 6 female) underwent initial DBS implantation, two of whom underwent a single revision (total of 14 surgeries) (Table 1 and Fig. 1A–C). The mean age and weight at the time of the procedures were 4.72 years (range 2.96–6.83 years) and 16.5 kg (range 9.3–30.8 kg). The mean head circumferences was 48.1 cm (range 44.0–52.0 cm, n = 9), with 6 of 9 measurements below the 3rd percentile for age and sex. The mean skull thickness at the bregma was 3.3 mm (range 1.8–5.0 mm, n = 9). Most children were medically complex with multisystem sequelae. The most common comorbidities were global developmental delay (n = 9, 75.0%), gastrostomy feeding (n = 7, 58.3%), and epilepsy (n = 3, 25.0%). One child was immunocompromised. The mean follow-up duration was 2.66 years (range 0.50–10.85 years).

Five children (41.7%) underwent DBS due to a monogenic etiology of dystonia (*TOR1A*, *GNAO1*, *EIF2AK2*, *KMT2B*, and *ADCY5* variants). Five other children (41.7%) had genetic dystonia with CNS pathology related to Lesch-Nyhan syndrome, early infantile developmental epileptic encephalopathy due to *SCN2A*, pantothenate kinase–associated neurodegeneration (PKAN), or spinocerebellar ataxia type 28 (SCA28). One participant was treated for acquired dystonia, and another for idiopathic dystonia for which history and extensive genetic studies did not yield a cause (Fig. 1D).

All children had severe refractory generalized dystonia. Half required ICU admission for dystonia at some point prior to DBS. Urgent DBS surgery was performed in 9 of 14 cases (64.3%) due to status dystonicus (n = 8) or rapid functional regression (n = 1) (Table 2 and Fig. 1E and F). The mean preoperative hospital LOS was 17.5 days (range 0–46 days, n = 12 cases).

Surgical Details

For all procedures, 3D T1-weighted MRI was used for direct targeting of the bilateral GPi (Fig. 2). For the 4 most recent participants, a fast gray matter acquisition T1-weighted inversion recovery (FGATIR) sequence was aquired.[28] Target coordinates were available for 10 participants, with mean distances from the midcommissural point of x = ±17.48 mm (range 16.50–20.00 mm), y = +0.28 mm (range −4.50 to 3.00 mm), and z = +2.46 mm (range 1.00–5.00 mm).

MERs were performed under general anesthesia (comprised of propofol and remifentanil infusions) in the 3 most recent cases, resulting in minor (1- to 2-mm) target adjustments along the same trajectory (Table 2). The IPG was placed in a subclavicular pocket in 8 of 14 cases (57.1%) and in a subcostal pocket in 6 cases (42.9%). One participant (patient 5) who previously had the IPG placed in the abdomen received an IPG in the chest during revision. All procedures were single-staged. Perioperative antibiotic prophylaxis varied, with the most common regimen being topical vancomycin powder with intravenous cefazolin, followed by oral cephalexin (71.4%, n = 10). Alternative regimens included vancomycin alone, or different combinations of piperacillin/tazobactam, cefazolin, cephalexin, vancomycin, and trimethoprim/sulfamethoxazole.

Complications

Complications, including pin-site injuries, major wound

TABLE 1. Characteristics of 12 patients who underwent 14 DBS surgeries targeting the GPi for the treatment of dystonia

Pt No.	Sex, Age (yrs)	Weight (kg)	HC (cm), Percentile	Skull Thickness (mm)	FU, yrs	Etiology	Etiology Details	Prior ICU Visit	Comorbidities
1	F, 2.96	9.3	46.0, 2.3	1.8	0.61	Genetic w/o CNS pathology	*GNAO1* variant	Yes	GDD, epilepsy, GJ-tube, respiratory, hip dysplasia, endocrine
2	F, 3.34	14.1	49.0, 40.7	2.0	0.50	Genetic w/ CNS pathology	Lesch-Nyhan syndrome	No	GDD, G-tube, SIB, urological
3	F, 3.35	12.5	44.0, 0.1	2.8	1.79	Genetic w/ CNS pathology	Early infantile developmental epileptic encephalopathy, *SCN2A*	Yes	GDD, epilepsy, visual impairment, hepatic, endocrine, hematological
4	M, 3.66	14.6	44.0, 0	2.8	1.21	Acquired	Kernicterus	Yes	Prematurity, CP, G-tube, hearing & visual impairment, respiratory, metabolic, hematological
5	M, 4.36	14.5	NA	3.8	1.94	Genetic w/ CNS pathology	PKAN	Yes	GDD, G-tube, hematological
5*	M, 5.38	17.3	50.5, 11.3	NA	0.92				
6	F, 4.39	14.9	47.5, 5.0	4.0	2.45	Genetic w/ CNS pathology	*SCA28*, *AFG3L2* variant	No	GDD, G-tube, visual impairment, GI, hip dysplasia, hematological
7	M, 4.88	16.1	49.5, 6.3	3.3	2.76	Idiopathic	Abnormal brain MRI, negative genetic studies	No	GDD, epilepsy, G-tube
7†	M, 5.39	16.2	49.5, 4.1	3.5	2.25				
8	M, 5.41	16.2	47.5, 0.3	3.8	0.72	Genetic w/o CNS pathology	*EIF2AK2* variant	No	Urological
9	M, 5.99	18.3	49.0, 2.3	3.7	2.65	Genetic w/o CNS pathology	*KMT2B* variant	No	GDD
10	F, 6.65	21.1	52.0, 43.4	5.0	0.75	Genetic w/ CNS pathology	PKAN	Yes	GDD, visual impairment, immunocompromised
11	M, 3.49	14.6	NA	NA	10.85	Genetic w/o CNS pathology	*ADCY5* variant	NA	GDD, G-tube
12	F, 6.83	30.8	NA	NA	7.90	Genetic w/o CNS pathology	*TOR1A* variant	NA	None

