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Functional Electrical Stimulation Therapy for Recovery of Reaching and Grasping in Severe Chronic Pediatric Stroke Patients

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Abstract

Stroke affects 2.7 children per 100,000 annually, leaving many of them with lifelong residual impairments despite intensive rehabilitation. In the present study the authors evaluated the effectiveness of 48 hours of transcutaneous functional electrical stimulation therapy for retraining voluntary reaching and grasping in 4 severe chronic pediatric stroke participants. Participants were assessed using the Rehabilitation Engineering Laboratory Hand Function Test, Quality of Upper Extremity Skills Test, Pediatric Evaluation of Disability Inventory, and Assisting Hand Assessment. All participants improved on all measures. The average change scores on selected Rehabilitation Engineering Laboratory Hand Function Test components were 14.5 for object manipulation ($P = .042$), 0.78 Nm for instrumented cylinder ($P = .068$), and 14 for wooden blocks ($P = .068$) and on the grasp component of Quality of Upper Extremity Skills Test was 25.93 ($P = .068$). These results provide preliminary evidence that functional electrical stimulation therapy has the potential to improve upper limb function in severe chronic pediatric stroke patients.

Keywords

functional electrical stimulation therapy, chronic, severe, stroke, grasping

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Every year on average, 2.7 children out of 100 000 are affected by stroke.[1] Twenty percent of these individuals will have a recurrent stroke. Many of them will have lifelong residual cognitive and/or physical impairments. For many decades, it was assumed that stroke is less devastating in children than in adults, not only as far as manifestation is concerned but also in relation to poststroke outcomes. However, a recent study by Steinlin[2] revealed that severity and outcomes of stroke in children and young adults are similar to those observed in adults. Two-thirds of children with stroke have neurological sequels, and the most dominant sequel is hemiparesis.[3] Ganesh et al[4] also reported that 42% of children who had stroke had residual neurological dysfunction in the form of hemiparesis.

Despite the participation in intensive rehabilitation programs, many of these individuals will continue to have high level of impairment in the upper limb,[5] which is very similar situation to the one already described in adult stroke population.[6] These residual impairments may have a negative impact on the child's emotional and social life.[7] The pediatric stroke patients often learn to cope with their physical impairments by excluding or neglecting the use of the hemiplegic upper limb. This frequently makes activities of daily living very difficult if not impossible, leading to a loss of independence.

Among the newer therapies that are being investigated in adult patients with hemiplegia, 1 of the most promising ones is functional electrical stimulation.[8-22] Functional electrical stimulation uses short bursts of electricity to create muscle contractions, which if sequenced properly can generate various body functions such as grasping, reaching and walking.[8,9] Functional electrical stimulation can be used in individuals with paralysis that resulted from an injury to the central nervous system, to generate body functions that these patients are unable to generate voluntarily. There are 2 approaches to functional electrical stimulation applications. In both approaches, functional electrical stimulation is used to create a

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Table 1. Demographics of the Study Participants.

Participant ID	Age at time of stroke (years)	Therapy administered following stroke (months)	Gender	Type of stroke
AAJR	11	14	Female	Left frontal parenchymal hemorrhage
AAJM	8	48	Female	Hypodensity of the left basal ganglia and internal capsule area
AAJH	9	51	Male	Diffusion of the left basal ganglia, left temporal and posterior parietal lobes
AAJI	6	84	Male	Right basal ganglia infarct with involvement of the caudate, putamen, and perisylvian region of the temporal lobe

neuroprosthesis that is able to generate a desired body function by properly sequencing contractions of different muscles. In 1 embodiment the neuroprosthesis is used as an orthosis that a patient has to use every day to be able to perform the desired function.[8,9] The second approach is to use the same neuroprosthesis as a short-term therapy (ie, functional electrical stimulation therapy) where the system is used to help the patient relearn how to control the limb voluntarily.[8,9] During functional electrical stimulation therapy the patient is trained on how to perform the desired body functions with the help of functional electrical stimulation, and with time the patient's central nervous system relearns how to perform the task on its own. The fundamental mechanism behind this therapy is neuroplasticity. Neuroplasticity enables uninjured parts of the central nervous system to relearn how to perform the motor function that was impaired or lost due to the neurological injury.

