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Computerized Adaptive Tests Detect Change Following Orthopaedic Surgery in Youth with Cerebral Palsy.

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Computerized Adaptive Tests Detect Change Following Orthopaedic Surgery in Youth with Cerebral Palsy

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Investigation performed at the Shriners Hospitals for Children, Philadelphia, Chicago, Canada, Greenville, Tampa, Portland, Sacramento, Houston, and St. Louis

Background: The Cerebral Palsy Computerized Adaptive Test (CP-CAT) is a parent-reported outcomes instrument for measuring lower and upper-extremity function, activity, and global health across impairment levels and a broad age range of children with cerebral palsy (CP). This study was performed to examine whether the Lower Extremity/Mobility (LE) CP-CAT detects change in mobility following orthopaedic surgery in children with CP.

Methods: This multicenter, longitudinal study involved administration of the LE CP-CAT, the Pediatric Outcomes Data Collection Instrument (PODCI) Transfer/Mobility and Sports/Physical Functioning domains, and the Timed “Up & Go” test (TUG) before and after elective orthopaedic surgery in a convenience sample of 255 children, four to twenty years of age, who had CP and a Gross Motor Function Classification System (GMFCS) level of I, II, or III. Standardized response means (SRMs) and 95% confidence intervals (CIs) were calculated for all measures at six, twelve, and twenty-four months following surgery.

Results: SRM estimates for the LE CP-CAT were significantly greater than the SRM estimates for the PODCI Transfer/Mobility domain at twelve months, the PODCI Sports/Physical Functioning domain at twelve months, and the TUG at twelve and twenty-four months. When the results for the children at GMFCS levels I, II, and III were grouped together, the improvements in function detected by the LE CP-CAT at twelve and twenty-four months were found to be greater than the changes detected by the PODCI Transfer/Mobility and Sports/Physical Functioning scales. The LE CP-CAT outperformed the PODCI scales for GMFCS levels I and III at both of these follow-up intervals; none of the scales performed well for patients with GMFCS level II.

Conclusions: The results of this study showed that the LE CP-CAT displayed superior sensitivity to change than the PODCI and TUG scales after musculoskeletal surgery in children with CP.

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Musculoskeletal surgery is a mainstay of orthopaedic care for children with cerebral palsy (CP), but evidence in support of its effectiveness is weak¹⁻⁴. In practice, outcomes instruments are selected to match content, levels of severity, and age groups⁵, making it difficult to monitor the effec-

tiveness of surgery across patients or programs. While many instruments are available for use in CP patient practices and research¹, burdensome, imprecise, and unresponsive instruments are barriers to building evidence⁶⁻¹⁴. Computerized adaptive tests (CATs) for measuring patient-reported outcomes

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TABLE 1 All Items in the Lower Extremity CP Item Pool

When lying on his/her back, my child can turn his/her head from side-to-side.

When in a seated position, my child can turn his/her head towards objects or sounds.

When lying on his/her belly, my child can lift his/her head up.

My child can roll onto his/her side.

My child can creep, crawl, or scoot within a room.

My child can sit on the floor for 5 minutes.

My child can sit on a bench or chair with no back.

A “small object” could be a toy or a book. While sitting, my child can reach for a small object without losing his/her balance.

My child can stand for 1 minute or longer.

My child can crawl or scoot up or down 5 or more steps.

From standing, my child can sit down slowly in a chair.

My child can stand on one foot or the other for 5 seconds or more.

While standing, my child can kick a non-moving ball.

A “small object” could be a toy or a book. My child can walk while carrying a small object.

A “fragile or spillable object” could be a glass of water or breakable dish. My child can walk while carrying a fragile or spillable object.

A “small object” could be a toy or a book. My child can jump over a small object.

A “small object” could be a toy or a book. When standing, my child can bend over and pick up a small object up from the floor.

From standing, my child can squat down and then stand back up.

A “small object” could be a toy or a book. My child can step over a small object.

A “narrow surface” could be a balance beam or curb. My child can walk forward on a narrow surface for 3 or more steps keeping his/her balance.

My child can jump up and down on both feet.

A “heavy object on wheels” could be a shopping cart or wagon. My child can walk while pushing or pulling a heavy object on wheels.

My child can jump down from objects 2 feet or higher keeping his/her balance.

A “level surface” means a flat surface with no bumps or ramps. My child can skip on level surfaces.

My child can hop 3 times or more on one foot or the other.

While waiting in line or at a bus stop, my child can stand for 5 minutes or more without sitting.

A “large object” could be a tray of food or a laundry basket. My child can carry a large object with two hands while walking.

A “heavy load” could be a full suitcase or a full shopping bag. My child can walk while carrying a heavy load in one hand.

A “level surface” means a flat surface with no bumps or ramps. On level surfaces, my child can run and stop to avoid objects or people.

A “large object” could be a tray of food or a laundry basket. While climbing a flight of stairs, my child can carry a large object with two hands.

“Assistive devices” include canes, crutches, a walker, or a wheelchair. Without using assistive devices, my child can run a mile without stopping.

A “level surface” means a flat surface without bumps or ramps, and “assistive devices” include canes, crutches, a walker, or a wheelchair. Without using assistive devices, my child can walk across level surfaces within a room.

“Assistive devices” include canes, crutches, or a walker. While standing without assistive devices, my child can kick a moving ball.

“Assistive devices” include canes, crutches, a walker, or a wheelchair. Without using assistive devices, my child can walk between rooms, opening and closing doors as needed.

“Assistive devices” include canes, crutches, a walker, or a wheelchair. Without using assistive devices, my child can get on and off an elevator including holding/catching doors.

A “heavy door” means a door to the outside or a fire safety door, and “assistive devices” include canes, crutches, a walker, or a wheelchair. Without using assistive devices, my child can open and close heavy doors.

A “slightly uneven surface” means a dirt road or path, or a brick or stone walkway, and “assistive devices” include canes, crutches, a walker, or a wheelchair. Without using assistive devices, my child can walk across slightly uneven surfaces.

“Assistive devices” include canes, crutches, a walker, or a wheelchair. Without using assistive devices, my child can walk up or down ramps.

A “backpack” is a bag/backpack worn on one or both shoulders, containing lightweight objects, and “assistive devices” include canes, crutches, a walker, or a wheelchair. Without using assistive devices, my child can walk and carry his/her backpack from the house to the car (30 feet/9 meters).