CP = cerebral palsy; FU = follow-up; GDD = global developmental delay; GI = gastrointestinal; GJ-tube = gastrojejunostomy tube; G-tube = gastrostomy tube; HC = head circumference; NA = not available; pt = patient; SIB = self-injurious behavior.
* Redo insertion IPG and extension leads only.
† Redo insertion of the entire DBS system.

complications, and minor wound complications, occurred in 8 of 12 participants (66.7%) and 9 of 14 surgeries (64.3%) (Fig. 3 and Table 3).

Perioperatively, stereotactic frame pin-site injuries occurred in 3 of 14 cases (21.4%), with inner table breach at the unilateral or bilateral posterior pin sites (Fig. 1G). None led to intracranial injury or affected the subsequent procedure. We observed that skull thickness increased with age, and a breach occurred at the sites where the underlying skull thickness was < 1.8 mm (Fig. 1H and I). Specifically, this included the 2 youngest participants who had bilateral posterior pin-site breaches and an older participant who had a unilateral posterior pin-site breach over an area of skull that was < 1.8 mm. There were no other intraoperative complications, including hemorrhages or lead malposition.

Postoperatively, 4 participants (33.3%; 4/14 cases, 28.6%) experienced major wound complications requiring hardware removal. Two participants developed infections at the chest IPG site and scalp on postoperative days 20 and 64, respectively. For the first participant (patient 7), methicillin-sensitive *Staphylococcus aureus* (MSSA) and coagulase-negative Staphylococci were cultured. For the second participant (patient 12), MSSA and *Cutibacterium acnes* were identified. A third participant (patient 10) presented close to 9 months postoperatively with wound dehiscence at the chest IPG site and subcutaneous MSSA infection in the pocket, along the extension leads (tunneled on the right side), and above the right burr hole. Of note, this child had recurrent seroma at the IPG site earlier in the course and was immunocompromised. The fourth participant (patient 5) had an atypical presentation nearly 10 months after surgery, with skin erosion at the abdominal IPG site resulting in exposed hardware and turbid drainage. This was initially presumed to be an infection based on the appearance of phlegmonous tissue and mild leukocytosis and was managed with hardware removal and empirical antibiotics; however, no organisms were cultured, and the final pathology revealed granulomatous tissue. Three participants underwent successful reimplantation.

Minor wound complications occurred in 4 participants (33.3%; 4/14 cases, 28.6%) within 4 months from surgery,