Clinical trials performed to date have shown that adult mild stroke individuals (Fugl-Meyer Upper Limb Function Scores $\geq$ 30) who received functional electrical stimulation therapy, both during early rehabilitation and in the chronic phase of their rehabilitation, often improved their grasping function to the point where they were able to perform the task voluntarily and no longer relied on a neuroprosthesis to perform these tasks.[10-21] Furthermore, clinical trials carried out by our team have also shown that adult severe stroke individuals (Fugl-Meyer Upper Limb Function Scores $\leq$ 15) and cervical level spinal cord injury individuals who received functional electrical stimulation therapy, both during early rehabilitation and in the chronic phase of their rehabilitation, often improved their reaching and/or grasping function to the point where they were able to perform the task voluntarily and no longer relied on a neuroprosthesis to perform these tasks.[22-27] At the present time literature review failed to identify any clinical trials in which functional electrical stimulation therapy was used to help improve upper limb function in pediatric stroke patients.

In the present study the authors applied Toronto Rehabilitation Institute's functional electrical stimulation therapy for reaching and grasping to chronic severe pediatric stroke patients. The authors hypothesized that the functional electrical stimulation therapy would be able to significantly improve voluntary upper limb function in chronic severe pediatric stroke patients as measured by the Rehabilitation Engineering Laboratory Hand Function Test.[26]

Methods

Study Design

This study describes results of a "before and after" trial with 4 severe chronic pediatric stroke patients, 2 male and 2 female, who had suffered a stroke between the ages of 6 and 11 years.

Inclusion/Exclusion Criteria

The inclusion criteria were (1) hemiplegia due to single stroke at least 1 year prior to the date of recruitment to the study; (2) severe hemiplegia with in ability to use the affected arm and hand for functional activities; (3) may or may not have any motor function preserved in the arm; (4) the upper limb muscles of interest must respond to electrical stimulation, that is, the authors must be able to evoke desired limb movements using functional electrical stimulation; and (5) ability to understand and follow instructions in English.

The exclusion criteria were (1) fixed contractures of the hand and wrist, (2) serious cognitive or psychological impairments, (3) presence of a skin rash at potential electrode site, (4) cardiac pacemaker, (5) shoulder hand syndrome, and (6) loss of proprioception as assessed using the Thumb Localization Test.

Study Population

Four pediatric stroke patients and their families that met inclusion criteria were invited to participate in the study. The conditions, risks, and benefits of the study were explained to the child and his or her legal guardian(s). To participate in this study a letter of consent was signed by legal guardian(s) of the participant. All 4 participants were 13 years of age at the time of recruitment. In 3 participants stroke involved the dominant hemisphere, and in the remaining participant the stroke involved the nondominant hemisphere. All 4 participants had history of a single stroke resulting in hemiplegia. The participants had a stroke between 14 and 84 months prior to the time of recruitment, by which time generally the recovery of upper extremity function is considered to have plateaued.[28] Motor function of the upper extremity was severely impaired in all participants and showed the typical flexor synergy pattern. All participants demonstrated increased resistance to passive stretch in the distal flexor musculature, and were not able to use their paretic upper limb for functional activities. Demographics of study participants are summarized in Table 1.

Ethics approval was obtained from Research Ethics Boards at the Toronto Rehabilitation Institute and Holland Bloorview Kids Rehabilitation Hospital, that is, at the site where the study was designed and the site where the study was conducted, respectively. Participants were

recruited at the Holland Bloorview Kids Rehabilitation Hospital in Toronto. The stroke was confirmed with a diagnostic imaging study (computed tomography scan or magnetic resonance imaging).

Intervention

In this case series all 4 chronic participants were trained with a multichannel transcutaneous functional electrical stimulation system developed by our team.[29] The functional electrical stimulation therapy was delivered during task-oriented activities for reaching and grasping. None of the study participants were receiving any other form of therapy at the time of participation in the study. The participants were trained using functional electrical stimulation therapy to reach, grasp, and manipulate various objects (as described in Thrasher et al[26]) encountered in activities of daily living.

