Comparative Impact Study between Two Different Orthotic Clinical Approaches of Shank Vertical Angle Alignment on GRF Vectors and Activation Profile of Tibialis Anterior in Subjects with Post Stroke Hemiplegic using Solid Ankle Foot Orthosis: A Prospective Study

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ABSTRACT

Background: Stroke is defined as the sudden onset of a focal neurologic deficit due to a presumed local disturbance in the blood supply to the brain. Orthotic treatment protocol in post stroke hemiplegic patients still is controversial topic. Numerous previous studies are concentrated upon providing the posterior heel wedge in outer side mainly with footwear's heel rising associated with molded Solid Ankle Foot Orthosis (SAFO) but this is an attempt of this study to check the effects of insole posterior heel wedge as well as outsole posterior heel wedge in SAFO on temporal and kinetic gait parameters and activation profile of tibialis anterior muscle in post stroke hemiplegic patients.

Aim & Objectives: The aim of the study was to compare between insole and outsole posterior heel wedge in molded solid ankle foot orthosis on working efficiency and activation profile of tibialis anterior muscle of the subject with post stroke hemiplegia.

Materials and Methods: 30 subjects with post stroke hemiplegia were included in this study by convenient sampling method. The subjects were given with solid ankle foot orthosis with insole and outsole posterior heel wedge. The temporal and kinetic gait parameters and EMG of T.A muscle was measured using eWalk-NILD (MAT), Force plate and AD instrument power Lab. All the measurements were acquired at the time of measurement (Baseline data), time of discharge (Pre data) and after 4 weeks Post data was taken.

Results: Pre-post conditions GRF Fx,Fy,Fz have significantly differences. Some parameters also have the non-significant differences. For all the cases to assist the parameters pre and post condition associated with and without AFO with insole posterior heel wedges on Group A and outsole Posterior heel wedge on Group B values are respected for GRF Fx pre without AFO (p=.147), pre with AFO (p=.037) and post without AFO (p=.253) with AFO (p=.009) For Fy pre without and with AFO (p=.025), (p=.682), post without and with AFO (p=.000), (p=.524) in case of Fz pre without and with AFO (p=.0759), (p=.999) post without and with AFO (p=.117), (p=.404). On TA muscle profile have also significant differences between two groups on pre without and with AFO (p=.005), (p=.613) and post without and with AFO (p=.000), (p=.000).

Discussion & Conclusion: As per present perspective clinical evident report it is concluded that molded SAFO with outsole posterior heel wedge have a significance impact for positive influences on GRF, without any deficit contraction (EMG signal) of T.A. muscle profile, as compare to insole posterior wedge with AFO.

Keywords: Hemiplegic, Gait kinetic parameters, Molded ankle foot orthosis, Insole and Outsole Posterior Heel Wedge.

INTRODUCTION

Hemiplegia is a common clinical consequence of a focal cerebral vascular (hemorrhagic or occlusive) insult better known as a stroke and other causes of hemiplegia include spinal cord injury, specifically Brown-Séquard syndrome, traumatic brain injury, or disease affecting the brain, brain infections and cancers.⁽¹⁾.

According to World Health Organization (WHO), 15 million people are suffering from stroke each year, and 5 million are left permanently disabled. The significant causes are hypertension 54%, hypercholesterolemia (15%), tobacco smoking (12%) and cerebral infarction leading to 81% of strokes ⁽²⁾.

Hemiplegic hypertonic posture is the consequence of ablation of higher centres and subsequent release of motor groups from pyramidal and extra pyramidal control ⁽³⁾. Hemiplegic gait is considered by weakness of the residual muscle, abnormal movement synergies, and spasticity result in altered gait patterns and contribute to poor balance, greater risk of falling, and increased energy expenditure during walking ⁽⁴⁾.

The Seattle design plastic AFOs and metallic AFOs are the most widely prescribed AFOs in hemiplegic patients, presumably assist retraining due to hemiplegic gait. The rationale for this is that the AFO provides medio-lateral stability in stance by limiting ankle and subtalar movement, and facilitates toe clearance and heel strike in swing phase. ⁽⁵⁾.Solid Ankle Foot Orthosis (SAFO) in case of post stroke hemiplegic patients, orthotic treatment is limited in long term treatment protocol for improving the hemiplegic gait.

AFO tuning suggest that with $>5^{\circ}$ thigh inclination during the mid-to-late stance (MTLS) phase, and a shank-to-vertical angle (SVA) of 10° – 12° , combined with adequate control of the knee, it is possible to achieve a ground reaction force

(GRF) alignment which successfully passes anterior to the knee joint centre, and posterior to the hip joint centre^{.(6)} Without correct segment orientation at this phase of the gait cycle, GRF alignment cannot be correct, and therefore, the correct signals cannot be sent from the hip proprioceptors to the central pattern generators, which are thought to use that signal as one of the inputs for swing phase initiation^{.(7)} The AFO can be used to directly control the SVA at mid-stance, which if correct should increase the likelihood of achieving correct segment orientation during the MTLS phase^{.(8)}

Further complications of hemiparetic gait arise due to abnormal alignment of the ground reaction force (GRF) relative to the joints of the lower limb, leading to altered moments and increasing the demand on a damaged neuromuscular system. ⁽⁹⁾.