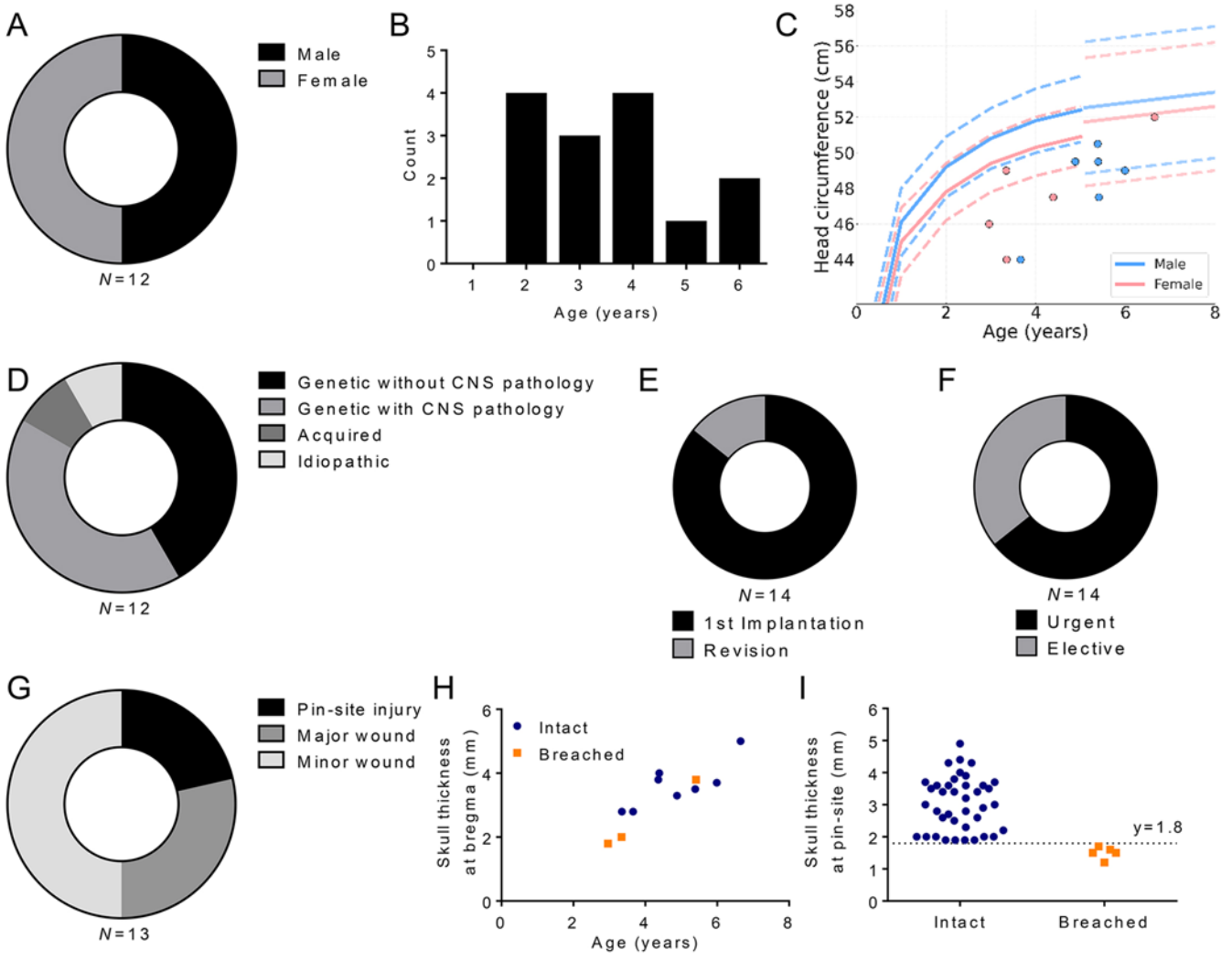

FIG. 1. Participant demographics, surgical details, and complications. **A:** Donut chart showing sex distribution. **B:** Bar graph showing age distribution. **C:** Graph showing head circumference plotted on the WHO chart (age ≤ 5 years) or Nellhaus chart (age > 5 years). The *middle solid line* represents the 50th percentile, and *dotted lines* above and below represent the 97th and 3rd percentiles, respectively. **D–G:** Donut charts showing dystonia etiology (D), first implantation versus revision (E), urgency of surgery (F), and type of complications (G). **H:** Graph showing skull thickness by age. **I:** Graph showing skull thickness at cranial pin insertion sites.

including wound dehiscence (n = 1), seroma (n = 2), and local erythema at the incision site (n = 2). The wound dehiscence at the scalp occurred 4 days following repeat DBS implantation (patient 7) and was managed with suture replacement and prophylactic oral antibiotics. One participant (patient 10) had recurrent and eventually resolved seroma at the chest IPG site during the early postoperative period, but developed an infection in the late postoperative period as described above. Another participant (patient 1) developed seromas at the infracostal IPG site and scalp, but did not require further intervention. Finally, wound redness or crusting at the scalp or chest incision without other signs or symptoms of infection occurred in two participants. These were treated with a precautionary course of oral antibiotics and resolved with no sequelae.

No permanent neurological deficits or death occurred in the perioperative period. There were no hardware issues, including malfunction, lead migration, or fracture.

Clinical Outcomes

Nine participants had at least 1 follow-up BFMDRS assessment at 6 months and/or 12 months. Two participants did not have a follow-up BFMDRS assessment, and one participant died prior to follow-up. Baseline BFMDRS-M scores varied, with a mean of 73.7 ± 20.1 (range 51.5–104.0, n = 9) (Fig. 4). Six months after DBS, 6 of 8 children showed clinically meaningful improvement (range 31.7%–79.6% vs baseline), while the score worsened in one child by 25.2% and another by 3.2%, resulting in an overall mean improvement of 40.1% ± 37.7% at 6 months (vs baseline, $p < 0.05$; n = 8), which was clinically and statistically significant. These improvements were main-

TABLE 2. Surgical details

Pt No.	Urgent Op	Reason for Urgent Op	Preop LOS (days)	Target	Intraop MER	IPG Location	Periop Antibiotics
1	Yes	SDys	38	Bilat GPi	Yes	Abdomen	VP, CFZ, cephalexin
2	No	—	5	Bilat GPi	No	Abdomen	VP, CFZ, cephalexin
3	Yes	SDys	30	Bilat GPi	No	Chest	VP, CFZ, cephalexin
4	Yes	SDys	16	Bilat GPi	No	Abdomen	VP, CFZ, cephalexin
5	Yes	SDys	37	Bilat GPi	No	Abdomen	VP, CFZ, cephalexin
5*	No	—	0	Bilat GPi	No	Chest	VP, CFZ, cephalexin
6	Yes	SDys	46	Bilat GPi	No	Chest	VP, CFZ, cephalexin
7	No	—	0	Bilat GPi	No	Chest	VP, CFZ, cephalexin
7†	No	—	1	Bilat GPi	No	Chest	VP, vancomycin, cephalexin
8	Yes	SDys	23	Bilat GPi	Yes	Chest	VP, CFZ, cephalexin
9	Yes	RFR	0	Bilat GPi	No	Chest	VP, CFZ, cephalexin
10	Yes	SDys	14	Bilat GPi	Yes	Chest	VP, vancomycin, TMP/SMX
11	No	—	NA	Bilat GPi	No	Abdomen	Vancomycin
12	Yes	SDys	NA	Bilat GPi	No	Abdomen	PIP/TAZ, CFZ, vancomycin