Participants received 1 hour of functional electrical stimulation therapy 3 times per week for 16 weeks (48 sessions in total). This treatment regiment (stimulation protocols as well as the therapy dose and frequency) was selected as it has previously demonstrated good outcomes in chronic severe adult stroke patients.[22,26,27] Since this treatment regiment was applied for the first time in pediatric population, the authors had no prior knowledge whether or not the participants would accept this protocol or if they would be compliant with it. The Compex Motion electric stimulator (Compex SA, Switzerland) was used to deliver the transcutaneous functional electrical stimulation therapy.[29] The Compex Motion stimulator is a programmable functional electrical stimulation system that uses standard self-adhesive surface stimulation electrodes and produces well-regulated current stimulation pulses that minimizes discomfort during stimulation.[29] Throughout the therapy program the participants tolerated the stimulation well and had excellent compliance with the therapy program.

The muscles stimulated were anterior and posterior deltoid, biceps and triceps brachii, flexor digitorum superficialis and profundus, extensor digitorum, the median nerve to stimulate the muscles of the thenar eminence, and lumbrical and interossei. Stimulus parameters used to stimulate the muscles and nerves were symmetrical biphasic current pulses with the pulse duration of 250 microseconds and a ramp up and ramp down times of between 0.5 to 2 seconds. The stimulus frequency was 40 Hz. Protocols used in this study are described in detail elsewhere.[22,26] The therapy consisted of preprogrammed coordinated muscle stimulation, and manually assisted externally generated passive motion to establish physiologically correct movement patterns.

Prior to a movement, the participants were asked to imagine that specific movement and were asked to try to carry out that movement themselves. After they were given this instruction the patients would "strain" both mentally and physically to execute a given task. The therapists would allow the participant to "strain" and try to perform the task for 10-20 seconds. Only after the participant had tried sufficiently long to carry out the task himself or herself was functional electrical stimulation triggered to help execute the task. This period of trying and applying conscious effort to reach, grasp, and manipulate objects is an essential aspect of the therapy protocol, in addition to sophisticated stimulation protocols.

Since the neuromuscular recovery in stroke patients starts proximally followed by the recovery of the distal parts, our training started with stimulation of shoulder and elbow extensor and flexor muscles, while the patient (assisted by the therapist) performed motions such as (1) touch nose, (2) touch opposite shoulder, (3) touch forehead, (4) move arm forward, (5) lift arm left side up, and (6) lift arm left side up and extend elbow. Only after the participants mastered the voluntary control over their shoulder and elbow did therapists proceed with the stimulation of the forearm muscles, that is, distal parts of the arm. Distal stimulation was focused at restoring voluntary control over the wrist and fingers, and consisted of the following movements that were assisted by the functional electrical stimulation system: (1) hand opening, (2) palmar grasp, (3) pinch grasp, (4) lateral pinch grasp, and (5) lumbrical grasp.

During the treatment, a therapist controlled the delivery of electrical stimulation to produce arm and hand movements using a push button. During the movement, the occupational therapist guided the arm and fingers, and assisted the patient with the neuroprosthesis in performing the desired task. This assistance ensured that all movements were carried out in a correct physiological manner. In the early sessions the tasks were performed by the combination of muscle stimulation and therapist's assistance. As the participants improved, the therapist assistance was reduced to the necessary minimum followed by reducing functional electrical stimulation assistance to the necessary minimum. Frequently at the end of the therapy therapists did not need to stimulate many muscles and muscle groups involved in carrying out reaching and grasping tasks. Stimulation protocols were adjusted biweekly. Participants were asked to repeat same task 10+ times for each motion during a single treatment session.

Outcome Measures

Each participant underwent a battery of assessments at baseline (ie, before they started treatment) and at discharge (ie, upon completion of 48 one-hour sessions). All assessments were performed by a researcher who was not involved in the delivery of the therapy.

