IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

DEVELOPMENT OF A NOVEL LOW-COST UNILATERAL CONTINUOUS PASSIVE MOTION MACHINE FOR ANKLE FOOT MOBILIZATION IN PATIENTS BELONGING TO SUBACUTE PHASE OF STROKE

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Abstract: This study aimed to develop a low-cost ankle continuous passive motion (CPM) machine and to check the effectiveness of the CPM in increasing the passive range of motion (PROM) of ankle dorsiflexion in stroke patients of the sub-acute phase.A quasi-experimental study was conducted. Stroke patients in the sub-acute phase with inadequate PROM of ankle dorsiflexion were selected as the study's participants. The patients were given intervention using the newly developed low-cost ankle CPM. The duration of the study lasted up to 2 weeks (5 sessions per week; total 10 sessions per participant). Each session remained for 20 minutes. Goniometry was used as an evaluation tool and collected the pretest and posttest data. The data were subjected to statistical analysis using the Statistical Package For The Social Sciences (SPSS) 26 ver. The calculations were carried out using the Paired-t test. The significant value or 'p' value was obtained and proved that there is a significant improvement in the posttest scores of PROM of ankle dorsiflexion compared to the pretest scores.The study concludes that the PROM of ankle dorsiflexion can be improved using the newly developed, low-cost ankle continuous passive motion machine (CPM).

Index terms: Stroke, Ankle Joint, Ankle Dorsiflexion, Passive range of motion, Continuous passive motion (CPM), CPM machine

I. Introduction

1.1 Stroke

Stroke is a neurological disorder characterized by blockage of blood vessels. In stroke, the blood clots interrupt the blood flow by clogging the arteries of the brain and causing the blood vessels to break and leading to bleeding. Rupture of the arteries or the obstruction of blood flow in the arteries which leads to the brain causes the sudden death of brain cells due to the unavailability of oxygen[1]. Stroke can produce different symptoms such as a sudden numbness of the face, arm, or leg, mainly on one side of the body, causing sudden confusion, showing difficulty in speaking or understanding, sudden trouble in vision, loss of balance or coordination etc[2]Spasticity is a common complication of stroke. Spasticity is a condition characterized by a rise in muscle tone or stiffness, which may cause impairment of the movement and along with that causing discomfort or pain. It is brought on by damage to the nerve pathways in the brain or spinal cord that regulate muscle action [3].

1.2 Ankle joint complex

The ankle joint complex is formed by the lower leg and the foot components. It's a hinge variety of synovial joint. The ankle-foot complex gets both stability and mobility through its articulating surfaces. The foot should be able to provide an adequate base of support and also be able to bear more amount of weight bearing forces for various functions like running, walking, jumping etc.[4][5]

The ankle joint complex includes various movements but among them two most important movements are plantar flexion and dorsi flexion, which takes place in the sagittal plane [6]. Limited functioning and difficulty in performing different occupations can be caused due to decreased range of motion. Range of motion can be affected as a result of any injury or a disease affecting the joint. These limitations interfere with the ability of the client to perform essential day-to-day activities or occupations. A person's speed and strength of the movement can also be adversely affected due to the limited range of motion[7].

In case of stroke survivors to regain the ability to walk is one of the major challenging tasks. The Dorsiflexion range is limited by the altered muscle tone in the ankle, and this is one of the reasons for the functional limitations in lower extremity related to post stroke cases. The insufficient dorsiflexion ROM of the ankle results in mobility issues such as unable to bear weight in the paretic leg, walking speed, cadence will be reduced and mainly the risk of falls will be increases thus preventing the sub-acute stroke patients from full participation in their activities of daily living[8]

1.3 Continuous passive motion therapy

Continuous Passive Motion (CPM) therapy is often used after surgical procedure of a joint or injury to help improve joint range of motion and reduce stiffness. It involves the use of a machine that gently moves a joint through a predetermined range of motion for an extended period of time, without any active effort from the patient. Number of people with locomotor dysfunction is increasing worldwide, thereby, automated assistive tools and machines have proven to be very efficient and crucial in treating physical injuries and disabilities. CPM helps to reduce muscle tightness and joint stiffness, pain, swelling, formation of scar tissue and helps increasing ROM and flexibility. Designs of such machines include two important features; firstly, the ability to mimic the kinematics of a human joint, with its time variability and secondly, geometrical self-adjustment of the machines to comply as much as possible, with the kinematics of the human joint[9]. There are also a number of other interventions which help in improving the passive ROM in joints they involve splinting, serial casting, joint mobilization techniques, in-clinic programs, exercise interventions, steroid injections, saline injections,etc[10].