CFZ = cefazolin; PIP/TAZ = piperacillin/tazobactam; RFR = rapid functional regression; SDys = status dystonicus; TMP/SMX = trimethoprim/sulfamethoxazole; VP = vancomycin powder.
All surgeries were performed in a single stage.
* Redo insertion IPG and extension leads only.
† Redo insertion of the entire DBS system.

tained at 12 months (mean 51.3% ± 44.8%, n = 6). An additional child with missing data at 6 months showed 100% improvement at 12 months.

There were no significant changes in the mean BFMDRS-D scores across follow-up (baseline: 26.6 ± 4.5 [range 17.0–30.0], n = 9; 6 months: 24.9 ± 7.6 [range 10.0–30.0], n = 8; 12 months: 26.8 ± 6.4 [range 14.0–30.0], n = 6). At the individual level, those with severe disability at baseline (BFMDRS-D scores 27–30) showed no or minimal change following DBS (range –13.3% to +11.1% at 6 months and –10.0% to +7.14% at 12 months), while those with less severe baseline disability (BFMDRS-D cores 17 and 21) showed a reduction of 41.2% and 23.8% at 6 months, respectively, and 33.3% at 12 months for the latter.

In addition, all 8 children who underwent urgent DBS surgery for refractory status dystonicus had resolution of status dystonicus and were discharged from the hospital.

Quality of Life

Quality of life assessments were available in 10 of 12 participants at baseline, 7 of 12 at 6 months, and 5 of 12 at 12 months. Baseline scores for the physical well-being subscale were low in most children, with a mean of 7.1 ± 2.0 (range 5–12) (Fig. 5). Baseline scores for the psycho-

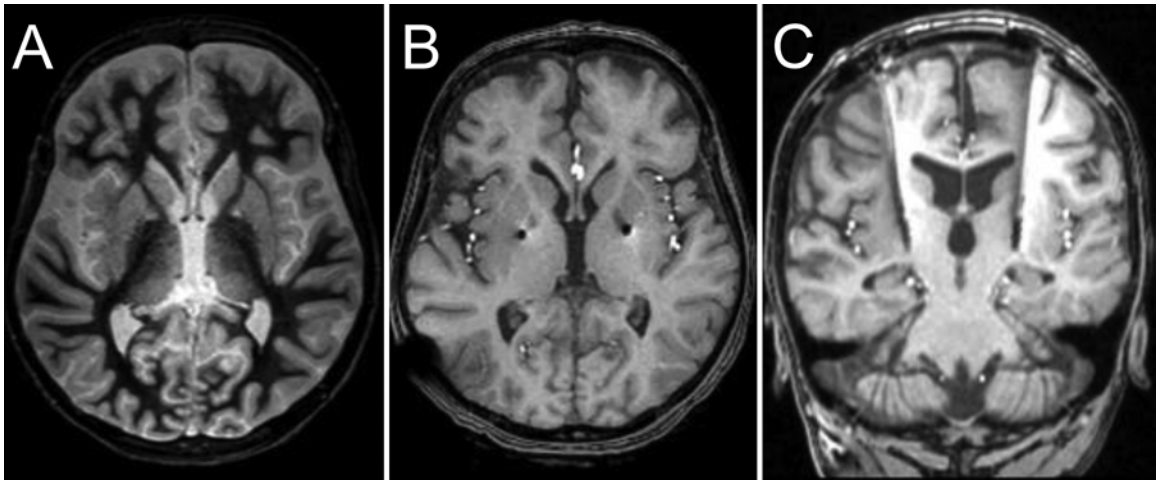

FIG. 2. Representative MRI. **A:** Preoperative axial FGATIR image at the level of the GPi. **B and C:** Postoperative axial (B) and coronal (C) MR images demonstrating DBS lead placement in the bilateral GPi.