The outcome assessments used were the following:

The Rehabilitation Engineering Laboratory Hand Function Test,[22,26] which is very responsive to functional electrical stimulation therapy, was used to assess gross motor function of the affected hand (this test is also referred to as the Toronto Rehabilitation Institute Hand Function Test; however, this subsequent version of the test is used to assess hand function in spinal cord injury population only, and has a different scoring system for object manipulation). This test has been used for hand assessment in the adult stroke population; however, its validity and reliability have not been studied in pediatric population.[22,26] The Rehabilitation Engineering Laboratory Hand Function Test has 5 outcome variables relating to the ability of the affected hand to perform the following tasks: (1) manipulate common household objects (itemized objects subtest)—maximum subtest score is 56, (2) pick up and release blocks of varying weight and surface properties (wooden blocks subtest)—maximum subtest score is 18, (3) produce axial torque on a cylinder with a palmar grasp (instrumented cylinder subtest)—maximum subtest score is 5 Nm, (4) produce a pinch force on a credit card using a lateral grasp to prevent it from slipping while card is pulled (instrumented credit card subtest)—maximum subtest score is 50 N, and (5) hold a cylindrical bar horizontally in a pronated palmar grasp with the center of mass of the bar at a varying distance from the hand in both the radial and ulnar directions (cylindrical bar subtest)—maximum subtest score is 60 cm.

The Quality of Upper Extremity Skills Test is an objective standardized measure evaluating the quality of upper extremity function in 4 domains: (1) dissociated movement, (2) grasp, (3) protective extension, and (4) weight bearing. This test was designed with minimal developmental sequencing so that scoring reflects the severity of the disability rather than age.[30]

Table 2. Mean Scores on Rehabilitation Engineering Laboratory Hand Function Test, Quality of Upper Extremity Skills Test, Pediatric Evaluation of Disability Inventory, and Assisting Hand Assessment With the *P* Values.

Test	Participants' average scores		*P* value
	Baseline	Postherapy	
Rehabilitation Engineering Laboratory Hand Function Test components			
Object manipulation	4.75	19.25	.042
Wooden blocks	4	18	.068
Instrumented cylinder torque values (Nm)	0.27	1.05	.068
Instrumented credit card force values (N)	14.75	27.25	.273
Wooden bar thumb direction length values (cm)	2.5	17.25	.109
Wooden bar little finger direction length values (cm)	3.75	10	.180
Quality of Upper Extremity Skills Test components			
Dissociated movements	25.77	44.52	.144
Grasp	11.10	37.03	.068
Weight bearing	1	6	.102
Protective extension	0	6.92	.180
Pediatric Evaluation of Disability Inventory			
Self-care functional skills	89.07	92.75	.180
Self-care caregiver assistance and modification	86.33	96.56	.276
Assisting Hand Assessment			
Sum score	53.5	57.25	.144
Scaled score	47.75	53.25	.144

Table 3. Individual Participant Scores at Baseline and Discharge (16 weeks of therapy) on Various Components of the Rehabilitation Engineering Laboratory Hand Function Test.

	Object manipulation		Wooden blocks		Instrumented cylinder		Instrumented credit card		Wooden bar thumb		Wooden bar little finger	
Subject	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
AAJR	2	17	0	18	0	0.5	9	16	0	9	0	0
AAJM	6	15	3	18	0	0.1	15	35	0	0	0	0
AAJH	6	25	11	18	1	2.5	25	11	10	30	15	30
AAJI	5	20	2	18	0.1	1.1	10	47	0	30	0	10

The Pediatric Evaluation of Disability Inventory is a validated tool used to determine how the individual patient and his or her primary caregiver view the patient's quality of life.[31] These same questionnaires were given to the participant and his or her primary caregiver at baseline and after the treatment to determine if the functional electrical stimulation therapy had altered the patient's quality of life. Scaled scores were used for data analysis as there is literature to support minimally clinically significant difference using scaled scores. An 11-point change on the scaled scores is indicated as minimally clinically significant difference.[32]

The Assisting Hand Assessment Test is intended for use in children who have 1 well-functioning and 1 dysfunctioning hand, influencing their performance on bimanual occupations. The test intends to measure how effectively a child uses his or her assisting hand in meaningful and common occupations (the affected hand in bimanual play participation, that is, using and maintaining toys requiring the use of 2 hands).[33]

Results

Four severe pediatric chronic stroke individuals were recruited in this study. All 4 completed baseline and discharge assessments. Participant demographics are listed in Table 1. The authors measured improvement using the Rehabilitation Engineering Laboratory Hand Function Test as the primary outcome measure and using the Quality of Upper Extremity Skills Test, Pediatric Evaluation of Disability Inventory, and Assisting Hand Assessment Test as secondary outcome measures. The baseline and posttherapy scores on all measures were compared using the Wilcoxon signed-rank test (SPSS version 19).

