Efficiency of Articulated Dorsiflexion Assisting Tone Reducing Ankle Foot Orthosis in Improving Gait in Persons with Hemiplegia as Compared to Solid Ankle Foot Orthosis

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ABSTRACT

Stroke is the primary cause of impairment in the motor function and gait of adults. In patients with hemiplegia due to stroke, they may experience muscle stiffness, spasms, pain, and spasticity in the affected limb(s). This may lead to abnormal positioning of the affected side, making it difficult to perform daily activities and increasing the risk of them developing muscle contractures, osteoarthritis, and muscle atrophy. Spasticity is one of the most common impairments that takes place after stroke, and may lead to impaired function and harmful effects including: pain, muscle contractures, poor skin hygiene, difficulty with voluntary movements, and problems with gait. Major deficit in hemiplegic gait is the plantar-flexed position the foot and extension of the knee, throughout the swing phase of the gait cycle. Foot clearance and stability issues can lead to fall risk, while abnormal joint kinematics can lead to joint damage

During rehabilitation, most prescribed AFOs are Solid ankle foot orthosis (AFO) and Articulated AFO; however, no study is done on Articulated Dorsiflexion Assist TRAFO effect in persons with hemiplegia in India. Solid ankle foot orthosis provides knee stability; eliminate excessive plantar flexion by limiting the normal ankle motion which compromises the normal gait pattern. Hence knee stability is achieved by blocking the available motion at the ankle joint. The Dorsiflexion Assisting Articulated AFO aids in ankle dorsiflexion and control the hyperextension of the knee without blocking motion at the ankle joint.

Tone Reducing AFO helps to reduce muscle tone by means of stretching of muscle which inhibits reflex pattern. Combination of Articulated Dorsiflexion Assist and Tone Reducing Feature will help to achieve biomechanically efficient gait pattern in persons with hemiplegia.

The results of this study will help the clinicians for the prescription of correct design of AFO in Rehabilitation of persons with hemiplegia and guiding future research studies on this subject, which is still incompletely defined in the literature.

Keywords: Stroke, Hemiplegia, Tone reducing ankle foot orthosis, Dorsiflexion assist, Spasticity

INTRODUCTION

Stroke is a major cause of morbidity and mortality, and it is the second most common cause of death worldwide after heart disease¹. As per WHO Geneva, article on Epidemiology and Burden of Disease, by Thomas Truelsen, Stephen Begg and Colin Mathers, who provided the first global

estimate on burden of 135 diseases and cerebrovascular disease ranked as the second leading cause of death after ischemic heart disease. In 2001 it was estimated that stroke (CVA) accounted for 5.5million deaths worldwide equivalent to 9.6% of all deaths. Two-thirds of these deaths occurred in people living in developing countries and 40% of the subjects were aged less than 70 years. Additionally, each year millions of stroke survivors have to adapt to a life with restrictions in activities of daily living.

Stroke patients are at higher risk of death in the first weeks after the event and between 20% to 50% die within the first month depending on type, severity, age, comorbidity and effectiveness of treatment complications. Patients who survive may be left with no disability or with mild, moderate or severe disability. Considerable spontaneous recovery occurs up to about six proportion of months. The patients achieving independence in self-care by one year after a stroke range from around 60% to $83\%^2$.

Many stroke patients suffer from locomotor deficits and postural control disability. These dysfunctions are caused by a variety of movement abnormalities, such as motor weakness caused bv hemiparesis, proprioceptive deficits. and abnormal synergic patterns. In particular, motor disability in the knee and ankle joints, such as knee hyperextension and foot-drop, impair functional walking ability³.

The orthotic management of stroke has garnered much interest recently, due to the growing number of persons rehabilitating from stroke and the push for evidence-based practice in orthotics⁴ to manage the motor impairments resulting from a stroke and othernon-progressive brain lesions.

In clinical settings, Solid Ankle Foot Orthosis and Articulated Ankle Foot Orthosis are frequently prescribed to enhance walking function by providing stability and foot clearance during the stance and swing phases⁵.

SAFO can be designed with sufficient mechanical lever arms to control the ankle-

foot complex directly and to influence the knee joint indirectly, especially in the sagittal plane instability of knee. Although solid AFOs do not incorporate joints, they may or may not allow motion at the ankle in the sagittal plane, depending on their flexibility and trimlines. Articulated AFOs incorporate mechanical joints at the ankle and may be used to control joint range of motion, provide assistance to motion (e.g., with a dorsiflexion assist joint), or limited motion (e.g., with plantar flexion or dorsiflexion stops)⁶.