Muscle recruitment of hemiplegic patient is characterized by disordered onsets and offsets of muscle contraction. Loss of selective Control may result in abnormal coactivation of agonist–antagonist muscles and the presence of co contraction due to poor selective control may be the reason for the disordered timing of Muscle activity ^{(10, 11, 12).}

Solid Ankle Foot Orthosis (SAFO) in case of post stroke hemiplegic patients, orthotic treatment is limited in long term treatment protocol for improving the hemiplegic gait. Last decade orthotic clinical studies are worked out in foot wares heel rising for shank vertical angle's effectiveness on gait kinematics. But this current prospect study is an attempt to find the comparison effect on insole and outsole posterior heel wedge with fixed Shank Vertical Angle (SVA) on gait kinetics and Tibialis Anterior (TA) muscle activation profile.

MATERIALS AND METHODOLOGY

Study location was at dept. of prosthetics and orthotics, national institute

for locomotor disabilities (divyangjan), B. T. Road, Bon-Hooghly, Kolkata-700090. Study population was subjects with either right or left side post stroke hemiplegia on a study period of 12 months on Sample size: -30,sampling technique: - convenient sampling technique on Study design of prospective two group post comparative quasi-experimental study design.

Inclusion Criteria for this study were subject with Post Stroke Hemiplegia around 1-12 months after stroke age within 16 to 45 years, must be able to follow simple verbal instructions and presented with a Modified Ashworth Score of less than 2 grades, also able to attend for follow-up. Samples of convenience of 30 persons with Post Stroke Hemiplegia were invited to take part in this study. According to the inclusion criteria the subjects were assessed & screened. Subjects who were consented to participate in the study signed the consent form. The detailed information was given to the subjects about the procedure. The informed consent ware obtained from the individuals prior to the study participations assessed and evaluated. ware The demographic data like age, gender etc. were taken. Then participants were conveniently allotted into two groups. One Group (Group A) were provided with Molded SAFO with insole posterior heel wedge and the other Group (Group B) with Molded SAFO with posterior heel outsole wedge. Then measurement and casting was done and started the modification procedure with consideration of following points (13). After fabrication of SAFO fabricated the posterior heel wedge by use of rubber and evathene. A specific inclination was maintained of angle should be 12 degree and attached to the inner or outer side of the SAFO.

Ground Reaction Force Vector (Fx, Fy, Fz) was measured by using Kistler Force Plate. Baseline data were taken at the day of measurement. Patients were instructed to walk on a force plate about on his/her normal speed and manner for 30 sec and then the data were taken. First baseline data were taken at the time of measurement. Pre data were taken on at the time of discharge with Molded Solid Ankle Foot Orthosis along with insole/outsole posterior heel wedge according to the previous process in case of both the groups. After 4 weeks of follow up period, the post data were taken with and without Molded SAFO with insole/outsole posterior heel wedge in case of both the group in the same manner. The data obtained from this procedure were analysed by MS-Microsoft Excel.

An electromyography system (8 channel recording unit power lab) was used for surface EMG measurement in this study. This consists of 8 pairs of electrodes, 8 channels pre amplifiers, patient unit, an optical fibre cable and a control unit. Each pair of surface EMG electrode (AgCl Disc Electrodes,) was applied to skin cleaned with an alcohol Swap, and the impedance was always controlled at less than 10 K Ω . The inter electrode distance was 3 cm. The electromyography signal was detected by electrode and was differentially the amplified by the pre amplifier (Input impedance > 1 M Ω and frequency of 240 Hz so as to reduce interface from electrical appliances. The signal from pre amplifier than transmitted into the 8channel EMG patient unit, the EMG signal was then converted from analogue to digital data inside the patient unit before transmitted to the condition unit through optical fibre cable.

Using measuring tape, a mark was made on the measured leg at one-third of the distance between the head of the fibula and the tip of the medial malleolus, to indicate the correct location of the TA EMG preamplifier and motor point of the muscle. The surrounding area was first shaven with a disposable razor and then cleaned with an alcohol swab to reduce the input impedance of the EMG recording site. Once the alcohol had dried, the EMG pre-amplifier was placed at the marked location, parallel to the direction of the muscle fibres. Subjects were requested to perform contractions of the ankle musculature and EMG was recorded from the TA to check for signal quality. It

however be noted that should the contribution of the peroneus longus activity to the EMG activity recorded by the TA electrodes was not measured and it is possible that some cross-talk from the patient was recorded by the TA electrodes. Round shaped Silver/Silver Chloride (Ag/AgCl) surface electrode was used to record the EMG and attached with doubled adhesive tape to the patient. Conductive electrode gel (ultrasonic gel) was required to increase conductivity of the EMG signal.

To lower the skin resistance, the skin preparation including washing, wiping was done to have better EMG recordings. After the preparation of skin, surface electrode was placed in midpoint of the Tibialis anterior muscle belly and parallel to the muscle fibre, so that the maximum signal can be collected.

In the study the muscle firing segment were manually determined. The segment of muscle firing was calculated by determining the start and the end of muscle activity. These segment were also used to calculate muscle contracting root mean square (RMS) value and median frequency (MF).After the raw EMG signals were adjusted to 0 mean in order to remove the offset from the amplifier the root mean square value (RMS) of each interval was then calculated. Pre data was taken at the time of intervention was given and post data was taken after 4 weeks for adaptation period. After got the raw data from the lab chart software and then analysed it to SPSS software.

