

EVALUATING THE CHANGES IN THE SPATIOTEMPORAL PARAMETERS OF GAIT WITH TONE INHIBITING ANKLE FOOT ORTHOSIS IN CEREBRAL PALSY

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Article Info: Received 28 February 2020; Accepted 24 March 2020

DOI: <https://doi.org/10.32553/ijmbs.v4i3.1062>

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Conflict of interest: No conflict of interest.

Abstract

Background: Tone inhibiting AFO can be there by an effective, non-invasive method of controlling deformity and reducing hypertonus of contracture musculature. This study explores the hypothesis that by reducing the instinct deforming reflexes, deformity can be corrected as well gait can be improved.

Methods: Prospective study conducted on all patients with cerebral palsy admitted to the dept. of PMR, SMS Medical College, Jaipur, who fulfill eligibility criteria and have given written informed consent, was included and evaluated.

Results: In our study phase duration increased in every phase of TUG test. During sit to stand mean change in phase duration was 0.245 ± 1.012 ($p=0.505$), during mid turn mean change in phase duration was 0.583 ± 2.998 ($p=.279$), during end turning mean change was 0.04 ± 2.24 ($p=0.925$) and during stand to sit phase mean change was 0.103 ± 0.862 ($p=0.505$).

Conclusion: Our study showed improvement in distance covered by patients with TIAFO which is statistically non significant through Six Minute Walk Test which exhibits the improvement in energy efficient walking.

Keywords: Cerebral palsy, TUG test, Six Minute Walk Test.

Introduction

Cerebral palsy (CP) describes a group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing fetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, perception, cognition, communication, and behaviour, by epilepsy, and by secondary musculoskeletal problems.¹

Cerebral palsy (CP) is in many ways the prototype for developmental neurodisability. A relatively prevalent condition, with an incidence of 2 to 2.5 per 1000 live births in the Western world², it is the most common cause of physical disability in children. Presenting early in life (usually in the first 2 years of a child's development), this 'Litter's disease' is a lifelong condition with which young people grow into adulthood³. Due to better care now a days is associated with a very low mortality rate in the developed countries of the world⁴.

The goal of treatment in motor disability is to alleviate associated motor impairments such as spasticity and contracture. Treatment is directed towards improving symptoms not only at the impairment level but also at improving function. Improving activity and participation are the major priority, but interventions that maintain the

status quo or minimize further deformity or disability are also beneficial.

The current standard of care for the motor disorders in CP consists of regular physical therapy, followed by multiple, and often concurrent, medical and surgical interventions, most intensively in early childhood through preadolescence.

Modification of central nervous system activity by peripheral management has become a well established basis for the physical therapy and orthotic intervention techniques.

For deformities described above, the instinct reflexes can be inhibited by spraying the skin with ethyl chloride, by denervating the reflexogenous area. Second method is counter stimulation of a reflex that is antagonistic to the deforming reflex.⁵

Tone inhibiting AFO can be there by an effective, non-invasive method of controlling deformity and reducing hypertonus of contracture musculature. This study explores the hypothesis that by reducing the instinct deforming reflexes, deformity can be corrected as well gait can be improved.

Materials and Methods:

Study Area: Patient with cerebral palsy admitted in the department of Physical Medicine and Rehabilitation, SMS Hospital, Jaipur.

Study Type: Interventional Study without control (Before & after Study).

Study Design: Prospective study.

Duration: September 2018 to December 2019

Material used:

- G- Sensor (BTS Bioengineering Italy) to calculate the gait parameters.
- Tone inhibiting AFO which has following characteristics:
- An internal heel will be added to unweigh the ball of the foot.
- A metatarsal arch will be added to unweigh the metatarsal heads
- A toe crest will be added at PIP joints to unweigh the metatarsal heads at late stance phase and extend MP joints to inhibit reflex hypertonicity.