Review of literature emphasizes that TRAFO modification enhances AFO function in hemiplegics while standing but no study was done while walking. As per review of the literature lot of studies had been done on Solid AFO, Articulated AFO and TRAFO, but combination of TRAFO and Articulated AFO has not yet tried.

The main aim of this research is to find out efficiency of articulated dorsiflexion assisting tone reducing ankle foot orthosis in terms of improving gait over solid ankle foot orthosis, which is a standard design prescribed in the rehabilitation programme of hemiplegics.

Aims

To check efficiency of articulated dorsiflexion, assist tone reducing ankle foot orthosis in improving gait in comparison with solid ankle foot orthosis in hemiplegic patients.

Objectives

To study the Efficiency of Articulated Dorsiflexion Assisting Tone Reducing Ankle Foot Orthosis in improving gait in persons with Hemiplegia as compared to solid ankle foot orthosis in terms of improving

- Spatiotemporal Parameters
- Stability
- To set an appropriate guideline for rehabilitation professionals.

LITERATURE REVIEW

1.Daryabor A, Arazpour M, Aminian G, Effect of different designs of ankle-foot orthoses on gait in patients with stroke: A systematic review ,Gait Posture. 2018 May, 62:268- 279.doi:

10.1016/j.gaitpost.2018.03.026,

https://www.ncbi.nlm.nih.gov/pubmed/2958 7246

(ACCESSED ON 3rd JAN 2020)

This paper discussed about the different designs of ankle foot orthosis and comparison between them on the gait parameters of individuals with hemiplegic stroke. The author concluded that all types of AFO had positive effects on ankle kinematics in the first rocker and swing phases but not on knee kinematics in the swing phase, hip kinematics or third rocker function. Articulated AFO had better effects but more investigations are needed. AFO can immediately improve the foot drop in stance and swing phases. Their long-term usage and comparison among different types of AFOs need to be evaluated.

2.Cyndi Ford, P.T. Robert C. Grotz, M.D. Joanne Klope Shamp, C.P.O. The Neurophysiological Ankle-Foot Orthosis, O&P Library, American Academy of Orthotists and Prosthetists Clinical Prosthetics & Orthotics,1986,Vol 10,No 1,15-23,

http://www.oandplibrary.org/cpo/1986_01_015.asp

Author had designed the neurophysiological AFO for Cerebrovascular accident and closed head injury. The design consists of

Three-point force system to control calcaneal varus, prevent excessive pronation Neuro physiological force to inhibit the toe grasp reflex by unweighting of the through the metatarsal head use of metatarsal arch.

The NP-AFO was biomechanically and Neuro-physiologically effective. It was light weight. It provided functional gait in the patient with CNS Disorder along with independentmotion at ankle, knee and hip. It encouraged weight bearing capacity in the affected lower extremity.

3.Aileen Ibuki, Timothy Bach, Douglas Rogers, Julie Bernhardt, An Investigation of the Neurophysiologic Effect of Tone-Reducing AFOs on Reflex Excitability in Subjects with Spasticity Following Stroke while Standing ,Prosthetics and Orthotics International, 2010, Volume: 34 issue 2, 154-165, https://journals.sagepub.com/doi/full/10.310 9/03093641003649405

(ACCESSED ON 10TH JAN 2020)

The primary purpose of this paper was to investigate the neurophysiologic effect of TRAFOs on Soleus muscle excitability in subjects with spasticity following stroke while standing. They presented method for testing the effect of TRAFOs on spasticity that separates biomechanical effect from neurophysiologic effect. They arrived at a result that there is no evidence to suggest that TRAFO modification enhances the AFO function while standing and further study of TRAFOs while walking is required to substantiate this.

4.Toshiki K. PhD, Aaron K.L. PhD, Stephen W. PhD, Design and Effect of Ankle-Foot Orthoses Proposed to Influence Muscle Tone: A Review, Journal of Prosthetics and Orthotics, April 2011, Volume 23 Number 2,52-57,

https://pdfs.semanticscholar.org/5a73/fddce 1dce358a8e3160e5fa2829f4b9c8de0.pdf

This paper specifically reviewed the design characteristic of AFOs, and clinical and biomechanical effects. The results suggested that level of evidence for AFOs being able to influence muscle tone was very low, hence further research with randomized control trials is required to investigate their clinical effects.