Baseline Data was taken on the day of measurement. Immediate pre data was taken on day of delivery through trails. 4 weeks of adaptation period for AFO was provided. After that post data was taken. Gait parameters were assessed by Force Plate, and EMG of Tibialis Anterior muscle was assessed by AD Instrument power Lab. Comparative study between both the groups was done between pre and post application orthosis by means of independent t- test.

Molded Solid Ankle Foot Orthosis

It acts upon the principle of three point pressure systems ⁽¹⁴⁾. The trimilines are the top must be horizontal, 2 cm below the fibula head, around the ankle, pass the line 1 cm anterior to the tip of the malleoli and on the forefoot, leave the sides of the toes and the head of the metatarsus completely clear and pass the trim line below them, this will allow the polypropylene to follow the movement of metatarso-phalangeal-joints⁽¹⁵⁾.

Posterior Heel Wedge



Photo-1: Posterior heel wedge.



Photo-2: Patient with AFO for GRF loading data.

Wedging is used to facilitate more normal gait pattern. Here posterior heel wedge will be used for making the tibia inclined thus providing the SVA angle at 12 degree. The posterior heel wedge placed at the inner and outer portion of the heel of the SAFO according to the requirement of the

patients. It's also has some specifications as Rubber was used for making this wedges which maintained the angulations on 12 degree and other parameters according to the patients requirement.(Photo-1, Photo-2)

Validity of posterior heel wedge in Ankle foot Orthosis in Stroke patients

Condie DN et al 1977. ⁽¹⁶⁾, Bahler A et al 1982 ⁽¹⁷⁾, Bregman DJ et al 2011 ⁽¹⁸⁾. Ferreira LA et al 2013 ⁽¹⁹⁾ defined that shank-to-vertical angle (SVA) of 10°-12°, adequate control of the knee, it is possible to achieve a ground reaction force (GRF) alignment which successfully passes anterior to the knee joint centre, and posterior to the hip joint centre.⁽⁶⁾ Without correct segment orientation at this phase of the gait cycle, GRF alignment cannot be correct, and therefore, the correct signals cannot be sent from the hip proprioceptors to the central pattern generators, which are thought to use that signal as one of the inputs for swing phase initiation.^(7,8). So here ankle is fixed on 12 degree for the effectiveness of SVA angle.

The AFO must not position the ankle in a more dorsi-flexed position than can be achieved with the knee fully extended (i.e. the gastrocnemius length). This means the AFO may in some circumstances hold the ankle in a plantar flexed position and should give an initial SVA of 0° when placed on a flat surface. 4mm polypropylene sheet was used for moulding of AFOs and trimlines was approximately 10 mm anterior to the midline of the malleoli, on the forefoot, the medial and lateral trimlines was close to the metatarsal heads, to allow for control of pronation and supination / forefoot adduction / abduction. The sole plate should extend at least 5 mm beyond the toes. Straps ware made of Velcro. The top strap was no more than 10-15 mm from the top of the AFO. The lower strap was applied a force in a posterior and inferior direction, at roughly 45° to the vertical, to the dorsum of the foot.

The study was approved by the Ethical Committee of National Institute for Locomotor Disabilities (Divyangjan),

Kolkata, India, in its 33rd meeting held on 28th February 2018 at 14:00 hours. Written informed consent was obtained from all the participants. All the participants' were informed that participation in the research was totally voluntary and if they refused to participate it would be not have any future negative consequences for them. In addition all aspects regarding confidentiality were explained to the participants, i.e., no name would be written on the questionnaires and that their names would not be mentioned in the reports. The researcher did explain that the only people that would have access to the information would be the researcher and the research supervisor.

RESULTS

In this present study we maintained the SVA angle set at 12 degrees and it was seen that there was no significant difference in mean of Pre and post GRF Fx without AFO between group A (.3300 ±.03543017), (.1347261 ± .04525672) and Group B (.2574378 ± .06483801), (.5955077 ± .05997699) p value (p=0.147), (p=0.253). And also in mean of Pre and of Post GRF Fx with AFO between group A (.3886667 ±.08449317), (.4257667 ±.05710349) and Group B (.4086667±.10091486), (.3247194 ± .03354711) p value (p=0.037), (p=0.009).

It was seen that there was significant difference in mean of Pre and Post GRF Fy (anterior ground reaction force) without AFO between group A (-.6564277 ± .06224248), (.6078163±.03745221) and Group B (.8465210 ± .03895972), (- $.6426709 \pm .11980430$), p value (p=0.025), (p=0.0001). But there was no significant difference in mean of Pre and Post GRF Fy with AFO between group A (-.1343920 \pm .04986860), (-.0788157±.04217144) and \pm Group B (-.8112641 .04531050), (.3021282 ± .04530411), p value (p=0.682), (p=0.524).

It was seen that there was no significant difference in mean of Pre and Post GRF Fz without AFO between group A (-.4812179 \pm .20904142), (.0419525 \pm .12282450) and Group B (-.6573776

 \pm .20638696), (-1.3485119 \pm .18347462) p value (p=0.759), (p=0.117), and in mean of Pre and Post GRF Fz with AFO between group A (-.0945951 \pm .22982767), (-.2956376 \pm .19018881) and Group B (1.4654869 \pm .21605790), (.3555335 \pm .21291099) p value (p=0.999), (p=0.404).