All 4 participants tolerated the treatment well, and no adverse events were recorded during the course of therapy sessions for any of the participants.

All participants improved their hand function as measured by the Rehabilitation Engineering Laboratory Hand Function Test (Tables 2 and 3). The authors found statistically significant improvements on the itemized objects subtest of the Rehabilitation Engineering Laboratory Hand Function Test ($P = .042$) and the improvements on the wooden blocks ($P = .068$) and the instrumented cylinder ($P = .068$) subtests approached statistical significance. However, the scores on the instrumented credit card and eccentric loading subtest were not statistically significant.

Table 4. Individual Participant Scores at Baseline and Discharge (16 weeks of therapy) on Various Components of the Quality of Upper Extremity Skills Test.

	Dissociated movements		Grasp		Weight bearing		Protective extension	
Subject	Pre	Post	Pre	Post	Pre	Post	Pre	Post
AAJR	43.7	40.6	18.51	33.34	0	0	0	0
AAJM	28.12	62.5	0	48.14	0	4	0	22.2
AAJH	31.26	53.12	25.92	37.03	4	12	0	5.5
AAJI	0	21.87	0	29.62	0	8	0	0

Table 5. Individual Participant Scores at Baseline and Discharge (16 weeks of therapy) on Paediatric Evaluation of Disability Evaluation Inventory (Scaled scores) and Assisting Hand Assessment.

	Paediatric Evaluation of Disability Evaluation Inventory				Assisting Hand Assessment			
	Self-care functional skills		Self-care caregiver assistance		Sum score		Scaled score	
Subject	Pre	Post	Pre	Post	Pre	Post	Pre	Post
AAJR	93	93	NA	NA	52	57	45	53
AAJM	93	100	100	89.7	58	57	55	53
AAJH	77.3	85	79.5	100	61	63	59	62
AAJI	93	93	79.5	100	43	52	32	45

Similar results were seen on all of the secondary measures (Tables 2, 4, and 5). All 4 participants improved on all domains of all secondary measures. However, due to the small sample size none of the measures reached statistical significance, except the grasp subcomponent of the Quality of Upper Extremity Skills Test scale.

Mean scores before and after therapy on each of the primary and secondary outcome measures are presented in Table 2. Note that since the total number of subjects enrolled in this study was limited, one should not overinterpret results of the statistical analysis. The purpose of this analysis was to show that the changes achieved, in particular with the Rehabilitation Engineering Laboratory Hand Function Test, were considerable and that they cannot be attributed to measurement error.

Discussion

This case series examined the efficacy of the functional electrical stimulation therapy as a clinical intervention for the purpose of treating severe unilateral upper extremity paralysis that resulted from chronic hemiplegia in children. The authors found considerable improvements in all 4 study participants on the primary outcome measure, that is, the Rehabilitation Engineering Laboratory Hand Function Test, and grasp component of the Quality of Upper Extremity Skills Test (one of the secondary outcome measures). The difference in scores between baseline and discharge on the Rehabilitation Engineering Laboratory Hand Function Test was clinically relevant. Furthermore, the difference in scores between baseline and discharge was also statistically significant for the itemized objects subtest and approached statistical significance on the wooden blocks and instrumented cylinder subtests, albeit with a very small sample size. The individual pre-post differences in scores on all measures very clearly demonstrate improvement in voluntary hand function following functional electrical stimulation therapy.

The results provide preliminary evidence that rehabilitation treatment consisting of repetitive functional electrical stimulation therapy designed to improve arm and hand function has potential to promote recovery of voluntary grasping function in children with chronic severe hemiplegia. The results also suggest that functional electrical stimulation therapy lead to subsequent improvements in the quality and complexity of tasks the participants were able to execute with their hands following study completion.