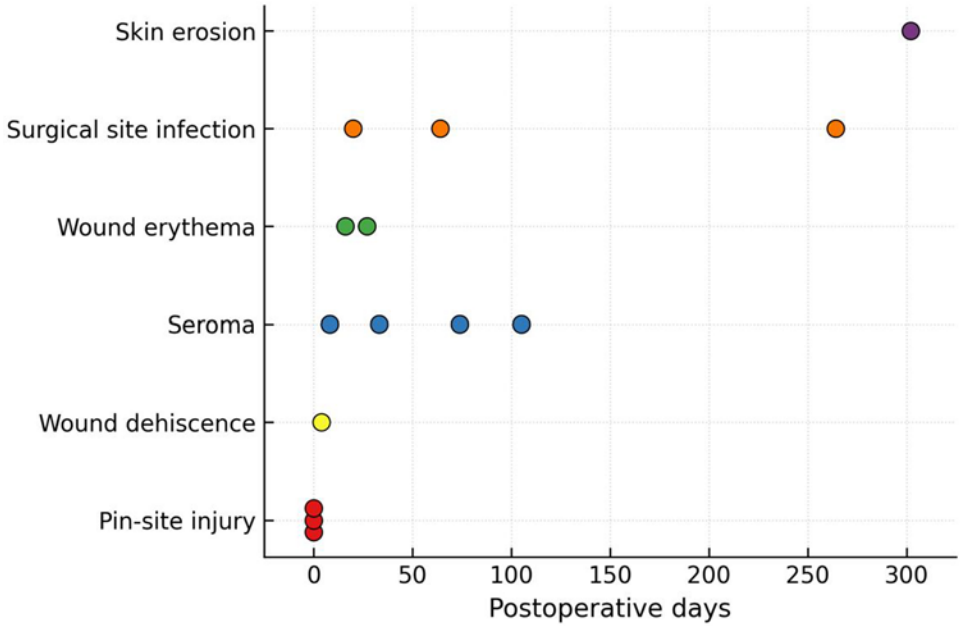

FIG. 3. Graph showing complications over time. Three cases of pin-site injury occurred perioperatively. Most wound complications occurred in the early postoperative period (≤ 6 months). One case each of surgical site infection and skin erosion presented in the late postoperative period (> 6 months).

TABLE 3. Complications

Pt No.	Complication	Timing (days)	Details	Microbiology &/or Pathology	Intervention	
					Surgical	Medical
1	Pin-site injury	Intraop	Inner table breach at bilat posterior pin sites w/o intracranial injury		None	None
	Seroma	8	Swelling over the abdominal IPG site		None	None
	Wound erythema	27	Erythema & crusting of scalp incision		None	Oral abx
	Seroma	74	Fluctuating scalp swelling over burr holes w/o drainage		None	None
2	Pin-site injury	Intraop	Inner table breach at bilat posterior pin sites w/o intracranial injury		None	None
3	None	—	—	—	—	—
4	None	—	—	—	—	—
5	Skin erosion	302	Exposed abdominal IPG w/ skin erythema, pain & swelling, mild leukocytosis	None isolated, granuloma	Removal of IPG & extension leads	Oral abx
5*	None	—	—	—	—	—
6	None	—	—	—	—	—
7	SSI	20	Erythema & tenderness at chest IPG site	MSSA, CoNS	Removal of entire DBS system	IV abx
7†	Wound dehiscence	4	Scalp incision dehiscence & suture breakage		Suture placement	Oral abx
8	Pin-site injury	Intraop	Inner table breach at lt posterior pin site w/o intracranial injury		None	None
9	Wound erythema	16	Erythema at chest incision w/o other symptoms or signs of infection		None	Oral abx
10	Seroma	33, 105	Recurrent swelling over chest IPG site		None	None‡
	SSI	264	Dehiscence & purulent discharge from chest IPG site, erythema & swelling along lead tract & right scalp incision	MSSA	Removal of entire DBS system	IV abx
11	None	—	—	—	—	—
12	SSI	64	Dehiscence & drainage from scalp incision	MSSA, *C. acnes*	Removal of IPG & extension leads	IV abx

abx = antibiotics; *C. acnes* = *Cutibacterium acnes*; CoNS = coagulase-negative Staphylococci; IV = intravenous; SSI = surgical site infection.
* Redo insertion IPG and extension leads only.
† Redo insertion of the entire DBS system.
‡ Received IV antibiotic treatment for transient MSSA bacteremia 1 month postoperatively.