It was seen that there was no significant difference in mean of Pre RMS Fx without and with AFO between group A (.9959653 \pm .48383495), (.6803693 \pm .41743346) and Group B (1.4195520 \pm .1.60347619), (.9004540 \pm .83053134) p value (p=0.058), (p=0.066) respectively. But there was significant difference in mean of Post RMS Fx without and with AFO between group A (.4676173 \pm .09948879), (.2013404 \pm .00079492) and Group B (1.2457827 \pm .40487811), (1.6839247 \pm .28368596) p value (p=0.0001), (p=0.0001) respectively.

In this present study we measured the gait kinetics on 3D force plate and it was seen that there was significant difference in mean of Pre and Post RMS Fy without AFO between group A (2.1933693±1.79441811), $(.7692880 \pm .27151880)$ Group and В (3.2430160 $(2.6906527 \pm 3.29311524),$ \pm 3.62298159), value (p=0.017), р (p=0.0001). But there was no significant difference in mean of Pre and post RMS Fy with AFO between group A (1.2111160 \pm .88571356), (.5318940 \pm .04206048) and Group B (1.0497633 ± .66379519), $(.9333527 \pm .57583014)$, p value (p=0.885), (p=0.007) between the group.

In RMS Fz, it was seen that there was no significant difference in mean of Pre and Post RMS Fz without AFO between group A (3.2387120 ± 3.02242674), (.7479480 \pm .39104066) and Group B (3.9212533 ± 3.11995945), ($1.7867000 \pm .43581187$) p value (p=0.546), (p=0.749). But there was significant difference in mean of Pre and Post RMS Fz with AFO between group A (.7479480 \pm .14445313), (.9705020 \pm .64968787) and Group B ($1.5110633 \pm$.63586779), ($1.6035733 \pm .14725080$), p value (p=0.0001), (p=0.0001).

It was seen that there was significant difference in mean of Pre without and Post with AFO in Range Fx between group A (6.1956467 \pm 3.73287764), (2.5651000 \pm 1.25611179) and Group B (6.0159933 \pm 2.09320938), (3.9407200 \pm .69829730), p value (p=0.048), (p=0.011) respectively. In this prospect there was no significant difference in mean of Post without and Pre with AFO in Range Fx between group A (2.1873200 \pm .57872792), (4.1705027 \pm 2.70601651) and Group B (5.2285933 \pm .48098907), (5.9822267 \pm 3.80780972) p value (p=0.983), (p=0.131).

In this present study we fixed the SVA 12degree and here it was seen that there was significant difference in mean of Pre Rnage Fy without and with AFO between group A (8.4190200±4.74492346), $(7.1564400 \pm 2.07507262)$ and Group B $(7.6549467 \pm 1.43886586), (10.0885733 \pm$ 6.22681609), value (p=0.011), р (p=0.0001). But also there was no significant difference in mean of Post Range Fy without and with AFO between group A $(4.2248587 \pm .98014337), (4.9359293 \pm$ 1.09802423) and Group B (6.7027600 \pm .59807181), (6.4333467 ± .81139494), p value (p=0.198) (p=0.138).

It was seen that there was no significant difference in mean of Pre and Post RMS Fz without AFO between group A (7.4214133 \pm 2.51669741), (3.8643067 \pm . 88741784) and Group B (7.7973067 \pm 1.91702999), (11.6605733 \pm 1.56684054) p value (p=0.249), (p=0.051). But there was significant difference in mean of Pre RMS Fz but not in Post with AFO between group A (5.7056533 \pm 1.60742533), (5.5543067 \pm 1.02925434) and Group B (9.8187267 \pm 5.21345858), (12.5819333 \pm 1.26683438) respectively, p value (p=0.0001), (p=0.095).

It was seen that there was significant difference in mean of Pre and Post EMG without AFO between group A ($.0492600 \pm .07514794$), ($1.2199367 \pm .80777588$) and Group B ($.0234267 \pm .00699872$), ($.0530400 \pm .01619664$), p value (p=0.005), (p=0.0001).

It was seen that there was significant difference in mean of Post but not in Pre EMG with AFO between group A (1.7353333 \pm 1.65291084), (1.0842773 \pm

.75247351) and Group B (2.5149973 \pm .55689250), (3.8536400 \pm .72754699) p value (p=0.0001), (p=0.613). (Table-1, Table-2).