Following issues need to be investigated regarding use of AFO with tone influencing designs.

Classification of patient's groups that may benefit from this type of AFO needs to be more accurately defined.

The design parameters used in this type of AFO need to be more quantitatively defined. The statistical and clinically significant effects of these types of AFOs in comparison with standard AFOs need to be demonstrated with randomized controlled trials.

5. Dr Sara J. Mulroy, PhD, PT, Valerie J. Eberly, Joanne K. Gronely, Walter Weiss, Craig

J. Newsam, Effect of AFO Design on Walking after Stroke: Impact of Ankle Plantar Flexion Contracture Prosthetics and Orthotics International,2010, Volume: 34 issue: 3, 277-292, https://journals.sagepub.com/doi/full/10.310 9/03093646.2010.501512?url_ver=Z39.88

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This study was conducted to compare the effects of three ankle foot orthosis designs on walking after stroke and determine whether ankle plantar flexion contracture impacts response to the A.F.O. Total 30 post stroke patients were tested in four conditions:

- Shoes only
- Dorsi assist/Dorsi stop A.F.O. (DA/DS)
- Plantar assist/Plantar stop
 A.F.O.(PA/PS)
- Rigid A.F.O.

Gait parameters were compared between the conditions and participants with and without moderate Ankle plantar flexion Contracture. All A.F.O. increased dorsiflexion in swing and early stance. Both PS and Rigid A.F.O. restricted ankle plantar flexion and increased knee flexion in loading.

Individuals without contracture benefitted from an A.F.O. that permits dorsiflexion mobility in stance and those with quadriceps weakness were easily tolerated an A.F.O. with plantar flexion mobility. 6. Mr Roy Bowers, Karyn Ross, Development of a Best Practice Statement on the Use of Ankle-Foot Orthoses Following Stroke in Scotland Prosthetics and Orthotics International, September 2010, Volume 34 issue: 3, 245-253, https://journals.sagepub.com/doi/full/10.310 9/03093646.2010.486392

(ACCESSED ON 28TH JAN 2020)

national health service А Quality Improvement Scotland scoping exercised in 2007 identified to the development of best practice statement (BPS) on A.F.O. use after stroke. This paper outlines the development process of the BPS. BPS is an example of professionals in prosthetics and orthotics working in collaboration with service providers from variety of professional background to produce guidance on practice in response to a need identified by those working in stroke rehabilitation. Successful implementation will raise standards and promote а consistent, cohesive and achievable approach to the use of A.F.O. after stroke.

MATERIALS & METHODS

- **Type of study design:** Interventional Prospective
- **Study setting:** Patients reported to the prosthetic and orthotics department of the tertiary level rehabilitation center with the required infrastructure.
- **Duration of study:** 9 months
- **Study population:** Persons with hemiplegia reported to the prosthetic and orthotic department of the tertiary level rehabilitation center with the required infrastructure.
- Sample size: 10
- **Sampling technique:** Convenience sampling. The subjects had recruited for the study after the prescription from outpatient department of the Institute.
- Method of selection of study subjects (Eligibility criteria):

A. Inclusion Criteria

- Both gender(male/female)
- Age group 30 to 60 years.

- Post stroke not used any A.F.O.
- Mild to moderate spasticity.
- No skin or other lesions
- Able to follow instructions and give inform consent

B. Exclusion criteria

- Patients with severe spasticity
- Hearing and visual impairment
- Mental Retardation
- Patients with history of more than one stroke
- Patients with fixed deformity

C. Withdrawal criteria

- Due to personal / family reason
- Discomfort during process
- Medical reasons
- Unwilling to participate in the study

• Operational definitions

Hemiplegia- It is a condition caused by brain damage that leads to paralysis on one side of the body.

Spasticity- It is a condition in which there is an abnormal increase in muscle tone or stiffness of muscle which might interfere with the movement, speech or be associated with discomfort and pain.

SAFO-Solid Ankle Foot Orthosis.

ADA-TRAFO – Articulated Dorsiflexion Assisting Tone Reducing Ankle Foot Orthosis.

Step length: It is the distance between two successive points of heel contact of the opposite feet.

Stride length: It is the distance between two successive points of heel contact of the same foot.

Cadence: Number of steps per minute.

Speed: Distance covered by the body in unit time.