A “curb” is a 6-inch single step that one steps up or down going from a street to a sidewalk, and “assistive devices” include canes, crutches, a walker, or a wheelchair. Without using assistive devices, my child can step up and down curbs.

A “slippery surface” means a surface that is wet or icy, and “assistive devices” include canes, crutches, a walker, or a wheelchair. Without using assistive devices, my child can walk on slippery surfaces without losing his/her balance.

continued

TABLE I (continued)

“Assistive devices” include canes, crutches, a walker, or a wheelchair. Without using assistive devices, my child can walk up or down a flight of 8-12 steps using the rail for support.

“Assistive devices” include canes, crutches, a walker, or a wheelchair. Without using assistive devices, my child can walk in line without bumping into other people.

My child can pick up his/her crutch(es) or cane and get ready to walk.

A “level surface” means a flat surface with no bumps or ramps. When using his/her crutch(es) or cane, my child can walk across level surfaces within a room.

A “small bump” means a threshold at a doorway or a gap between carpets. When using his/her crutch(es) or cane, my child can walk over small bumps.

When using his/her crutch(es) or cane, my child can change his/her direction of walking by turning around.

When standing using his/her crutch(es) or cane, my child can kick a moving ball.

When using his/her crutch(es) or cane, my child can walk between rooms, opening and closing doors as needed.

When using his/her crutch(es) or cane, my child can get on and off an elevator including holding/catching doors.

A “heavy door” means a door to the outside or a fire safety door. When using his/her crutch(es) or cane, my child can open and close heavy doors.

A “slightly uneven surface” means a dirt road or path, or a brick or stone walkway. When using his/her crutch(es) or cane, my child can walk across slightly uneven surfaces.

When using his/her crutch(es) or cane, my child can walk up or down ramps.

A “backpack” is a bag/backpack worn on one or both shoulders, containing lightweight objects. When using his/her crutch(es) or cane, my child can walk and carry a backpack from the house to the car (30 feet/9 meters).

A “curb” is a 6-inch single step that one steps up or down going from a street to a sidewalk. When using his/her crutch(es) or cane, my child walks up and down curbs.

A “slippery surface” means a surface that is wet or icy. When using his/her crutch(es) or cane, my child can walk on slippery surfaces without losing his/her balance.

When using his/her crutch(es) or cane, my child can walk in line without bumping into other people.

When using his/her crutch(es) or cane, my child can walk up a flight of 8-12 steps using the rail for support.

My child can stand and position him/herself in his/her walker and get ready to walk.

A “level surface” means a flat surface with no bumps or ramps. When using his/her walker, my child can walk across level surfaces within a room.

When using his/her walker, my child can walk across a carpeted floor.

A “small bump” means a threshold at a doorway or a gap between carpets. When using his/her walker, my child can walk over small bumps.

When using his/her walker, my child can change direction of walking by turning around.

When standing with his/her walker, my child can kick a moving ball.

When using his/her walker, my child can walk between rooms, opening and closing doors as needed.

When using his/her walker, my child can get on and off an elevator including holding/catching doors.

A “slightly uneven surface” means a dirt path, a brick walkway, or uneven pavement. When using his/her walker, my child can walk across slightly uneven surfaces.

When using his/her walker, my child can walk up and down ramps.

A “backpack” is a bag/backpack worn on one or both shoulders, containing lightweight objects. When using his/her walker, my child can walk and carry his/her backpack from the house to the car (30 feet/9 meters).

A “slippery surface” means a surface that is wet or icy. When using his/her walker, my child can walk on slippery surfaces without losing his/her balance.

When using his/her walker, my child can walk in line without bumping into other people.

A “gait trainer” is an assistive device that has extra supports for the trunk and pelvis, such as a seat. When using his/her gait trainer, my child can stand for 5 or more seconds.

A “gait trainer” is an assistive device that has extra supports for the trunk and pelvis, such as a seat. A “level surface” means a flat surface with no bumps or ramps. When using his/her gait trainer, my child can walk across level surfaces within a room.

A “gait trainer” is an assistive device that has extra supports for the trunk and pelvis, such as a seat. When using his/her gait trainer, my child can walk across a carpeted floor.

A “gait trainer” is an assistive device that has extra supports for the trunk and pelvis, such as a seat. A “slightly uneven surface” means a dirt path, a brick walkway or uneven pavement. When using his/her gait trainer, my child can walk on slightly uneven surfaces.

A “gait trainer” is an assistive device that has extra supports for the trunk and pelvis, such as a seat. When using his/her gait trainer, my child can walk up or down a ramp.

continued

TABLE I (continued)

A "level surface" means a flat surface with no bumps or ramps. My child can wheel across level outdoor surfaces.

While wheeling his/her wheelchair, my child can change direction.

While in his/her wheelchair, my child can get on and off an elevator including holding/catching doors.

A "heavy door" means a door to the outside or a fire safety door. While in his/her wheelchair, my child can open and close heavy doors.

A "slightly uneven surface" means a dirt road or path, or brick or stone walkway. While in his/her wheelchair, my child can wheel across slightly uneven surfaces.

While in his/her wheelchair, my child can wheel up or down a ramp.

When using his/her wheelchair, my child can move in line without bumping into other people.

My child can adjust his/her wheelchair footrests.

My child can bear weight on his/her legs to help with transfers between his/her bed and wheelchair.

My child can transfer into and out of a van or sport utility vehicle (SUV) from his/her wheelchair.

A "seat" could be a chair or toilet at the same level as the wheelchair. My child can transfer between a seat and his/her wheelchair.

My child can lock and unlock his/her wheelchair brakes.

A car is a sedan or other type of 4-door car. From his/her wheelchair, my child can transfer into and out of a car.

My child can stand and transfer between his/her bed and wheelchair.

My child can briskly wheel his/her wheelchair for 1 mile without stopping to rest.

offer a promising method to address the challenges with measuring these outcomes.

CATs require large item banks for a particular outcome domain (e.g., mobility)¹⁵; these item banks can contain hundreds of items that are calibrated with use of item response theory methods to consistently scale along a continuum from low to high ability. CATs are administered with use of predefined rules for starting, stopping, and scoring¹⁶. A CAT first asks questions in the middle of the ability range, and then directs questions to the appropriate ability level based on the person's response to previous items. Filter questions are used to "bucket" items so that they are made available only as appropriate. In this manner, patients never answer items that are irrelevant to their function. Despite the fact that respondents may answer different items on repeated administrations of the CAT and items may differ from those answered by another patient, all CAT scores are calibrated with use of a common scale and therefore can be compared¹⁶.