Table-1	: GRF parameters during p	ore post condit	ion between tv	vo groups.
PARAMETER	GROUP (CONDITION)	MEAN	SD	SIGNIFICANCE
GRF Fx	GR. A PRE (WOB)	0.3300899	0.03543017	0.147
OKI 1X	GR. B PRE (WOB)	0.2574378	0.06483801	0.147
RMS	GR. A PRE (WOB)	0.9959653	0.48383495	0.058
KNIS	GR. A PRE (WOB)	1.419552	1.60347619	0.050
RANGE	GR. A PRE (WOB)	6.1956467	3.73287764	0.048
	GR. B PRE (WOB)	6.0159933	2.09320938	0.048
GRF Fx	GR. A PRE (WB)	0.3886667	0.08449317	0.037
UNITA	GR. B PRE (WB)	0.4086667	0.10091486	0.037
RMS	GR. A PRE (WB)	0.6803693	0.41743346	0.066
	GR. B PRE (WB)	0.900454	0.83053134	0.000
RANGE	GR. A PRE (WB)	4.1705027	2.70601651	0.121
TURITOR	GR. B PRE (WB)	5.9822267	3.80780972	0.131
GRF Fx	GR. A POST (WOB)	0.1347261	0.04525672	0.252
Old TX	GR. B POST (WOB)	0.5955077	0.05997699	0.253
RMS	GR. A POST (WOB)	0.4676173	0.09948879	0
Rivis	GR. B POST (WOB)	1.2457827	0.40487811	
RANGE	GR. A POST (WOB)	2.18732	0.57872792	0.000
REIGE	GR. B POST (WOB)	5.2285933	0.48098907	0.983
GRF Fx	GR. A POST (WOB)	0.4257667	0.05710349	0.009
UKI TX	GR. B POST (WB)	0.3247194	0.03354711	0.009
RMS	GR. A POST (WB)	0.2013404	0.00079492	
KIVI3	GR. B POST (WB)	1.6839247	0.28368596	0
DANCE	× /		1.25611179	
RANGE	GR. A POST (WB)	2.5651 3.94072		0.011
	GR. B POST (WB)	-0.6564277	0.6982973 0.06224248	
GRF Fy	GR. A PRE (WOB)			0.025
	GR. B PRE (WOB)	0.846521	0.03895972	
RMS	GR. A PRE (WOB)	2.1933693	1.79441811	0.071
	GR. B PRE (WOB)	2.6906527	3.29311524	
RANGE	GR. A PRE (WOB)	8.41902	4.74492346	0.011
	GR. B PRE (WOB)	7.6549467	1.43886586	
GRF Fy	GR. A PRE (WB)	-0.134392	0.0498686	0.682
	GR. B PRE (WB)	-0.8112641	0.0453105	
RMS	GR. A PRE (WB)	1.211116	0.88571356	0.885
	GR. B PRE (WB)	1.0497633	0.66379519	
RANGE	GR. A PRE (WB)	7.15644	2.07507262	0
	GR. B PRE (WB)	10.0885733	6.22681609	
GRF Fy	GR. A POST (WOB)	0.6078163	0.03745221	0
	GR. B POST (WOB)	-0.6426709	0.1198043	
RMS	GR. A POST (WOB)	0.769288	0.2715188	0
	GR. B POST (WOB)	3.243016	3.62298159	
RANGE	GR. A POST (WOB)	4.2248587	0.98014337	0.198
	GR. B POST (WOB)	6.70276	0.59807181	
GRF Fy	GR. A POST (WB)	-0.0788157	0.04217144	0.524
	GR. B POST (WB)	0.3021282	0.04530411	0.007
RMS	GR. A POST (WB)	0.531894	0.04206048	0.007
	GR. B POST (WB)	0.9333527	0.57583014	
RANGE	GR. A POST (WB)	4.9359293	1.09802423	0.138
	GR. B POST (WB)	6.4333467	0.81139494	
GRF Fz	GR. A PRE (WOB)	-0.4812179	0.20904142	0.759
	GR. B PRE (WOB)	-0.6573776	0.20638696	
RMS	GR. A PRE (WOB)	3.238712	3.02242674	0.546
	GR. B PRE (WOB)	3.9212533	3.11995945	
RANGE	GR. A PRE (WOB)	7.4214133	2.51669741	0.249
	GR. B PRE (WOB)	7.7973067	1.91702999	
GRF Fz	GR. A PRE (WB)	-0.0945951	0.22982767	0.999
	GR. B PRE (WB)	1.4654869	0.2160579	
RMS	GR. A PRE (WB)	0.747948	0.14445313	0
	GR. B PRE (WB)	1.5110633	0.63586779	
RANGE	GR. A PRE (WB)	5.7056533	1.60742533	0
	GR. B PRE (WB)	9.8187267	5.21345858	
GRF Fz	GR. A POST (WOB)	0.0419525	0.1228245	0.117
	GR. B POST (WOB)	-1.3485119	0.18347462	

	Table-1: GRF parameters during	ore post condition between two groups.
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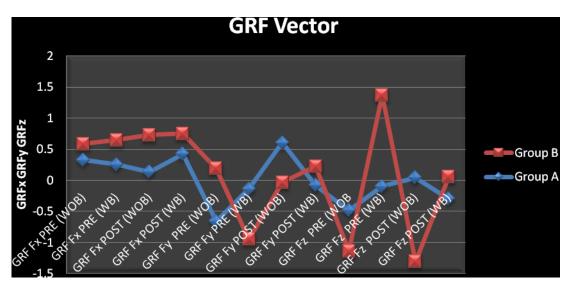
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Table-1: Continued						
RMS	GR. A POST (WOB)	0.763156	0.39104066	0.749		
	GR. B POST (WOB)	1.7867	0.43581187			
RANGE	GR. A POST (WOB)	3.8643067	0.88741784	0.051		
	GR. B POST (WOB)	11.6605733	1.56684054			
GRF Fz	GR. A POST (WB)	-0.2956376	0.19018881	0.404		
	GR. B POST (WB)	0.3555335	0.21291099			
RMS	GR. A POST (WB)	0.970502	0.64968787	0		
	GR. B POST (WB)	1.6035733	0.1472508			
RANGE	GR. A POST (WB)	5.5543067	1.02925434	0.095		
	GR. B POST (WB)	12.5819333	1.26683438			

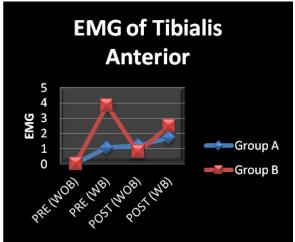
TABLE FOR EMG DATA
 Table-2:
 EMG parameters during pre post condition between two groups.