Although the results of our study are very encouraging, the study has certain limitations which should be acknowledged and discussed. The study is a single-arm non–randomized control trial with no control group. This makes it difficult to comment on comparative improvements that could have been achieved if the participants were administered a same dose of conventional occupational therapy instead of functional electrical stimulation therapy. However, the authors have to acknowledge that the children who decided to take part in our study did so because they all already reached plateau in recovery, and at the point in time when they joined our program the conventional therapy was not helpful to them any longer. Second, the sample was a small sample of convenience, and hence the results should be generalized to the entire population with caution. However, it is noteworthy that all 4 of the study participants had severe upper extremity involvement and even though the sample size was small the authors obtained statistically significant differences before and after therapy. These findings are very similar to those our team achieved previously

with adult severe stroke patients and because of that the authors believe that the presented findings warrant a larger scale randomized control trial in this patient population.

The current rehabilitation model is strongly influenced by the traditional view that significant improvements in motor recovery occur only within the first year after stroke.[28] However, recent studies have shown that intensive therapeutic training, such as constraint induced movement therapy, can significantly improve functional use of the affected arm in individuals who are more than a year poststroke and have mild residual paralysis. Intensive use of the hemiparetic hand has been associated with cortical reorganization in primates as well as in individuals with stroke.[34] Although research suggests that constraint induced movement therapy can enhance motor function and cortical reorganization, it is only effective in patients with mild impairment (patients who are already able to extend the fingers and wrist before they join the therapy program).[35] Constraint induced movement therapy was not able to show improvements in subacute and chronic severe stroke patients.

Literature review showed that the outcome poststroke in pediatric population is poor for about half of the patient population, and that all children with poor outcome have neurological deficits.[36-39] The fact that our functional electrical stimulation therapy was able to elicit considerable and clinically relevant improvements in hand function in chronic severe stroke patients, both adult[22,27] and pediatric, suggests that this therapy may be effective in severe chronic stroke population. This finding is further strengthened by the fact that the proposed therapy has been already found effective in subacute severe adult stroke patients.[26] The findings of this study also suggests that this therapy potentially has a much broader application in the stroke population than constraint induced movement therapy, which is currently considered best practice.

The mechanism of recovery in stroke, induced by functional electrical stimulation therapy, can be attributed to neurological recovery such as an increase in muscle controllability, better synchronization of different muscle groups, reduction in tone, and reactivation of previously inactive muscle groups.[22,26,27] The authors also have strong evidence that the repetitive application of functional electrical stimulation therapy promotes neural plasticity.[22,26,27]

The results of our research to date[22,26,27] indicate that the following practices with Toronto Rehab's functional electrical stimulation therapy are useful toward maximizing recovery: (1) application of individualized functional electrical stimulation protocols that are monitored and adjusted by an occupational therapist on a regular basis and (2) functional electrical stimulation therapy incorporated with functional tasks typically performed in activities of daily living. Our long-term follow-ups with subacute incomplete SCI individuals suggest that the results of the functional electrical stimulation therapy are long-lasting and persist undiminished for months and years following discharge.[23,24]

Among clinical rehabilitation experts it is commonly believed that motor improvement plateaus at 12 months poststroke[5,28] and that one should not expect significant improvements thereafter. However, the results of this study clearly suggest that this assumption may be incorrect both for severe pediatric and adult stroke patients, and that further studies are warranted with larger sample sizes to demonstrate beyond doubt that the functional electrical stimulation therapy for reaching and grasping is able to improve upper limb function in chronic pediatric stroke individuals.

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Author Contributions

MKN, PR, and MRP made substantial contribution in the areas of therapy development and conceptualizing and design of the study. NMK and VZ wrote the first draft of the manuscript. JB and JW contributed to the selection of outcome assessments and to data acquisition. NMK performed data analysis and interpretation. MRP, VZ, and NMK were involved in revising the manuscript for intellectual content. All other authors contributed to proofreading and approved the final version of the article.

Declaration of Conflicting Interests

All authors, except for Dr Popovic and Naaz Kapadia, declared no potential conflicts of interest with respect to the authorship and/or publication of this article. Dr Popovic is a shareholder in the company Simple Systems Inc, which intends to develop and manufacture functional electrical stimulation–based devices in the near future. Naaz Kapadia is a paid consultant working for Simple Systems Inc.

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Ethical Approval

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