Inclusion criteria:

- Age: 3 years to 16 years
- Cerebral Palsy patients with GMFCS-ER Level 1/2/3
- Patient with spastic diplegia/ monoplegia/ hemiplegia
- Cerebral Palsy with spasticity of grade 1, 1+, 2 or 3 on MAS score in any one lower limb or both lower limb.
- Those patients of cerebral palsy who are taking tablet baclofen and will not require any titration of dose during study period.

Exclusion criteria:

- Cerebral Palsy patients with GMFCS-ER Level 4/5.
- Patient with spasticity grade 4 on MAS score
- Patient with fixed deformity.
- Patient who has gone through denervation previously for spasticity.
- Patient suffering from any other movement disorder like dystonia, chorea, etc.
- Those patients of cerebral palsy who are taking tablet baclofen and require titration of dose during study period.

Methodology:

- All patients with cerebral palsy admitted to the dept. of PMR, SMS Medical College, Jaipur, who fulfill eligibility criteria and have given written informed consent, was included and evaluated.
- Tone Inhibiting AFO measurement was done at the workshop of RRC.

- Measurement of spatiotemporal parameters of gait without Tone Inhibiting AFO with waist wearing G-Sensor was done.

Follow up:

Patients were assessed after 6 weeks from baseline test with G-Sensor. During this period all children are allowed to walk with Tone Inhibiting AFO and also received routine physiotherapy and standard care.

Sample size:

Sample size is calculated at 80% study power and alpha error of 0.05 assuming standard deviation of 13.96 cm in stride length as per result of seen articles. For minimum detectable mean difference of 10cm in stride length. 32 patient of CP are required as sample size which is further enhanced and rounded off to 40 patients as final sample size expecting 20% drop out / loss to follow up / attrition.

Statistical analysis:

Statistical analysis was done using computer software (SPSS trial version 23 and primer) the qualitative data was expressed in proportion and percentages and the quantitative data expressed as mean and standard deviations. The difference in proportion was analyzed by using chi square test and the difference in means was analyzed by using student T Test or paired T test. Significant level for tests was determined as 95% ($p < 0.05$)

Results:

Table 1: Distribution of the cases according Socio-demographic variable

Mean age	6.39±3.252
Male : female	18:14

As per the age group, 50% of the cases belong to 5 to 10 years of age followed by 34.38% of cases belong to less than 5 years of age and so on. The mean \pm SD value for the age group was 6.39 \pm 3.252. As per the gender, 56.25% of the cases belong to Males followed by 43.75% of cases belong to Females.

Table 2: Distribution of the cases according to diagnosis

Diagnosis	No.	Percentage (%)
Diplegic CP	28	87.5
Lt Hemiplegic CP	2	6.25
Rt Hemiplegic CP	1	3.125
Tetraplegic CP	1	3.125
Total	32	100

As per the diagnosis, 87.5% of the cases belong to Diplegic CP followed by 6.25% of cases belong to Lt Hemiplegic CP and so on.

Table 3: Mean of gait parameters by six minutes walking test with and w/o TIAFO

		Mean	No.	Std. Deviation	Std. Error Mean
Distance (m)	With TIAFO	96.094	32	43.8497	7.7516
	Without TIAFO	83.781	32	55.1805	9.7546
GSI	With TIAFO	94.109	32	6.0272	1.0655
	Without TIAFO	91.053	32	17.3672	3.0701
Speed (m/s)	With TIAFO	.462	32	.2145	.0379
	Without TIAFO	.473	32	.2727	.0482
Cadence (steps/m)	With TIAFO	114.450	32	19.3635	3.4230
	Without TIAFO	114.419	32	28.7214	5.0773
Stride Length (m)	With TIAFO	.497	32	.2022	.0358
	Without TIAFO	.4903	32	.26955	.04765

The above table depicts the mean as per six minutes walking test, Distance (m) with TIAFO 96.094 \pm 43.8497 and without TIAFO 83.781 \pm 9.7546, GSI with TIAFO 94.109 \pm 6.0272 and without TIAFO 91.053 \pm 17.367; Speed (m/s) WITH TIAFO .462 \pm .2145 and without TIAFO .473 \pm .2727; Cadence with TIAFO 114.450 \pm 19.3635 and w/o TIAFO 114.419 \pm 28.7214; Stride length with TIAFO .497 \pm .2022 and w/o TIAFO is 0.4903 \pm 0.26955.