The purpose of the CP-CAT was to replace multiple and long, burdensome assessment instruments and to establish psychometrically sound ways to evaluate outcomes across the broad range of function of youth with CP. CP-CAT scales were developed to assess lower-extremity function and mobility¹⁷, upper-extremity function¹⁸, activity^{18,19}, and global health²⁰ using parents' reports of their children's ability. Depending on one's research purpose, the CP-CATs can be administered separately, or in combination as an overall outcome measure of physical functioning, activity, and/or global health.

The purpose of this study was to evaluate the ability of the Lower Extremity/Mobility (LE) CP-CAT to detect change after orthopaedic surgery. There were two primary research questions: (1) Does the LE CP-CAT detect change in functional mobility after lower-extremity orthopaedic surgery in children with CP? (2) How does the LE CP-CAT compare with traditional fixed-length and performance-based comparison instruments?

Materials and Methods

We recruited a convenience sample of youth with CP (age range, four to twenty years) who were undergoing elective orthopaedic surgery for functional improvement at one of nine facilities across North America between April 2009 and August 2013. Children were excluded if they had orthopaedic surgery for reasons other than to improve physical function (e.g., to improve position or the ability to carry out hygiene) or had diagnoses other than CP. Each of the participating sites obtained local institutional review board approval.

Clinical Assessment

The Gross Motor Function Classification System (GMFCS)²¹ was used to characterize the sample according to the severity of limitations on mobility. The GMFCS rates ambulation on a scale of I (walks without limitations) to V (fully dependent on others for transport in a manual wheelchair).

LE CP-CAT

The LE CP-CAT is a parent-reported outcomes instrument based on a large bank of items that reflect basic mobility, body transfers, ambulation with and without assistive devices, and wheeled mobility (Table I). The response option involves a 5-point difficulty scale: "unable to do," "with much difficulty," "with some difficulty," "with little difficulty," and "without difficulty." For this study, the first question asked was: "What is the longest period of time your child can stand without help or support?" The response ("less than thirty seconds," "about thirty seconds," "about five minutes," "about ten minutes," or "about thirty minutes") was used to select the first item. Subsequent items were administered on the basis of the response to the previous item such that if an item was rated as "with much difficulty" or "with some difficulty," an easier item was administered and if an item was rated as "with little difficulty" or "without difficulty," a more difficult item was administered. This procedure continued until the parent answered fifteen items. The LE CP-CAT item bank, described in detail elsewhere¹⁷ and provided in Table I, was calibrated with a sample of 308 parent-responders of children with CP and is scored on a T metric where the mean equals 50 and the standard deviation (SD) equals 10. The time to complete the CAT was recorded by the CAT software program.

Traditional Patient-Reported Outcomes Instrument: Pediatric Outcomes Data Collection Instrument (PODCI)

The PODCI²² was administered for comparison. It is a 114-item measure with five subscales (Upper Extremity/Physical Function, Transfer/Mobility,

TABLE II Sample Characteristics and Scores at Baseline and Each Follow-up Period Between Those Who Completed and Those Who Missed Follow-up

	Baseline (N = 255)	6 Mo		12 Mo		24 Mo	
		Completed Follow-up (N = 190)	Missed Follow-up (N = 65)	Completed Follow-up (N = 169)	Missed Follow-up (N = 86)	Completed Follow-up (N = 103)	Missed Follow-up (N = 152)
Mean age ± SD (yr)	11.6 ± 3.8	11.6 ± 3.8	11.7 ± 3.8	11.4 ± 3.9	12.0 ± 3.6	10.7 ± 3.9*	12.2 ± 3.6*
Sex (no. [%])							
Female	110 (43.1)	83 (43.7)	27 (41.5)	77 (45.6)	33 (38.4)	38 (36.9)	72 (47.4)
Male	145 (56.9)	107 (56.3)	38 (58.5)	92 (54.4)	53 (61.6)	65 (63.1)	80 (52.6)
Race (no. [%])							
White	197 (77.3)	150 (78.9)		132 (78.1)		83 (80.6)	
Black	35 (13.7)	25 (13.2)		25 (14.8)		13 (12.6)	
Asian	16 (6.3)	11 (5.8)		8 (4.7)		5 (4.9)	
American Indian	1 (0.4)	1 (0.5)		1 (0.6)		1 (1.0)	
Hawaiian or Pacific Islander	2 (0.8)	1 (0.5)		1 (0.6)		0 (0.0)	
Other	2 (0.8)	1 (0.5)		2 (1.2)		1 (1.0)	
Missing	2 (0.8)	1 (0.5)		0 (0.0)		0 (0.0)	
Ethnicity (no. [%])							
Non-Hispanic	203 (79.6)	155 (81.6)		145 (85.8)		90 (87.4)	
Hispanic	49 (19.2)	33 (17.4)		23 (13.6)		12 (11.7)	
Missing	3 (1.2)	2 (1.1)		1 (0.6)		1 (1.0)	
GMFCS classification (no. [%])							
Level I	85 (33.3)	62 (32.6)	23 (35.4)	56 (33.1)	29 (33.7)	28 (27.2)	57 (37.5)
Level II	117 (45.9)	91 (47.9)	26 (40.0)	80 (47.3)	37 (43.0)	51 (49.5)	66 (43.4)
Level III	48 (18.8)	34 (17.9)	14 (21.5)	32 (18.9)	16 (18.6)	24 (23.3)	24 (15.8)
Missing	5 (2.0)	3 (1.6)	2 (3.1)	1 (0.6)	4 (4.7)	0 (0.0)	5 (3.3)
Mean score ± SD (points)							
LE CP-CAT	52.6 ± 6.7	52.4 ± 6.6	53.0 ± 7.0	52.5 ± 6.8	52.8 ± 6.5	51.6 ± 7.1	53.2 ± 6.3
PODCI Transfer/ Mobility	80.4 ± 19.2	80.4 ± 19.3	80.3 ± 19.2	79.7 ± 20.1	81.6 ± 17.4	76.6 ± 22.0*	82.9 ± 16.6*
PODCI Sports/ Physical Functioning	53.5 ± 21.4	53.3 ± 21.0	54.1 ± 22.7	53.4 ± 21.2	53.8 ± 21.8	51.4 ± 22.2	55.0 ± 20.7
TUG	13.2 ± 15.9	12.9 ± 15.9	14.1 ± 16.1	12.3 ± 12.8	14.8 ± 20.6	13.2 ± 14.9	13.2 ± 16.6

*A significant difference between those who completed and those who missed follow-up ($p < 0.05$).