1.4 Low-cost machines in rehabilitation

In rehabilitation, the machines are considered as invaluable. The machines will help in measuring a patient's progress with much better accuracy, also they are used widely in comparing the outcomes. The machines will also shift the way a treatment is delivered. As the technology cost gets dropped and along with that the cost of manual labor rises, is been found that the machines will not only provide support but also will be able to give intense therapies cost-effectively [11].

Nowadays the cost of the machine remains as the biggest barrier to its widespread use. When the portable machines or devices are made available only then we can look into the cost saving aspect. If these machines or robots are inexpensive then it can be delivered at people's doorstep without any difficulty, making the therapy much easier. The use of simpler, portable machines help in the home-based treatment needs of each individual rather than the large machines which are more suitable for clinical setups[12]

The gadgets that are available for this purpose are still out of reach for the majority of people, mostly because of their price, availability, and capacity to adjust to various patients. So, a low-cost rehabilitation machine is required since there aren't enough professional medical facilities or staff to handle the growing demand in medical services, especially in many rural areas of India[13].

II ANKLE CONTINUOUS PASSIVE MOTION MACHINE (PROTOTYPE)

The newly developed ankle continuous passive motion machine is a motor-driven machine which can be used to promote movement in both sagittal plane and frontal plane by shifting the machine accordingly. The machine can be operated manually by adjusting the ankle, speed and direction. The ankle CPM machine works by gently and passively moving the ankle joint through a range of motion. The CPM can be used to stretch the tight muscles in the ankle area, to give continuous passive movements, to improve ankle flexibility and prevent joint stiffness, to help by promoting the ankle range of motion and strengthening the ankle muscles, which can further improve gait and balance and to relieve the workload of therapists from manual labour. The machine can also be easily operated by all people.

2.1 Design of the machine

A manual draft was prepared which explains the design and working of the machine. The machine parts were prepared through 3d printing technology using a transparent and rigid plastic known as polymethyl methacrylate or PMMA, gypsum board, and fiberglass. The machine has a cross shaped footplate which is supported using a trapezoid shaped plate on both sides which are also made of PMMA. The trapezoid plates are attached to a base which is made using fiberglass and the control unit is made of gypsum board. The footplate consists of four gaps to insert the velcro straps or bands to fix the foot to the footplate for stabilization.

The machine controlled by using a 250 N arduino servo motor which is connected to the foot plate. The control unit has four switches which coordinates the angles and movement direction of the foot plate, three switches are fixed to control the speed of the movement ranging from maximum, moderate, minimum; a knob is also attached to fix the desired joint range of motion to be moved.