Width of walking base: distance between the center of heel of two feet.

• Orthotics and Prosthetics Users' Survey (OPUS): It is a self-evaluation report given by the users which allow orthotic and prosthetic practitioners to evaluate the quality and effectiveness of their services.

 Specification of Instruments and related measurements

Machinery and Equipment's in the department of Prosthetics and Orthotics.

- Study of parameters
- Step length
- Stride length
- Cadence
- Speed
- Width of walking base
- 6m walk on level ground
- Time for Ascending ramp (10meter)
- Time for Descending ramp(10meter)
- Time for Ascending stairs (11 number of steps)
- Time for Descending stairs (11 number of steps)
- Study instrument / data collection tools:
- Stopwatch
- Goniometer
- Methods of data collection relevant to objectives:
- The different parameters of the study were observed and recorded.
- The data was collected from the same patient with solid ankle foot orthosis (SAFO)and Articulated Dorsiflexion Assisting tone reducing ankle foot orthosis (AD-ATRAFO) after use of 1 month each.
- Data management and analysis procedure:
- Data has recorded manually.
- Data analysis plan and method:
- To interpret and compare the data obtained with both the orthosis on the same patient Paired t-test was used for statistical data analysis and at $p \le 0.05$ levelof significance.

Protocol And Procedure

First the approval of the institutional ethics committee was obtained. Study has carried out in three different phases.

Phase-I

In this phase patients reporting to the prosthetic and orthotic department were selected and recruited as per the inclusion criteria. The patient has then counseled and informed in detail about the proposed study followed by obtaining a voluntary written consent from the patient. Required evaluation of the patient was done.

Phase-II

Measurement and casting were taken for SAFO and ADA-TRAFO. It took at least 5 working days to fabricate the orthosis. After satisfactory fit of SAFO gait training was given and the orthosis was delivered to the patient to use for one month. After one month follow up has done during which subject has assessed for 10-meter walk test and various study parameters was studied. Readings with SAFO was studied and recorded at that time. Patient satisfactory survey for SAFO was taken.

After this SAFO was retained by the department and ADA-TRAFO was fitted and gait training with the orthosis has given. Orthosis was delivered to the patient for the period of one month. After one month follow up was done to assessed for 10-meter walk test again and various study parameters was studied. Readings with ADA- TRAFO was studied and recorded. Patient satisfactory survey for ADA-TRAFO were taken.

Phase-III

Analysis of above two data with both the orthosis was carried out and the results has been recorded with level of significance at $p \le 0.05$.

Efficacy of the Articulated Dorsiflexion Assist TRAFO was studied in terms of various gait parameters (step length, Stride length, Cadence, Speed, Width of walking base, 10- m et er walk test, time for Ascending and Descending ramp, Ascending and descending stairs) and OPUS: Lower-Extremity Functional Status Measure is taken.

STATISTICAL ANALYSIS

DATA COLLECTION Spatiotemporal parameters of gait with SAFO and ADA-TRAFO

No	Parameters	SAFO	ADA – TRAFO
1	Step length	0.30	0.34
2	Stride length	0.60	0.57
3	Cadence	56	55
4	Speed	0.27	0.23
5	Width of walking base	0.18	0.17
6	Time for 10meter walk	36.74	42.84
7	Time for Ascending ramp (10 m)	39.88	14.11
8	Time for Descending ramp (10 m)	56.25	51.38
9	Time for Ascending stairs (11 steps)	28.58	26.05
10	Time for Descending stairs (11 steps)	25.57	24.50

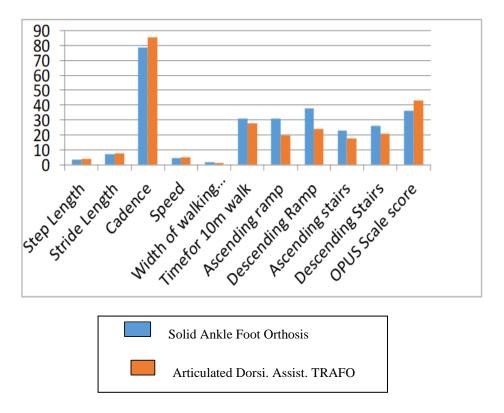
OPUS: Lower-Extremity Functional Status Measure