Sports/Physical Functioning, Pain/Comfort, and Happiness). A total standardized score ranging from 0 to 100 for each subdomain is calculated, with a score of 100 representing a "best health outcome." Despite its limitations²³⁻²⁵, the PODCI is used routinely in studies of CP. For this study, we compared the PODCI Transfer/Mobility (eleven items) and Sports/Physical Functioning (twenty-one items) subscales with the LE CP-CAT scale.

Parent Anchor Scores of Perceived Change

We asked parents to "rate how much their child's lower extremity mobility has changed since surgery" using a 7-point scale ("very much worse," "much worse," "a little worse," "about the same," "a little better," "much better," and "very much better"). We used these scores as verification of parent-perceived change.

Performance-Based Measure

The timed "Up & Go" test (TUG)²⁶ was administered by recording the time it took for a child to rise from a chair, walk straight for 3 m at a normal pace, and

return to and sit in the chair. TUG scores were recorded as the average time in seconds across three trials.

Data Collection Procedures

The LE CP-CAT and PODCI subscales were administered to parents of children with CP within a week prior to surgery and again at six, twelve, and twenty-four months following surgery; a parent-rated change question was asked at twelve and twenty-four months. The child was evaluated with the GMFCS and TUG prior to surgery and at each follow-up visit.

Statistical Analysis

The mean, SD, and range of scores for the LE CP-CAT, PODCI, and TUG were calculated at the preoperative baseline assessment and the three postoperative follow-up visits to determine if the scores were in a valid range. For each measure, we calculated the effect size (ES) with the formula: (mean postoperative score – mean

TABLE III Reasons for Decrease in Number of Subjects at Each Follow-up Period

Reason	6 Mo	12 Mo	24 Mo
Withdrawn by investigator	2	0	0
Lost to follow-up*	18	12	26
Dropped out†	8	14	23
Aged out of pediatric care‡	1	3	4
Missed the data collection window§	36	57	99
Total	65	86	152

*Could not be contacted despite multiple attempts. †Subject requested to drop out (usually citing time and transportation as reasons). ‡Facility policy states that no one over twenty-one years of age can be seen. §Subject did not return for clinical or research appointment within study-specific window for data collection for the given time interval.

preoperative score)/SD of preoperative score. We also calculated the standardized response mean (SRM) with the formula: (mean postoperative score – mean preoperative score)/SD of change score. The ES and SRM values were adjusted so that positive values indicate improved function and negative values indicate a decline in function. Five thousand bootstrap samples were generated from the original data set, and the ES and SRM from each of those samples were used to calculate the values at the 2.5th and 97.5th percentiles in the complied distribution, which represented the 95% confidence interval (CI). We also applied bootstrap methods to determine if there were significant differences between ES and SRM estimates for the LE CP-CAT, PODCI, and TUG. If the 95% CI for the difference in ES or SRM included zero, the difference was considered non-significant. For twelve and twenty-four-month follow-up data, correlations between the LE CP-CAT scores and parent-rated change scores were significant and met the criteria for conducting analyses of minimally important differences (>0.3). Analysis of variance (ANOVA) was conducted to examine differences in LE CP-CAT scores based on parent-rated change scores at these two time intervals.

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TABLE IV Comparison, Among Outcomes Instruments, of Mean Scores at Baseline and Mean Differences in Scores from Baseline to Follow-up Time Points

Measure/Domain	Mean Score ± SD at Baseline (N = 255*)	Mean Difference in Score from Baseline (95% CI)		
		At 6 Mo (N = 190*)	At 12 Mo (N = 169*)	At 24 Mo (N = 103*)
LE CP-CAT (mean T score ± SD = 50 ± 10) (points)				
Entire sample	52.6 ± 6.7	0.26 (–0.28, 0.81)	1.70 (1.11, 2.28)	2.20 (1.45, 2.96)
GMFCS I (n = 84, 62, 53, 27†)	57.4 ± 3.8	1.20 (0.33, 2.07)	2.67 (1.67, 3.67)	3.02 (1.57, 4.47)
GMFCS II (n = 113, 90, 77, 51†)	52.9 ± 4.9	–0.71 (–1.56, 0.14)	0.85 (–0.08, 1.78)	1.16 (0.09, 2.24)
GMFCS III (n = 47, 33, 32, 23†)	43.1 ± 4.1	0.87 (–0.29, 2.03)	2.08 (1.06, 3.10)	3.62 (2.18, 5.06)
PODCI Transfer/Mobility (standardized score = 0-100, 100 = best health outcome) (points)				
Entire sample	80.4 ± 19.2	–1.11 (–2.84, 0.63)	2.67 (0.72, 4.62)	6.37 (3.36, 9.38)
GMFCS I (n = 85, 57, 54, 25†)	92.1 ± 7.7	–1.65 (–3.98, 0.68)	0.69 (–1.70, 3.07)	2.92 (0.91, 4.93)
GMFCS II (n = 114, 84, 73, 48†)	81.6 ± 13.7	–2.07 (–4.93, 0.78)	2.51 (–0.52, 5.55)	4.06 (0.50, 7.62)
GMFCS III (n = 48, 27, 27, 22†)	56.2 ± 23.4	3.04 (–1.21, 7.29)	7.15 (0.99, 13.31)	15.32 (5.38, 25.26)
PODCI Sports/Physical Functioning (standardized score = 0-100, 100 = best health outcome) (points)				
Entire sample	53.5 ± 21.4	–3.04 (–5.61, –0.47)	3.20 (0.92, 5.48)	6.66 (3.46, 9.86)
GMFCS I (n = 85, 57, 54, 25†)	67.1 ± 18.5	–2.72 (–6.93, 1.49)	4.19 (0.54, 7.83)	8.52 (2.44, 14.60)
GMFCS II (n = 114, 84, 73, 48†)	52.9 ± 17.4	–5.52 (–9.52, –1.51)	2.67 (–0.75, 6.09)	3.58 (–0.92, 8.09)
GMFCS III (n = 48, 27, 27, 22†)	31.6 ± 14.8	4.44 (–0.63, 9.52)	1.74 (–4.37, 7.85)	11.27 (4.00, 18.54)
TUG (mean of 3 trials) (sec)				
Entire sample	13.2 ± 15.9	2.17 (–0.54, 4.88)	–0.57 (–1.76, 0.63)	–1.73 (–4.17, 0.72)
GMFCS I (n = 83, 55, 55, 24†)	7.9 ± 1.8	1.25 (–0.29, 2.78)	0.05 (–0.42, 0.52)	0.19 (–0.73, 1.11)
GMFCS II (n = 113, 84, 74, 47†)	10.1 ± 3.4	1.77 (0.32, 3.22)	0.49 (–0.26, 1.23)	0.10 (–0.83, 1.02)
GMFCS III (n = 40, 26, 23, 20†)	33.3 ± 31.8	6.05 (–13.15, 25.25)	–5.91 (–14.09, 2.27)	–9.83 (–23.05, 3.39)