Table 4: Mean Change of gait parameters by SMWT with and w/o TIAFO

SIX MINUTES WALKING TEST WITH TIAFO/- SIX MINUTES									
Paired Samples Test									
	Paired Differences					t	df	Sig. (2-tailed)	
	Mean Difference	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference					
				Lower	Upper				
DISTANCE (m) WITH TIAFO -W/O TIAFO (m)	12.31	57.69	10.20	-8.49	33.11	1.207	32	.236	
SPEED (m/s) WITH TIAFO – W/O TIAFO (m/s)	-0.01	0.30	0.05	-0.12	0.10	-.204	32	.840	
CADENCE WITH TIAFO (steps/m) – W/O TIAFO (steps/m)	0.03	29.71	5.25	-10.68	10.74	.006	32	.995	
STRIDE LENGTH (m) WITH TIAFO – W/O TIAFO	0.01	0.30	0.05	-0.10	0.12	.136	32	.893	

The above table depicts mean difference of gait parameters with TIAFO and without TIAFO through Six Minute Walk Test. Mean difference of distance is 12.31 \pm 10.20 with p value of 0.236 which exhibits no significant differences among the pre and post data.

Mean difference of speed is 0.01 \pm .05 with p value of 0.840 which exhibits no significant difference among pre and post data.

Mean difference of cadence is 0.03 \pm 5.25 with p value of 0.995 which exhibits no significant difference among the pre and post data.

Mean difference of stride length is 0.01 \pm .05 with p value of 0.893 which exhibits no significant difference among the pre and post data.

Table 5: Mean change of gait parameters by Tug test during sit to stand

Paired Samples Test								
	Paired Differences					t	df	Sig. (2-tailed)
	Mean Change	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
WITH TIAFO Phase Duration- W/O TIAFO Phase Duration	.247	1.012	.179	-.118	.612	1.380	32	.177
WITH TIAFO Antero Posterior Acceleration – W/O TIAFO Antero Posterior Acceleration	.003	4.061	.718	-1.467	1.461	-.004	32	.997
WITH TIAFO Lateral Acceleration – W/O TIAFO Lateral Acceleration	.656	4.778	.845	-2.379	1.066	-.777	32	.443
WITH TIAFO Verticle Acceleration – W/O TIAFO Verticle Acceleration	.306	6.693	1.183	-2.107	2.719	.259	32	.797

The above table depicts mean differences in different gait parameters with TIAFO and without TIAFO through TUG test. Mean difference of AP acceleration is 0.003 \pm .718 with p value of .997 which exhibits no significant difference among the pre and post data.

Mean difference of Lateral acceleration is $0.656 \pm .845$ with p value of .443 which exhibits no significant difference among the pre and post data.

Mean difference of Vertical acceleration is 0.306 ± 1.183 with p value of .797 which exhibits no significant difference among the pre and post data.

Table 6: Mean change in gait parameters by Tug test during stand to sit phase

	Paired Differences							t	df	Sig. (2-tailed)
	Mean Change	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference						
				Lower		Upper				
WITH TIAFO Phase Duration-W/O TIAFO Phase Duration	.103	.862	.152		-.208		.414	.675	32	.505
WITH TIAFO AP Acceleration – W/O TIAFO AP Acceleration	-.078	4.270	.755		-1.618		1.462	-.103	32	.918
WITH TIAFO Lateral Acceleration – W/O TIAFO Lateral Acceleration	.325	3.210	.567		-.832		1.482	.573	32	.571
WITH TIAFO Vertical Acceleration – W/O TIAFO Vertical Acceleration	-.766	7.863	1.390		-3.600		2.069	-.551	32	.586

Above table depicts the mean difference of different gait parameters with TIAFO and without TIAFO during stand to sit phase of TUG test

Mean difference of AP acceleration is $-0.078 \pm .755$ with p value of .918 which exhibits no significant difference among the pre and post data.