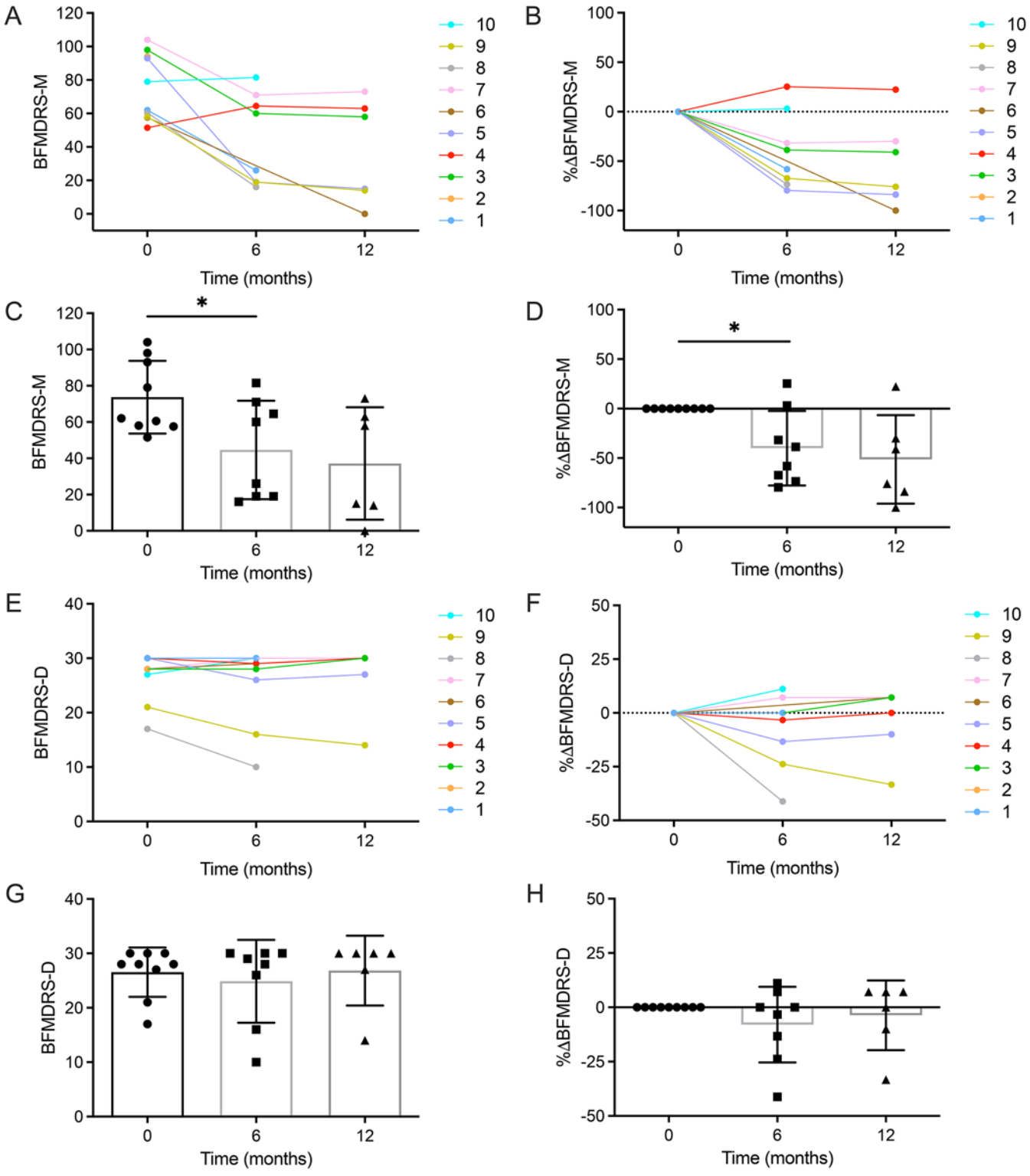

FIG. 4. BFMDRS scores at baseline (0 months) and 6 and 12 months after DBS. **A and B:** Line graphs showing individual BFMDRS-M raw scores (A) and the percent change from baseline (B). **C and D:** Bar graphs showing group BFMDRS-M scores (C) and the percent change (D). **E and F:** Line graphs showing individual BFMDRS-D raw scores (E) and the percent change from baseline (F). **G and H:** Bar graphs showing group BFMDRS-D scores (G) and the percent change (H). *p < 0.05 compared with baseline.

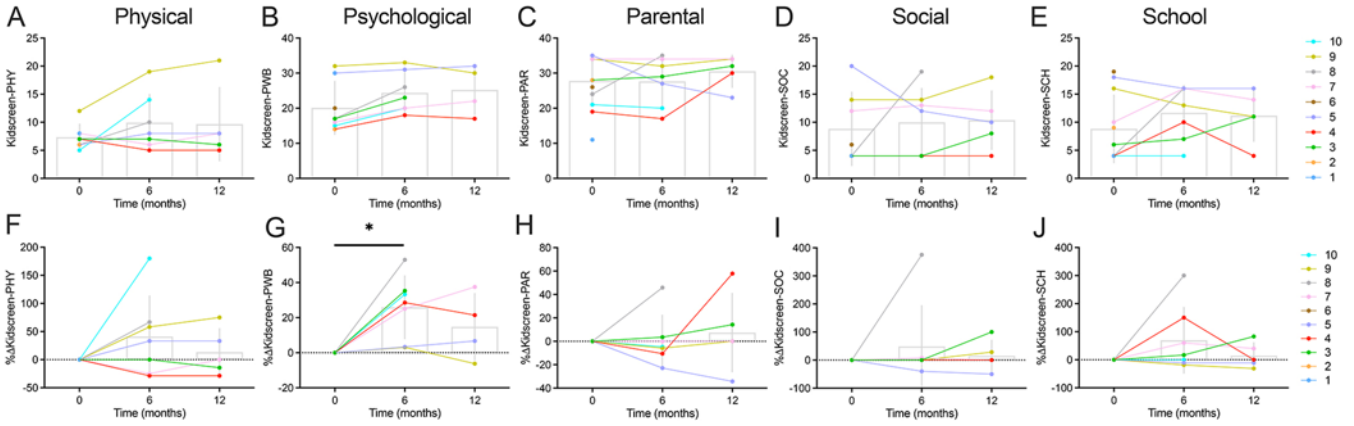

FIG. 5. Quality of life at baseline (0 months) and 6 and 12 months after DBS. **A–E:** Graphs showing individual subscale scores (*circles* and *lines*), with superimposed group means ± SDs (*bars* and *error bars*), across the 5 domains of KIDSCREEN-27. **F–J:** Graphs showing individual percent change subscale scores (*circle* and *lines*), with superimposed group means ± SDs (*bars* and *error bars*), across the 5 domains of KIDSCREEN-27. The higher the score, the better the quality of life. *p < 0.05 compared with baseline. PAR = parental relations and autonomy; PHY = physical well-being; PWB = psychological well-being; SCH = school; SOC = social support and peers.