*Number of subjects in entire sample (all GMFCS levels combined). †Number of subjects at each GMFCS level at each time period.

TABLE V SRM Estimates at Follow-up Time-Points for Entire Sample

Measure/Domain	Baseline to 6 Mo	Baseline to 12 Mo	Baseline to 24 Mo
LE CP-CAT			
SRM (95% CI)	0.07 (-0.07, 0.22)	0.45* (0.30, 0.62)	0.58* (0.40, 0.78)
Sample size	183	160	100
PODCI Transfer/Mobility			
SRM (95% CI)	-0.10 (-0.24, 0.06)	0.22* (0.06, 0.38)	0.43* (0.25, 0.61)
Sample size	169	154	95
PODCI Sports/Physical Functioning			
SRM (95% CI)	-0.18* (-0.33, -0.03)	0.22* (0.07, 0.39)	0.42* (0.24, 0.63)
Sample size	169	154	95
TUG†			
SRM (95% CI)	-0.12 (-0.32, 0.03)	0.08 (-0.09, 0.21)	0.15 (-0.06, 0.29)
Sample size	162	149	86

*A significant value. SRM values of <0.2 are clinically trivial. †The SRM calculations were adjusted so that a negative value indicates a decline in walking speed.

Results

We screened 440 children with CP who had single-event musculoskeletal surgery. Six children declined to participate, and thirty-three did not meet study eligibility criteria. Children treated with upper-extremity surgery ($n = 94$), who were non-ambulatory (GMFCS IV or V, $n = 16$), and for whom only baseline data were available ($n = 14$) or who had incomplete data ($n = 22$) were excluded. Demographic information for the remaining 255 children is displayed in Table II.

The mean age (and SD) was 11.6 ± 3.8 years (range, 4.0 to 20.0 years) at the time of surgery. Ninety-four patients (36.9%) had multi-level procedures¹. The reasons for the decrease in sample size at each follow-up interval are provided in Table III. At each time point, we compared the age, GMFCS level, sex, race, and ethnicity of those who had completed follow-up up to that point with those who had not. No differences were noted at six or twelve months; however, at twenty-four months dropouts were significantly older than those who had completed follow-up (12.2 versus 10.7 years) and had

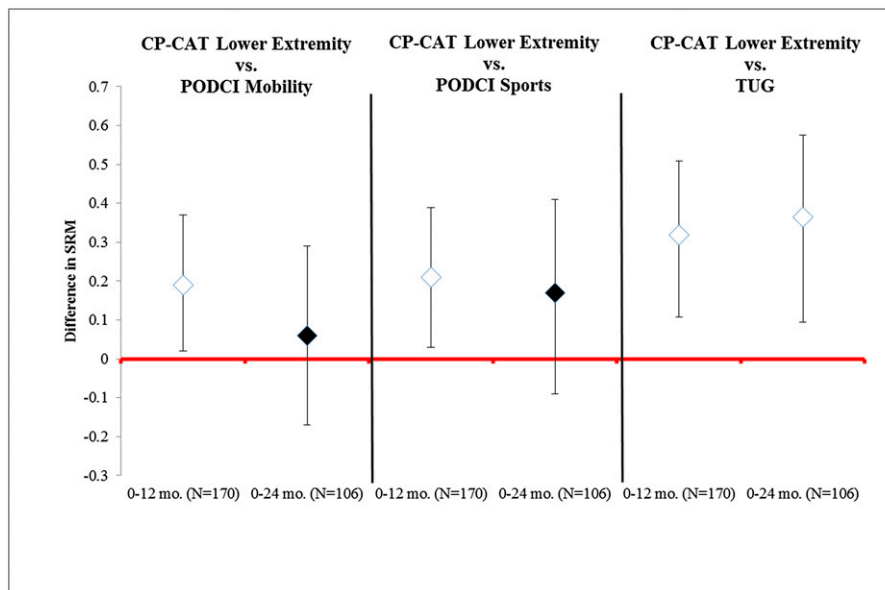


Fig. 1
Comparison of standardized response means (SRMs) between the LE CP-CAT and the PODCI and TUG measures. The white diamonds represent comparisons where the LE CP-CAT was significantly more responsive than the comparison measure. The black diamonds indicate that the difference between measures was not significant.

significantly higher PODCI Transfer/Mobility scores (82.9 versus 76.6) (Table II).

Descriptive Characteristics

Table IV shows the means and SDs for each measure at baseline and the mean differences from baseline at six, twelve, and twenty-four months. As expected, the baseline mean values for the LE CP-CAT decreased with each functional GMFCS level. Likewise, the PODCI Transfer/Mobility and Sports/Physical Functioning standardized scores decreased with each functional GMFCS level, as did walking speed. At six months, the mean differences in the PODCI scores, compared with baseline, reflected a decline in function for the entire sample and for the GMFCS-I and II subgroups; both PODCI subscales showed an improvement in the GMFCS-III subgroup at six months. The mean differences in the LE CP-CAT scores of the GMFCS-II subgroup showed a decline. At twelve and twenty-four months,

the mean differences in the LE CP-CAT and PODCI scores, compared with baseline, reflected increasing improvement.