 PARAMETER
 GROUP (CONDITION)
 MEAN
 SD
 SIGNIFI
SIGNIFICANCE GR. A PRE (WOB) 0.04926 0.07514794 E.M.G 0.005 GR. B PRE (WOB) 0.0234267 0.00699872 GR. A PRE (WB) 1.0842773 0.75247351 0.613 GR. B PRE (WB) 3.85364 0.72754699 GR. A POST (WOB) 1.2199367 0.80777588 0 GR. B POST (WOB) 0.05304 0.01619664 GR. A POST (WB) 1.7353333 1.65291084 0 GR. B POST (WB) 2.5149973 0.5568925

DISCUSSION



Graph1: GRFx, GRFy and GRFz parameters between groups.



Graph2: EMG data of Tibialis Anterior between groups.

Previous clinical studies are based on providing the posterior heel wedge in outer side mainly with footwear's heel rising associated with molded Solid Ankle Foot Orthosis (SAFO) but this is an attempt of this study to check the effects of insole posterior heel wedge as well as outsole posterior heel wedge in SAFO on temporal and kinetic gait parameters and activation profile of tibialis anterior muscle in post stroke hemiplegic patients and investigated the result. (Graph1,Graph2).

This study was conducted to quantify and compare the insole (Group-A) and outsole (Group-B) posterior heel wedge

in molded Solid Ankle Foot Orthosis (SAFO) by measuring the temporal and kinetic gait parameters and activation profile of tibialis anterior muscle in post stroke hemiplegic patients and also Compare the effects of two types of posterior heel wedges associated with molded SAFO on temporal and kinetic gait parameters and activation profile of tibialis anterior muscle in post stroke hemiplegic patients.

A study done by Schmid A et al 2007 and Oberg T e t al 1993 reported that the AFO intervention is to get the patient to walk as close to normal as possible. In order to achieve that, it was proposed that for the paretic limb, the SVA at mid-stance should be 10° -12° inclined and at MTLS, the thigh should be inclined $(>5^{\circ})$ with the knee slightly flexed at approximately 10°–18°.By using the AFO to directly control the SVA at mid-stance, the likelihood of achieving correct segment orientation during the MTLS phase should have been increased, thus allowing a correct GRF alignment. Intervening with segment orientations in this way is likely to influence motor control by attempting to ensure that the correct signals are sent to the central pattern generators ⁽²⁰⁾.

Sharma S et al (2015) conducted a clinical study report to compare stroke patients' with healthy subjects' in terms of anterior, medial, and lateral ground reaction forces generated during gait initiation. They found that Anterior ground reaction forces acting on the right and left stance limbs of healthy subjects were greater than anterior forces acting on the non-paretic (mean 20.171 %BW, SD 4.264) (p = 0.001) and paretic limbs (mean 11.694 %BW, SD (4.846)(p = 0.001) of stroke patients. Medial ground reaction forces for the non-paretic and paretic limbs of stroke patients and for the right and left stance limbs of healthy subjects were equivalent. While lateral ground reaction forces acting on the nonparetic and paretic limbs were equivalent for left paretic patients, and for right paretic patients lateral forces acting on the nonparetic limb were greater in compared to the paretic limb and also greater in compared to the left limb of healthy subjects ⁽²¹⁾.

In a study conducted by Susan Niam et al1993 expressed significant differences in postural sway were found among different stance in eyes-open (p = .00 to .02) with impaired ankle proprioception had significantly increased postural sway and decreased Balance ⁽²²⁾

Were De Sèze et al (2011) concluded that the time point at which the maximum response to a solid AFO occurs is currently not known. It is likely the case that improvements in all kinematic parameters (except for SVA at mid-stance) do not occur immediately; therefore, it would be useful to take further 3D gait analysis measurements with these participants at 3 and 6 months, which could prove to be particularly important given the varying rates of improvement seen with different AFOs ⁽²³⁾.

The previous studies limitations 3D gait analysis, present study supports to complete the limitations. Here we analysis the gait kinetics by using gold standard 3D force plate. We got better result in 3D gait GRF parameters.

Kerkum YL et al (2015) performed a clinical study and concluded that the effectiveness of an Ankle-Foot Orthosis footwear combination (AFO-FC) may be partly dependent on the alignment of the ground reaction force with respect to lower limb joint rotation centres, reflected by joint angles and moments. The AFO-FC heel height was increased, aiming to impose a Shank-to-Vertical-Angle of 5degree. 11degree and 20 degree, and combined with a flexible or stiff footplate. The Shank-to-Vertical-Angle significantly increased with increasing heel height (p < 0.001), resulting in an increase in knee flexion angle and internal knee extensor moment (p < 0.001). The stiff footplate reduced the effect of heel height on the internal knee extensor moment (p = 0.030), while the internal ankle plantar flexion moment increased (p = 0.035)⁽²⁴⁾

This is in accordance to this present study that found increased GRF force

having more AP/ML stability in outsole Posterior heel wedge with AFO in compare to insole posterior heel wedge with AFO.