Parameter	SAFO	ADA – TRAFO
OPUS SCORE	36	42

RESULT

Summary	of Result
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	Mean		StandardDeviation(SD)		
Gait Parameters	SolidAFOADA- TRAFO			t-value	Remark
Step length	0.33	0.37	0.09	1.226	p>0.05
(meter)					
Stride length	0.68	0.74	0.11	1.443	p>0.05
(meter)					
Cadence	78.50	85.70	7.48	3.044	P<0.05
Speed	0.41	0.49	0.10	2.368	P<0.05
(meter/sec.)					
Width of walking base					
(meter)	0.15	0.13	0.02	2.475	P<0.05
TIME FOR 10 METER WALK (sec)	30.77	27.63	6.19	1.606	p>0.05
Time for 10meter Ascending					
Ramp (sec)	31.04	19.45	10.48	3.497	P<0.05
Time for 10-meter Descending					
Ramp (sec)	38.03	24.01	15.48	2.861	P<0.05
Time for Ascending Stairs 11 steps (sec	23.01	17.40	4.83	3.670	P<0.05
Time for Descending Stairs 11steps (see	c)26.03	21.02	4.84	3.288	P<0.05



SUMMARY

- 1. ADA-TRAFO improved all the gait parameters significantly than SAFO.
- 2. Patient was more stable and faster with ADA-TRAFO during walking on stairs and ramps.
- 3. Orthotic user survey score was higher for ADA-TRAFO as compared to SAFO

DISCUSSION

According to Indian Stroke Association, every year close to 17 million people suffer from strokes, out of which 6.2 million die and 5 million suffer disabilities. The reason for so many cases of strokes and disabilities is because of lack of preventative strategies organization of and poor stroke management facilities. Post-stroke motor impairments cause difficulty in controlling the joints of the affected limbs to produce useful movements. Effective way to manage all this limitation is to use an orthosis to control the movement of the affected joints or to provide support to weak part of the limb. But evidence of use of orthosis in the management of stroke is lacking.

The majority of stroke patients will use some form of ankle foot orthoses (AFO) for

stability, safety and efficiency of walking. According to Lupinacci, two types of AFOs are used with stroke patients - plastic AFOs and double-upright conventional AFOs. Lupinacci said that patients who are dragging their foot (drop foot) due to reduced dorsiflexion strength or are unable to lift their leg to swing the foot through because of reduced hip flexion or a combination of both may be a candidate for an AFO.

Alistair Gibson, CPO, LPO, area manager of Hanger Prosthetics & Orthotics in Winter Park, Fla., said that some stroke patients do display drop foot with or without lateral instability due to weakness in the anterior tibial muscle group. They may exhibit weakness in the dorsiflexors so the AFO is there to prevent the foot from dragging on the ground when they walk," said Gibson. "When a patient has drop foot, their increased energy demands on walking are significant." Additionally, Gibson said that due to quadriceps weakness combined with plantarflexor tone, patients will attempt to stabilize

their knee by firing off their hip extensors and going into recurvatum. "The AFO can

be a significant aid in managing and controlling recurvatum of the knee," he said. Chad Kettler, a physical therapist at Health South Rehabilitation Center in Wormley burg, Pa., said he will adjust an AFO, possibly adding a bit more dorsiflexion to break up extensor synergy patterns. He also used AFOs for patients who have balance issues. If we normalize the situation at the foot and ankle with an AFO, then we have a beneficial effect at the knee and hip joint. The hip joint typically remains in a flexed position throughout stance phase and the patient has difficulty extending his or her hip. So, Orthotists favoured approach is to get an AFO in which the tibia is held inclined forward at some angle to the vertical."

Review of literature suggests that all types of AFOs had positive effects on ankle kinematics however not on knee kinematics in swing phase. Articulated AFOs had better effects than other types AFOs, nevertheless their long-term usage and comparison among different types of AFO is to be evaluated. There is less research on TRAFO function in reducing spasticity, improving weight bearing ability, etc. and in stroke management it is again rare to find its evidence.

Various researcher suggests that level of evidence of AFOs being able to influence muscle tone was very low and there is no confirmation that TRAFO modification improve AFO function while standing however further study is required to prove their role in overall improvement in the gait. Thus, in stroke patient's classification of patients group that may benefit from AFO needs to be more accurately defined. The design parameters used in prescription of AFO needto be more quantitatively defined. Lot of studies had been done on solid AFO, Articulated AFO, TRAFOs and many of other type of AFOs which are specifically designed for Stroke patients. Relatively less evidence is available on combination of Articulated AFOs and Tone reducing AFO in the management of stroke. Hence there is

gap in this area to find out the efficacy of both of these designs.