social domains were more variable, with a mean of 20.5 ± 7.2 (range 14–32) for psychological well-being, 26.0 ± 7.6 (range 11–35) for parent relations and home life, 7.6 ± 5.7 (range 4–20) for social support and peers, and 9.4 ± 6.1 (range 4–19) for school environment. Following DBS, the participants showed heterogeneous trajectories for each subscale. There were no statistically significant changes in raw quality of life scores across any domain or time point; however, the percent difference showed significant improvement (mean 25.9% ± 17.8%) in the psychological well-being subscale at 6 months compared with baseline ($p < 0.05$, $n = 7$).

Participant Deaths

Three participants died ≥ 6 months after surgery due to sequelae of the underlying disease with transition to comfort-focused care. The first had an uncomplicated postoperative course but continued to decline with feeding intolerance, aspiration, and severe irritability. The participant died 6 months postoperatively. The second had almost 2 years of stability after surgery, followed by a decline in their genetic condition, leading to several ICU admissions with seizures, respiratory and urinary tract infections, and sepsis. The participant developed aspiration pneumonia with hypoxic cardiac arrest 22 months postoperatively. The third participant had an uncomplicated surgery and favorable response to DBS. Nonetheless, they continued to have prolonged and frequent hospitalizations due to progression of the genetic condition, and dystonia worsened when the IPG was depleted after more than 2 years, yet the IPG was not replaced due to severe frailty. The participant died of respiratory failure 2.5 years after surgery.

Discussion

In this multicenter study, we report a North American experience of DBS in children younger than 7 years of age who generally had severe symptoms and often experienced benefit albeit with a high-risk profile. We found clinically meaningful improvement in motor symptoms in 78% (7/9) of participants with follow-up BFMDRS assessments, and termination of status dystonicus for all participants. This study represents the largest prospective cohort of this age group that is excluded from the FDA HDE.

All participants had severe refractory dystonia, with half requiring ICU care for refractory status dystonicus and 64% undergoing urgent DBS surgery. Many had other comorbidities, most commonly neurodevelopmental delay, gastrostomy feeding, and epilepsy. In most cases, DBS represented a last resort for this vulnerable and medically complex population.

The current rates of 64.3% overall complications and 28.6% major complications requiring explantation (21.4% infection and 7.1% skin erosion) were higher than those in the movement disorder cohort of the entire CHILD-DBS, with 33.5% overall and 10.4% major complications requiring explantation.[19] This is consistent with our prior finding that younger age, lower weight, a movement disorder indication, and urgent surgery were associated with increased risks of major complications.[19] Therefore, children younger than 7 years of age undergoing DBS experience higher surgical risks, which is important information to convey when counseling caregivers.

Similar to other studies, wound-related issues represented the most common complications in our study.[6,16–19] The rate of infection requiring hardware removal varies widely in the literature, ranging from 9.1% to 40% in older children with dystonia[16–21] and from 4.7% to 57% in children aged 7–10 years.[6,18] Skin erosion has been documented at rates ranging from 2.3% to 18.1%, particularly in undernourished children.[16,18] In our cohort, most wound-related complications occurred within the first 4 months postoperatively, with the exception of a case of surgical site infection and another of skin erosion that presented at 9 and 10 months, respectively. Importantly, skin erosion and granuloma have been reported between 11 and 42 months after surgery,[18] warranting long-term surveillance for such complications.

Pin-site injury (breach of the inner table of skull) was common in our series (21.4%) and was associated with an underlying skull thickness < 1.8 mm. The risk of skull breach during frame-based stereotactic procedures is considered to be the highest in children younger than 4 years of age due to thin variably ossified bone, which decreases progressively with age and skull maturation such that most children have sufficient skull thickness by 7 years of age.[29] Nonetheless, a larger study reported low risk (5%) in children < 7 years of age.[30] Importantly, none of our patients developed intracranial injury, hematoma, or neurological sequalae from the pin-site injuries; however, these remain potential risks, and meticulous attention is warranted to avoid placing pins over high-risk areas such as the transverse sinus. All breaches occurred at the posterior pin sites, likely reflecting additional pressure from supine positioning. Use of a gauss pillow, designed to support the occiput, has prevented skull injury during frame-based procedures in children < 2 years of age.[31] Alternatively, frameless stereotactic approaches might offer a safer option in very young children. Frameless robot-assisted procedures have demonstrated sub–2-mm accuracy and safety in children undergoing biopsy, stereoelectroencephalography electrode placement, and DBS implantation, whereas optical neuronavigation-based techniques were less accurate, with a reported median error of 4.5 mm.[32–34]

We did not observe any hardware-related issues, such as malfunction, migration, or fracture of electrodes or extension leads, which reportedly occur in up to 27.1% of cases.[18,19,21] Growth-related lead issues can be mitigated by placing redundant safety loops, which is standard practice at our institution. The discrepancy might also be due to the relatively short follow-up for our cohort.