Ability to Detect Change

Since ES and SRM results were similar, we will limit our report to SRM estimates. SRM estimates are displayed in Table V. The LE CP-CAT detected a significant small improvement in function at twelve months (SRM = 0.45) and a moderate improvement at twenty-four months (SRM = 0.58). The PODCI Transfer/Mobility and Sports/Physical Functioning domains detected a significant small improvement at twelve months (SRM = 0.22 and 0.22, respectively) and twenty-four months (SRM = 0.43 and 0.42, respectively). The LE CP-CAT, TUG, and PODCI Transfer/Mobility scale did not detect changes at six months, whereas the PODCI Sports/Physical Functioning scale detected a small negative change (SRM = -0.18). As shown in Figure 1, the SRM estimates for the LE CP-CAT were significantly greater than the SRM estimates for

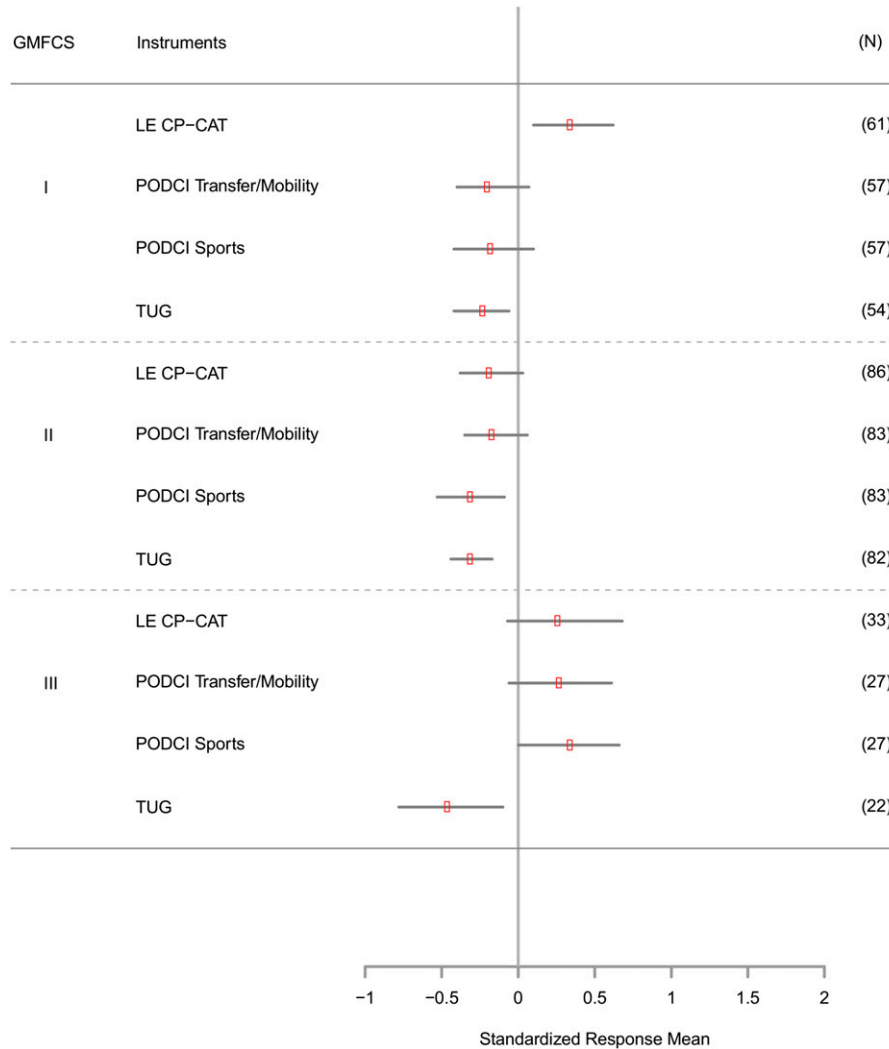


Fig. 2-A

Figs. 2-A, 2-B, and 2-C Standardized response means (red rectangles) and 95% CIs (horizontal lines) for each measure as a function of GMFCS classification. **Fig. 2-A** From baseline to six months.

the PODCI Transfer/Mobility domain (at twelve months), the Sports/Physical Functioning domain (at twelve months), and the TUG (at twelve and twenty-four months). There were no instances in which PODCI or TUG SRM estimates were significantly greater than those of the LE CP-CAT.

Figures 2-A, 2-B, and 2-C display the results of the SRM estimates organized by GMFCS levels. At six months (Fig. 2-A), the LE CP-CAT detected a small significant improvement for children at GMFCS level I (SRM = 0.35), the PODCI Sports/Physical Functioning scale detected a small significant decline for those at GMFCS level II (SRM = -0.30) and a small significant improvement (SRM = 0.35) for those at GMFCS level III, and the TUG detected a small significant decline for those at GMFCS levels I, II, and III (SRM = -0.22, -0.30, and -0.45, respectively). At six months, the PODCI Transfer/Mobility scale did not detect a change in any GMFCS-level subgroup. At twelve months (Fig. 2-B), the LE CP-CAT detected a large significant improvement for children at GMFCS levels I and III (SRM =

0.73 and 0.74, respectively), the PODCI Transfer/Mobility scale detected a small significant improvement for those at GMFCS level III (SRM = 0.46), and the PODCI Sports/Physical Functioning scale detected a small significant improvement for those at GMFCS level I (SRM = 0.31). At twelve months (Fig. 2-B), the TUG did not detect a change in any GMFCS-level subgroup. At twenty-four months (Fig. 2-C), the LE CP-CAT detected a large significant improvement for children at GMFCS levels I and III (SRM = 0.82 and 1.11, respectively) and a small significant improvement for those at GMFCS level II (SRM = 0.30), the PODCI Transfer/Mobility scale detected a moderate significant improvement for children at GMFCS levels I and III (SRM = 0.60 and 0.68, respectively) and a small significant improvement for those at GMFCS level II (SRM = 0.33), and the PODCI Sports/Physical Functioning scale detected a moderate significant improvement for children at GMFCS levels I and III (SRM = 0.58 and 0.69). At twenty-four months, the TUG did not detect a change in any GMFCS-level subgroup. Table VI provides a visual