Articulated dorsiflexion assist tone reducing AFO incorporates articulated AFO with dorsiflexion assist joint and TRAFO modification feature in one AFO. Major deficit in hemiplegic gait is the plantarflexed position of the foot due to spasticity and extension of the knee throughout the swing phase of the gait cycle. The dorsiflexion assists joint helps in preventing foot drop and indirectly controls the knee extension in swing phases of the gait cycle. Result of this study in comparing efficiency of spatiotemporal parameters of SAFO and ADA-TRAFO with paired t-test at 0.05 level of significance, showed significant difference in statistical analysis of data. It has been seen that distance of step length increases in the ADA-TRAFO as compared to SAFO in acomfortable walking speed of 10meter walkway test on even surface. But it is not statistically significant at 0.05 level of significance, to conclude that ADA-TRAFO and SAFO are equally effective in improving step length of the patient. In most of the cases stride length increases in the ADA-TRAFO as compared to SAFO in a comfortable walking speed of 10meter walkway test on even surface. But it is not statistically significant at 0.05 level of significance hence we can conclude that ADA-TRAFO and

SAFO are equally effective in improving stride length of the patient. ADA-TRAFO significantly improves the cadence and speed of the patient as compared to SAFO in a comfortable walking speed on level surface. The available range in the dorsiflexion in the ADA-TRAFO provides ground clearance during terminal stance of the gait cycle. It has been seen that width of walking base is reduced in case of ADA-TRAFO. Similarly, with ADA-TRAFO patient needs less time to cover 10meter walkway on ascending rampand descending ramp in a comfortable walking speed as compared to SAFO. Dorsiflexion assist ankle joint helps to clear the ground and also increases the stability while walking on

the ramp. Thus, we can conclude that ADA-TRAFO is effective in comparison with SAFO while ascending and descending ramp. With ADA-TRAFO patient can ascend and descend 11Number of steps in a comfortable walking speed in less time as compared to SAFO. Dorsiflexion assist ankle joint helps the patient to allow passive dorsiflexion and also increases the stability while walking on stairs. Thus, we can conclude that ADA-TRAFO is effective in comparison with SAFO while ascending and descending stairs.

Also, the OPUS Score satisfactory score was much higher in ADA-TRAFOs as compared to SAFO.

CONCLUSION

The main aim of this research was to find out the efficacy of ADA-TRAFO in improving gait and stability in comparison with SAFO in hemiplegic patients. For of gait, we had used assessment spatiotemporal parameters and for assessment of stability we had used ramps and stair walking criteria.

According to data analysis of this study ADA-TRAFO improved cadence and speed of the patient while walking on the level ground. ADA-TRAFO allowed patient to walk faster on ramps and stairs as it provided more stability than SAFO. Patient's compliance with ADA-TRAFO was more satisfactory than SAFO. More number of patients preferred ADA-TRAFO over SAFO while walking on level surface or on ramps or stairs. Patients were more confident while walking with ADA-TRAFO and had less fear of fall asdorsiflexion assist controls foot drop which indirectly controls knee extension. Easy anterior progression of tibia over talus helps in smooth roll over action which improves rocker of the gait. ADA-TRAFO will be benefitted to the patients having typical hemiplegic gait with mild to moderate spasticity, absence of contracture or deformity and independent ambulator. Patients' daily activities like rising from chair, picking up any objects, walking on even and uneven surface with or

without support, etc. had become easier than with SAFO. ADA-TRAFO not only improves the gait of the patient but also increases stability and reliance on the orthosis.

The study concluded that ADA-TRAFO has significantly effective in terms of improving gait and stability of the hemiplegic patients as compared to solid ankle foot orthosis.

Limitations of the study

- The study is conducted on a small sample size
- The time duration to conduct study was less.
- Patient with severe spasticity were excluded from the study.
- Patients who had experienced more than one stroke were excluded from thestudy.
- Patients with other medical illness like disease of heart, kidney, etc. other than stroke are not included.
- Chronic stroke patients were not included in the study.
- Results would have been more reliable and validated if gait motion analysis was done which was not possible due to corona pandemic situation.

Declaration by Authors

Ethical Approval: Approved by Ethical Committee of the Institute

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Conflict of Interest: The authors declare no conflict of interest.

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