Mean difference of Lateral acceleration is $-0.325 \pm .567$ with p value of .571 which exhibits no significant difference among the pre and post data.

Mean difference of Vertical acceleration is -0.766 ± 1.390 with p value of .586 which exhibits no significant difference among the pre and post data.

Table 7: Mean Change in gait parameters by TUG Test during Mid turning phase

	Paired Differences					t	df	Sig. (2-tailed)
	Mean Change	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
With TIAFO Phase Duration – W/O TIAFO Phase Duration	.583	2.998	.530	-.497	1.664	1.101	32	.279NS
With TIAFO Maximum Duration Speed – W/O TIAFO maximum Duration Speed	-4.850	74.077	13.095	-31.558	21.858	-.370	32	.714NS
With TIAFO Average Rotation Speed – W/O TIAFO Average Rotation Speed	9.894	81.751	14.452	-19.581	39.368	.685	32	.499NS

Above table depicts the mean difference of different gait parameters with TIAFO and without TIAFO during mid turning phase of TUG test.

Mean difference of Maximum Duration Speed is -4.850 ± 13.095 with p value of .714 which exhibits no significant difference among the pre and post data.

Mean difference of Average Rotation Speed is 9.894 ± 14.452 with p value of .499 which exhibits no significant difference among the pre and post data.

Table 8: Mean Change in gait parameters by TUG Test during End Turning Phase

	Paired Differences					t	df	Sig. (2-tailed)
	Mean Change	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Phase Duration with TIAFO – Phase Duration w/o TIAFO	.04	2.24	.40	-.77	.85	.095	32	.925
Maximum Duration Speed with TIAFO -Maximum Duration Speed w/o TIAFO	-8.40	72.38	12.80	-34.49	17.70	-.656	32	.517
Average Rotation Speed with TIAFO – Average Rotation Speed w/o TIAFO	-1.30	33.13	5.86	-13.25	10.64	-.222	32	.825

Above table depicts the mean difference in different gait parameters with TIAFO and without TIAFO during end turning phase of TUG test.

Mean difference of Maximum Duration Speed is -8.4 ± 12.8 with p value of .517 which exhibits no significant difference among the pre and post data.

Mean difference of Average Rotation Speed is -1.3 ± 5.86 with p value of .825 which exhibits no significant difference among the pre and post data.

Discussion

Cerebral palsy (CP) is not a single disease entity with a known causal pathway, but is instead a heterogeneous group of disorder with varying etiologies, brain injury patterns, and associated health conditions. Most children with cerebral palsy have a deviating gait pattern. This is often caused by muscles imbalance resulting from a combination of spasticity of agonist and antagonist muscles.

In our study we have observed the change in the gait parameters with tone inhibiting AFO in cerebral palsy patient. The principal concerns is to provide good heel alignment, and reduction of contact and pressure in the reflexogenous area of overactive tonic reflex.

We took 32 children with cerebral palsy and measured the difference between gait parameters of two group with and without TIAFO by using Six Minute Walk Test and TUG Test .

Energy efficient walking is a major goal of treatment in children with CP. Distance covered by six minute walk test has been used as a measure of the energy efficient walking of patients. In our test we found there was improvement in distance covered by patients with mean difference of 12.31 ± 10.20 although it is non significant ($p=0.236$). Crenshaw et al⁶ also reported that the addition of tone reducing properties to a standard articulating AFO yielded no significant functional changes in the gait of children with spastic diplegia which is similar to the result of our study.