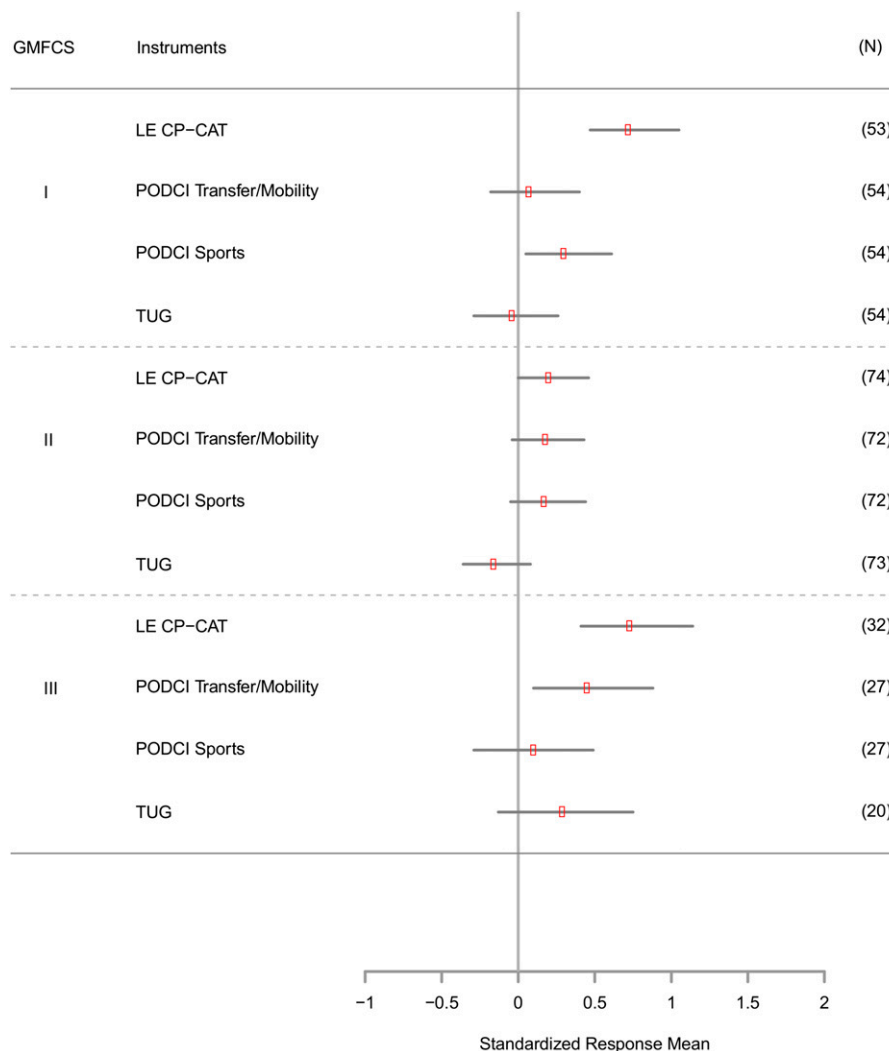


Fig. 2-B
From baseline to twelve months.

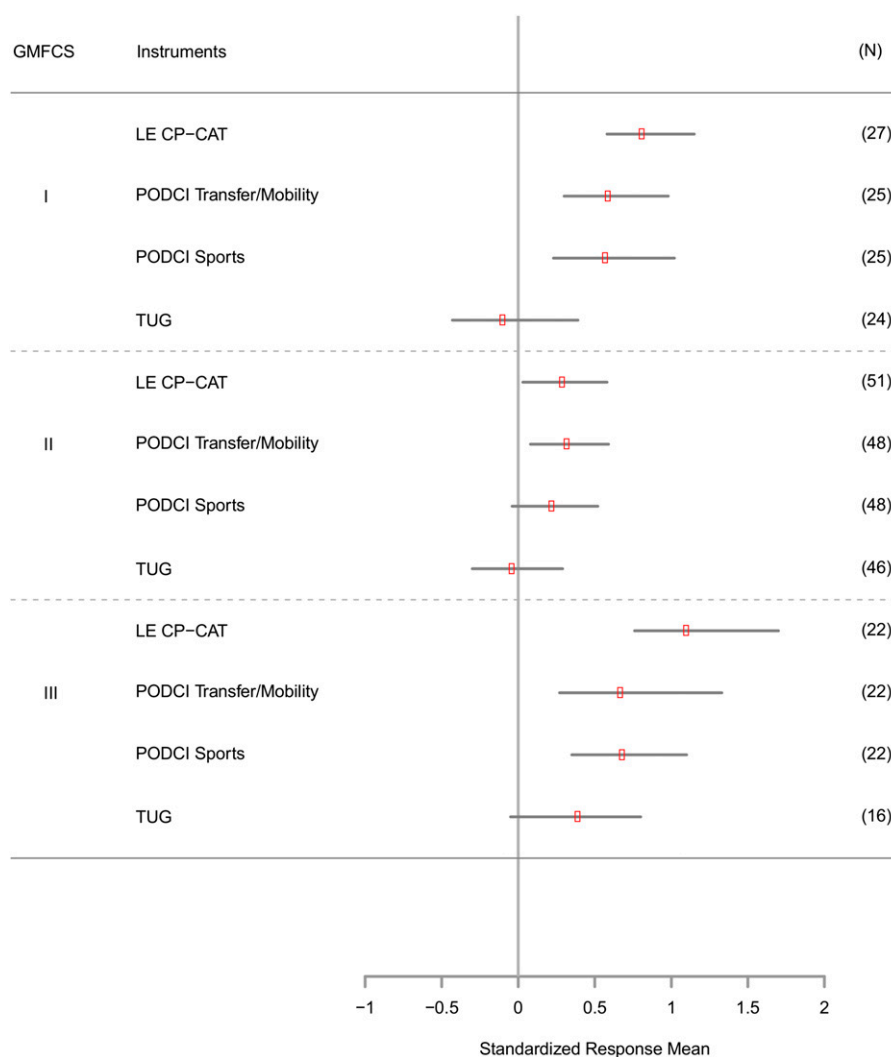


Fig. 2-C
From baseline to twenty-four months.

comparison between the performance of the LE CP-CAT and the performance of the PODCI scales across GMFCS categories at each follow-up period.

As summarized in Table VII, at twelve and twenty-four months after surgery, the majority of parents reported that their child's lower-extremity function was "much better" (43.8% at twelve months and 40.7% at twenty-four months) or "very much better" (20.1% and 25.3%). At twelve months, there were significant differences in LE CP-CAT scores between parents who rated their child's lower-extremity function as "very much better" or "much better" and those who rated it as "a little better" or "about the same." At twenty-four months, the LE CP-CAT scores were significantly different between the parents who rated their child's lower-extremity function as "very much better" or "much better" and those who rated it as "about the same."