One concern regarding DBS implantation in young children is the accuracy of targeting. We used MRI-based targeting methods, including the FGATIR sequence,[28] and confirmed satisfactory positioning of bilateral GPi leads in all participants, including those with microcephaly. In our cohort, the mean target coordinates were x = ±17.48 mm, y = +0.28 mm, and z = +2.46 mm, relative to the midcommissural point, which are considerably different from standard indirect targets in adults (x = ±18–21 mm, y = +2–4 mm, and z = +4 mm).[35] This suggests traditional indirect methods might result in inaccurate targeting in young children, which can lead to suboptimal treatment effects or off-target adverse effects; therefore, we advocate the use of direct targeting in children.

Herein, we report clinically and statistically significant improvement in the motor symptoms of dystonia 6 months after DBS, which was sustained at 12 months. The efficacy of DBS has been shown to be variable depending on the underlying etiology.[22] The most evidence exists for monogenic dystonia, particularly DYT-*TOR1A* and DYT-*KMT2B* (*TOR1A*- and *KMT2B*-associated dystonia, respectively),[3,36] which are represented in our cohort, along with *GNAO1* and *EIF2AK2* variants. We also demonstrated improvement in children with *SCN2A*-related developmental epileptic encephalopathy[37] and SCA28, conditions previously not known to respond to DBS, with DBS also proving effective in PKAN and Lesch-Nyhan syndrome.[22,38,39] One participant with acquired dystonia, which is known to be associated with a worse response to DBS,[3,40] deteriorated at 6 months and remained stable at 12 months. In addition, we observed resolution of status dystonicus in all affected children after DBS, in line with previous studies.[4]

We did not observe any significant change in disability or quality of life following DBS, except for a significant improvement in the percent difference in the KIDSCREEN-27 psychological well-being subscale at 6 months. This is in contrast to prior studies that reported functional and quality of life benefits even in the absence of motor gains.[41,42] Several factors might explain this discrepancy, including younger age, profound baseline disability, and the presence of multisystem comorbidities. The lack of change in BFMDRS-D and quality of life measures is likely a reflection of floor effect driven by neurodevelopmental disabilities. It is generally accepted that the disability subscore is quite poor at measuring changes in this context.[43] The interpretation of quality of life results is further constrained by the sole reliance on caregiver-reported outcomes. These findings emphasize the need for more comprehensive, standardized, and patient-centered outcome measures tailored to children with dystonia to better capture meaningful changes for patients and their families.[42,43]

Limitations and Future Directions

Our study was limited by a small sample size, missing data, and a relatively short follow-up duration. A small sample size is inherent to the current regulatory constraints, which highlights the importance of the present report focusing on this understudied population. We used mixed-effects models to mitigate the effects of incomplete data on statistical power. Finally, long-term complications, such as delayed wound complications and hardware failure might be underrepresented in our study. Nonetheless, a better understanding of the early complication risk profile is a valuable addition to the literature.

We did not investigate the effects of age on the efficacy of DBS. Future studies will evaluate motor and quality of life outcomes in the entire CHILD-DBS cohort, including associations with timing of intervention. In addition, the long-term effects of DBS in young children remain to be elucidated. Ongoing data collection in the registry, and collaborative research through global platforms, such as DBSMatchMaker,[44] will allow us to address these limitations in the future.

Finally, we would be remiss to neglect the ethical concerns raised by performing a procedure outside of FDA-approved indications in vulnerable children. We previously published a framework to guide the conduct of DBS in children.[45] The decision to offer surgery must be made in consideration of a child and family's best interests, as holistically assessed by a multidisciplinary team. The ultimate goal is to decrease suffering while mitigating known risks and addressing unanticipated ones as they arise. To achieve this, constant communication, collaboration, and careful application of lessons learned from the literature are required. The current study contributes meaningfully to our understanding of the risk-benefit profiles of young children undergoing DBS.

Conclusions

We provide evidence to inform the risk-benefit profile of DBS in children younger than 7 years of age with severe refractory dystonia. Based on our findings, clinicians might consider DBS in selected children with appropriate counseling and caregiver expectations. Further studies are needed to better understand the long-term efficacy and safety of DBS in this population, and to develop risk mitigation strategies. Such efforts will help all stakeholders make evidence-based decisions about these vulnerable patients and ultimately expand the accessibility of DBS therapy.

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Disclosures

J. Raskin reported personal fees from Medtronic, Synergia, Iota, and Blackrock Neurotech during the conduct of the study. A. Weil reported personal fees from Monteris Medical during the conduct of the study. C. Gorodetsky reported personal fees from Medtronic, Acadia, and Ipsen outside the submitted work. G. Ibrahim reported being a consultant for Medtronic; an investigator-initiated grant from LivaNova; and being on the scientific advisory board for Synergia.

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Supplemental Information

Previous Presentations

Portions of this work were presented at the 2025 Joint Pediatric Section Annual Meeting, Memphis, TN, December 4–7, 2025.

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