Ferdous wahid et al⁷ studied gait parameters in cerebral palsy patients by using multiple regression equations to identify gait differences in children with CP walking without AFOs , children with CP wearing AFOs , and healthy controls. They observed that gait data with stride length, cadence , in children with cerebral palsy wearing AFO's was closer to those of the control subjects and there difference was non significant.

Radka et al⁸ compared the effects of Dynamic Ankle Foot Orthosis (DAFO) with Planter Flexor stop , propylene AFO and no AFOs on the gait of children with CP. They found that there was no difference in gait variables for the two orthosis. Twelve children with spastic diplegic CP wore no AFOs for an initial 2-week period, solid AFOs for 1 month, no AFOs for 2 weeks, and hinged AFOs for 1 month. No significant differences were found for the gait variables when comparing these orthoses.

Shin et al⁹ studied the AFO for tonic toe flexion reflex used to prevent deformity and to support normal joint alignment. They found that the use of a toe spreader during gait, as compared with walking barefoot, didn't produce a statistically significant increase in all temporal-distance gait variables.

Stephenic Crenshaw et al⁶ studied the effects of tone-reducing features in ankle-foot orthotics (AFOs) on the gait of eight children (ages 4-11 years) with spastic diplegic cerebral palsy. A standard gait analysis was performed on each subject .A 4-week accommodation period was allotted for each of the three devices: a standard hinged AFO, an AFO with tone-reducing features, and a supramalleolar orthotic with tone-reducing features. They found no significant functional changes in gait with the addition of tone-reducing properties to a standard articulating AFO.

Aileen ibuki et al¹⁰ conducted study on 15 adult subjects with stroke who were recruited from the community. Custom-made articulated ankle-foot orthoses (AFOs) and TRAFOs (Tone Reducing Ankle Foot Orthosis) with orthokinetic compression garments (OCGs) were fabricated for each subject. Five conditions were tested: (1) Shoes only, (2) AFO, (3) TRAFO, (4) TRAFO with OCG, (5) shoes only, to determine if the TRAFOs were most effective in decreasing spasticity .The results demonstrated that the tone-reducing devices had no significant neurophysiologic effect on spasticity.

Above studies shows the similar result to our study in which change in gait parameters were statistically not significant [cadence 0.03 ± 29.71 ($p=0.995$) , speed -0.01 ± 0.30 ($p=0.840$) , stride length 0.01 ± 0.30 ($p=0.893$)].

Time Up and Go test is designed to measure functional balance, which is an element of postural control, allows a child to perform activities of daily living, social activities , and recreational activities at home, school and in the community. Therefore secondary objective of this study was to evaluate balance parameters through TUG test. Main parameter in

TUG test is phase duration which determined the functional balance. Shorter times indicates better functional balance. In our study phase duration increased in every phase of TUG test. During sit to stand mean change in phase duration was 0.245 ± 1.012 ($p=0.505$), during mid turn mean change in phase duration was 0.583 ± 2.998 ($p=.279$), during end turning mean change was 0.04 ± 2.24 ($p=0.925$), and during stand to sit phase mean change was 0.103 ± 0.862 ($p=0.505$) .

Although there was increased in phase duration in TUG test by using TIAFO but this was non significant. This may be due to lack of training to cerebral palsy patients at hospital. Michal Katz Leurer¹¹ et al also founded the non significant difference in phase duration by TUG test in cerebral palsy patients using orthotics and shoes , which they compared in post-TBI patients.

Conclusion

Tone Inhibiting AFO is a non invasive method of controlling deformity and reducing hypertonicity of muscles in cerebral palsy patients and there by improve energy efficient walking and functional balance , which is the major goal in the

treatment of such patients. Our study showed improvement in distance covered by patients with TIAFO which is statistically non significant through Six Minute Walk Test which exhibits the improvement in energy efficient walking.

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