Discussion

The results of this study revealed that the LE CP-CAT displayed superior sensitivity to change compared with the

PODCI scales twelve and twenty-four months after musculo-skeletal surgery in children with CP. When used for children at GMFCS level I, the LE CP-CAT detected increasingly greater change at each of the three follow-up points, whereas the PODCI Sports/Physical Functioning scale detected only small and moderate improvements at twelve and twenty-four months, respectively, and the PODCI Transfer/Mobility scale did not detect improvement until twenty-four months after surgery. The LE CP-CAT also outperformed the PODCI scales for children with GMFCS level III, at twelve and twenty-four months. These findings of improvement with the LE CP-CAT are consistent with the anchor scores that showed that 89.9% and 87.9% of the parents perceived improvement at twelve and twenty-four months following surgery.

The ability of the LE CP-CAT to better detect change is highly relevant since the PODCI is used frequently in CP patient practice and research, despite varying reports of psychometric rigor^{7,27-30} and in light of recent systematic reviews indicating low-level evidence for use after orthopaedic surgery for CP^{1,2}. The finding that the LE CP-CAT had greater sensitivity to change than the PODCI scales

TABLE VI Comparison of Outcomes Instruments

GMFCS/Measure	Change Detected*		
	6 Mo	12 Mo	24 Mo
GMFCS I			
LE CP-CAT	+	++	+++
PODCI Transfer/Mobility			++
PODCI Sports/Physical Functioning		+	++
GMFCS II			
LE CP-CAT			+
PODCI Transfer/Mobility			+
PODCI Sports/Physical Functioning	-		
GMFCS III			
LE CP-CAT		++	+++
PODCI Transfer/Mobility		+	++
PODCI Sports/Physical Functioning	+		++

*+ = small positive change detected, ++ = moderate positive change detected, +++ = large positive change detected, - = small decline detected, and blank cell = no change detected.

was not entirely unanticipated. The PODCI was designed to provide a broad perspective for children with musculoskeletal conditions^{31,32}. In contrast, the LE CP-CAT was developed to have a high relevance with regard to the functional mobility repertoire of children with CP and the results of the orthopaedic interventions and rehabilitation that they receive. While the PODCI allows for comparison across musculoskeletal health conditions, we found that it is less likely to be able to detect intervention-related change than disease-specific or condition-specific measures are³³.

None of the scales performed well for children at GMFCS level II. There are several potential explanations for this finding. In contrast to the relatively large effect that surgery has on the functional mobility of children at GMFCS level I, who often have an improvement in community ambulation¹, and on the mobility of children at GMFCS level III, who often have a decreased need for assistive devices³⁴, the effect of surgery on the functional mobility of children at GMFCS level II may be better detected by instruments that evaluate outcomes beyond mobility; work is currently under way to evaluate the ability of the CP activity and global health CATs to detect change following orthopaedic surgery in children at GMFCS level II. Another potential explanation may be that the LE (lower-extremity) item bank does not contain items that are most relevant to the functional mobility outcomes realized after surgery for children at GMFCS level II. New items can be added to the LE item bank to address gaps in content, thereby enhancing the CAT's ability to detect change in this group. As examples, medical records of orthopaedic surgery can be reviewed to determine if the documented results are reflected in the LE item pool and children can be asked to describe how their functional mobility changed after surgery to ensure those changes are also reflected in the item pool.

One of the greatest benefits of adaptive tests, such as the CP-CATs, is their broad content range that makes them effective for populations with wide variation in function, such as children with CP, without losing precision or creating undue burden through administration of long or multiple questionnaires. In this study, we used a stop rule of fifteen items, which required, on average, 5.3 minutes to complete. We have shown a high correlation between simulated five and ten-item CATs and the full LE item bank¹⁷, suggesting that even with a lower number of items, the LE CP-CAT may be able to detect change after orthopaedic surgery. Given the financial and time constraints of busy orthopaedic practices as well as the issue of respondent burden, limiting

TABLE VII Parent Anchor Scores for Perceived Change Following Surgery

"Rate How Much Your Child's Lower Extremity Mobility Has Changed Since Surgery"*	Baseline to 12 Mo (N = 144)			Baseline to 24 Mo (N = 91)		
	No.	Mean Change in LE CP-CAT Score	MID†	No.	Mean Change in LE CP-CAT Score	MID†
About the same	16	-0.603		11	0.025	
A little better	36	0.645		20	1.332	
A little better vs. about the same			1.25			1.31
Much better	63	2.312‡§		37	2.579‡	
Much better vs. a little better			1.67			1.25
Very much better	29	2.959‡§		23	3.679‡	
Very much better vs. much better			0.65			1.1

*Not enough parents reported that their child's lower-extremity function was "worse" to conduct analysis of those responses. †Minimally important difference. ‡Significantly different from "about the same." §Significantly different from "a little better."

the number of items needed to detect change is paramount. Future work will be done to examine if the results of this study are upheld with a five and a ten-item CAT.

Our study had several limitations, one of which is that the CP-CAT was developed and validated as a parent-report instrument with the absence of a child-report version. Parent-report instruments provide perceived outcomes and are not substitutes for direct measures. Another limitation is that a large number of participants missed follow-up assessments. Although there were no differences between those who did and those who did not return for follow-up at six and twelve months, at twenty-four months the dropouts were older and had better functional mobility. Finally, the TUG was selected because of its low burden and common use; however, walking speed may not be the most relevant comparison measure. While objective kinematic studies may have been preferable, not all of the participating sites had access to a motion analysis laboratory.

While the PODCI and the TUG showed a decline in function at six months for the entire sample and for children at GMFCS levels I and II, the LE CP-CAT detected a decline only in children at GMFCS level II. The inability of the LE CP-CAT to detect a decline in function at six months is a potential limitation of the instrument.

We recognize that goals of orthopaedic surgery for youth with CP include a cadre of outcomes including decreases in pain and spasticity and improvements in hygiene, activities of daily living, and global health. The study was not designed or powered to evaluate these outcomes of orthopaedic surgery.

In conclusion, when compared with the PODCI and TUG outcome measures, the LE CP-CAT is better able to detect change

in functional mobility following orthopaedic surgery in children with CP. ■

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