In this current prospect we found Group A(insole posterior heel wedge) having significant increase of ground reaction force vector Fx, Fy, Fz within reliable RMS and Range values as compared between the Group B (outsole posterior heel wedge).

Magnitude of the ground reaction force in AFO on hemiplegic patients to stabilize the knee form buckling in mid stance phase and also to initiate the swing phase as well as prevent foot drop and dragging of foot. Within AFO insole or outsole posterior heel wedge the GRF is increased significantly, so outsole posterior heel wedge having a significant geometrical influence to increase GRF vector x, y & z and provide more narrow based gait in terms of GRF x, y, z less abnormal deviations So ML Ground Reaction force magnitude is decreased which may affect M-L stability but here this deviation is adopted by the patients.

There was a significant difference between two group in pre post condition in Tibialis anterior muscle profile, in long term with AFO group A muscle profile activation improved in terms of nearer to the resting potation of the muscle. So AFO is effective in group A for reducing hyperactivity of TA muscle profile in post hemiplegic patients.

Corien Nikamp et al (2018) reported the use of ankle-foot orthosis over a period of 26 weeks affects tibialis anterior muscle. After 26 weeks, no differences were found in tibialis anterior muscle activity between both groups in the swing phase, with (p =0.207) or without ankle-foot orthosis (p =0.310) ⁽²⁵⁾. In this current study we found significant differences between two groups.

Johanna F. Geboers et al (2002) in paretic and healthy subjects, tibialis anterior muscle activity decreased by 7% and 20% (P = .01, P = .04), respectively, when using an AFO and in the paretic group, electromyographic activity decreased when calculated over the step cycle as a whole. They also found that a significant decrease of tibialis anterior muscle activity in healthy persons in the first 15% of the gait cycle and in paretic muscles during the entire gait cycle. However, the variability in motor patterns during the gait cycle was much larger in the paretic group in case of foot drop ⁽²⁶⁾. This is in accordance to current study.

Chad Lairamore et al (2011)conducted a clinical study to determine the tibialis anterior change in muscle electromyography, ankle angle, or gait velocity when individuals post stroke walk with a posterior leaf-spring AFO (PLAFO) or a dynamic ankle orthosis (DAO). Research has shown a decrease in TA muscle EMG during the swing phase of gait with use of the DAO and a decline in EMG, although statistically insignificant, with use of a PLAFO. When comparing the DAO and the PLAFO, the normalized EMG were quite similar, at 80% and 82% respectively ⁽²⁷⁾. This also accordance to present study with significant differences between two groups.

Specific aimed for this prospective orthotic clinical evidence based practice scenario was found significant improvement in patients gait with GRFx, GRFy and GRFz and it have a positive impact on improving Temporal and kinetic gait parameters in post stroke hemiplegic patients. Here in Group A Step length was improved in short term and long term both within AFO in respect to without AFO.

CONCLUSION

As per present perspective clinical evident report it is concluded that molded SAFO with outsole posterior heel wedge have a significance impact for positive influences on GRF, improving gait with any excessive EMG signal of T.A. muscle profile, as compare to insole posterior wedge with AFO. It was provided a significant efficient gait in outsole posterior heel wedge with SAFO in terms of gait parameters without any excessive hyper tonicity of T.A muscle profile.

Although one centre prospect clinical evident result cannot generalised the effectiveness of standard position of wedge in AFO for better pathway of GRF on gait, improving gait parameters without any excessive contraction of TA muscle. As the SAFO with outsole posterior heel wedge provides proprioceptive feedback by virtue of effective lower extremity SVA alignment to the hemiplegic stroke and also gives psychological satisfaction after improvement in gait and better acceptance in short term orthotic treatment protocol.

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REFERENCES

- 1. Shapiro Blanco DA (2017).M. "Neurological Complications of Gastrointestinal Disease". Semin Pediatr Neurol (Review). 24 (1):4353.doi:10.1016/j.spen.2017.02.001. PMID 28779865.
- 2. Bamford J, Sandercock P, Dennis M, et al: prospective study А of acute cerebrovascular disease in the community: the Oxfordshire Community Stroke Project 1981-1986, 11: incidence, case fatality rates and overall outcome at one year of cerebral infarction, intracerebral primary haemorrhage and subarachnoid haemorrhage, J Neurol Neurosurg Psychiatry. 53:16-22, 1990.
- Giuliani CA. Adult hemiplegic gait. In: Smidt GL, editor. Gait in rehabilitation: Clinical physical therapy. New York (NY): Churchill Livingstone Inc; 1990. p. 253–66.
- 4. Da Cunha IT Jr, Lim PA, Qureshy H, Henson H, Monga T, Protas EJ. Gait outcome after acute stroke rehabilitation with supported treadmill ambulation training: A Page 22 randomized controlled pilot study. Arch Phys Med Rehabil. 2002;83(9):1258–65. [PMID: 12235606]
- 5. Tyson SF, Thornton HA. The effect of a hinged ankle foot orthosis on hemiplegic

gait: objective measures and users' opinions. Clin Rehabil 2001; 15: 53–58.

- 6. Owen E. The importance of being earnest about shank and thigh kinematics especially when using ankle-foot orthoses. Prosthet Orthot Int 2010; 34(3): 254–269.
- Dietz V. Spinal cord pattern generators for locomotion. Clin Neurophysiol 2003; 114(8): 1379–1389
- 8. Pang MYC and Yang JF. The initiation of the swing phase in human infant stepping: importance of hip position and leg loading. J Physiol 2000; 528(2): 389–404.
- 9. Condie E, Bowers R. J.: Lower limb orthosis for persons who have had a stroke, Atlas lower limb orthotics 4th edition 2008;33:433.
- Lehmann JF, Esselman PC, Ko MJ et al. Plasticankle-foot orthoses: evaluation of function. Arch Phys Med Rehabil 1983; 664: 402–407.
- Hesse S, Werner C, Matthias K, Stephen K, Berteanu M.Non-velocity-related effects of a rigid double-stopped ankle-foot orthosis on gait and lower limb muscle activity of hemiparetic subjects with an equinovarus deformity. Stroke. 1999;30(9):1855–61. [PMID: 10471436]
- 12. H. S. Jorgensen, H. Nakayama, H. O. Raaschou, and T. S.Olsen. "Recovery of walking function in stroke patients: the Copenhagen stroke study," Archives of Physical Medicine and Rehabilitation. 1995; vol. 76, no. 1, pp. 27–32. Pezer C. An Instrumented cane Devised for Gait Rehabilitation and Research. Journal of physical Therapy Education2011:36–48.
- 13. Carse B, Bowers R, Meadows BC, Rowe P. The immediate effects of fitting and tuning solid ankle–foot orthoses in early stroke rehabilitation. Prosthetics and orthotics international. 2015 Dec;39(6):454-62.
- 14. Orthotics clinical practice and rehabilitation technology by John B. Redford page no 21.
- 15. ICRC's "Manufacturing Guidelines" Ankle foot orthosis Physical Rehabilitation Programme.
- Condie DN, Meadows CB. Some biomechanical considerations in the design of ankle-foot orthoses. OrthotProsthet. 1977 Jan 1;31(3):45-52.
- Bahler A. Principles of design for lowerlimb orthotics. Orthot. Prosthet. 1982 Jan 1;36:33-9.Current orthotic clinical practice

for preparing AFO the SVA angle is martin in AFO during Casting to modification.

- Bregman DJ, Van der Krogt MM, De Groot V, Harlaar J, Wisse M, Collins SH. The effect of ankle foot orthosis stiffness on the energy cost of walking: a simulation study. Clinical Biomechanics. 2011 Nov 1;26(9): 955-61.
- Ferreira LA, Neto HP, Christovão TC, Duarte NA, Lazzari RD, Galli M, Oliveira CS. Effect of ankle-foot orthosis on gait velocity and cadence of stroke patients: a systematic review. Journal of physical therapy science. 2013;25(11):1503-8.
- 20. Schmid A, Duncan PW, Studenski S, et al. Improvements in speed-based gait classifications are meaningful. Stroke 2007; 38(7): 2096–2100.
- Sharma S, McMorland AJ, Stinear JW. Stance limb ground reaction forces in high functioning stroke and healthy subjects during gait initiation. Clinical Biomechanics. 2015 Aug 1;30(7):689-95.
- Niam S, Cheung W, Sullivan PE, Kent S, Gu X. Balance and physical impairments after stroke. Archives of physical medicine and rehabilitation. 1999 Oct 1;80(10):1227-33.
- 23. De Sèze MP, Bonhomme C, Daviet JC, et al. Effect of early compensation of distal motor deficiency by the Chignon ankle-foot orthosis on gait in hemiplegic patients: a randomized pilot study. Clin Rehabil 2011; 25(11): 989–998.
- 24. Kerkum YL, Houdijk H, Brehm MA, Buizer AI, Kessels ML, Sterk A, van den Noort JC, Harlaar J. The Shank-to-Vertical-Angle as a

parameter to evaluate tuning of Ankle-Foot Orthoses. Gait & posture. 2015 Sep 1;42(3):269-74.

- 25. Nikamp, C., Buurke, J., Schaake, L., Van der Palen, J., Rietman, J. and Hermens, H., 2019. Effect of long-term use of ankle-foot orthoses on tibialis anterior muscle electromyography in patients with sub-acute stroke: A randomized controlled trial. Journal of rehabilitation medicine, 51(1), pp.11-17.
- 26. Geboers JF, Drost MR, Spaans F, Kuipers H, Seelen HA. Immediate and long-term effects of ankle-foot orthosis on muscle activity during walking: a randomized study of patients with unilateral foot drop. Archives of physical medicine and rehabilitation. 2002 Feb 1;83(2):240-5.
- 27. Lairamore C, Garrison MK, Bandy W, Zabel R. Comparison of tibialis anterior muscle electromyography, ankle angle, and velocity when individuals post stroke walk with different orthoses. Prosthetics and orthotics international. 2011 Dec;35(4):402-10.

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