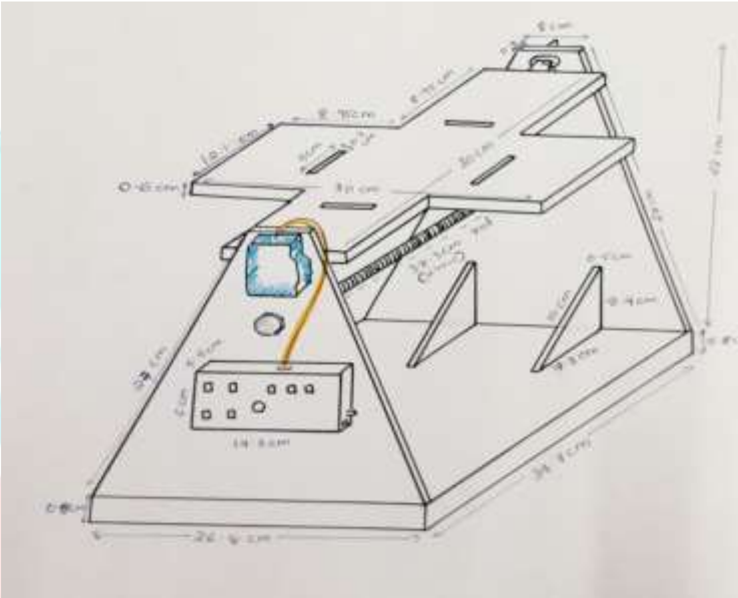

Figure 1 : Graphical design of the machine

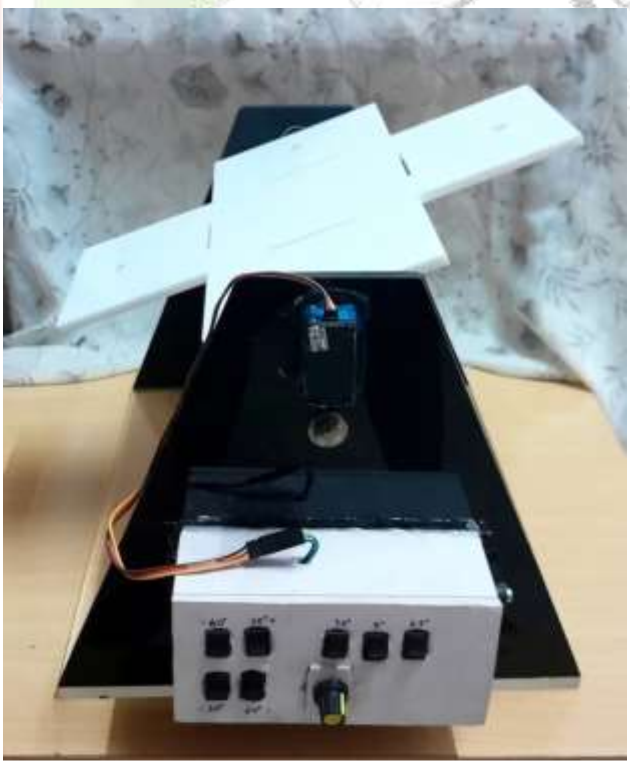

Figure 2: Image of the machine

III. METHODOLOGY

3.1 Research design:
This is a quasi-experimental pre and post-design research.

3.2 Sampling technique:
Convenient sampling was used for this study.

3.3 Sample population:
Stroke patients of the sub-acute phase were chosen for inadequate dorsiflexion passive range of motion at the ankle joint

3.4 Sample size:
10

3.5 Inclusion Criteria:
- Ages between 18 and 75years.
- First-ever stroke with less than 6 months duration of spasticity of the affected ankle.
- Modified Ashworth Scale(MAS):3 at the ankle joint
- Adequate cognitive and language functions to understand instructions.
- Residual hemiparetic gait deficits.

3.6 Exclusion Criteria:
- Patients with communication problems.
- Patients who have co-morbidities affecting motor performance such as dementia, orthopaedic, and arthritic inflammatory conditions that could cause limited ankle movement.

3.7 Instruments used for the data collection
The goniometer used in this study is theHalf Circle (180-degree) goniometer. Goniometer measurements are used to measure the number of limitations in the range of motion and use it to decide the appropriate intervention plan. Estimating the range of motion visually is unreliable when it comes to precision and accuracy, but compared to that measurements with the goniometer are more reliable to estimate ROM [20]. The reliability of the goniometer depends upon the joint and the range of motion that is being assessed but generally is been proved that the universal goniometer shows good to excellent reliability [21]. Studies show that the universal goniometer has high intra-rater and inter-rater reliability, along with reliability on the non-experts improved with the clear instructions on the placement and alignment of the goniometers. So, it's important that, if possible, the same therapist should measure and carry out the process to improve the accuracy in measurements [22].

3.8 Data collection
The design of the ankle CPM machine was prepared to develop the machine. The machine was developed and produced before the authority and got the approval to use it for the patients. Out of 13 patients, 10 patients were selected for the study based on the selection criteria. The purpose of the study and procedures were explained to the patients clearly. Informed consent was collected, along with the patient's sociodemographic data in respect to confidentiality. The patient pretest value of ROM is recorded using a goniometer. Patients have been given total 10 sessions (5 sessions per week) over 2 weeks for each session lasting about 20 minutes of continuous passive stretching training using the ankle CPM machine. After a period of 2weeks, the post-test value was recorded

3.9 Study protocol
The patient was comfortably seated. The leg was lifted and the patient's foot was stabilized. The goniometer axis and arms were fixed and the ankle joint was moved in the dorsiflexion, through its range of motion. The passive range of motion of the ankle dorsiflexion movement was measured and the pretest scores were recorded. Then the patient's knee was flexed at an angle of 30 degrees and strapped the patient's foot into the footplate using a Velcro strip with the ankle joint in 0-degree dorsiflexion. The foot was secured to the footplate by strapping the Velcro strip at the dorsal side of the foot. The stretching velocity of the CPM machine was set at 5 degrees per second and a 5-second holding period at the extreme positions. While receiving the stretching exercises, the patients were asked to look at the display screen where an ankle joint was moved in dorsiflexion from the neutral position and made the patient try to feel the

normal ankle joint movement. After the 10th session, the post-test was done and the ankle PROM of dorsiflexion was measured and recorded.

Figure 3: Stabilizing the leg on the foot plate

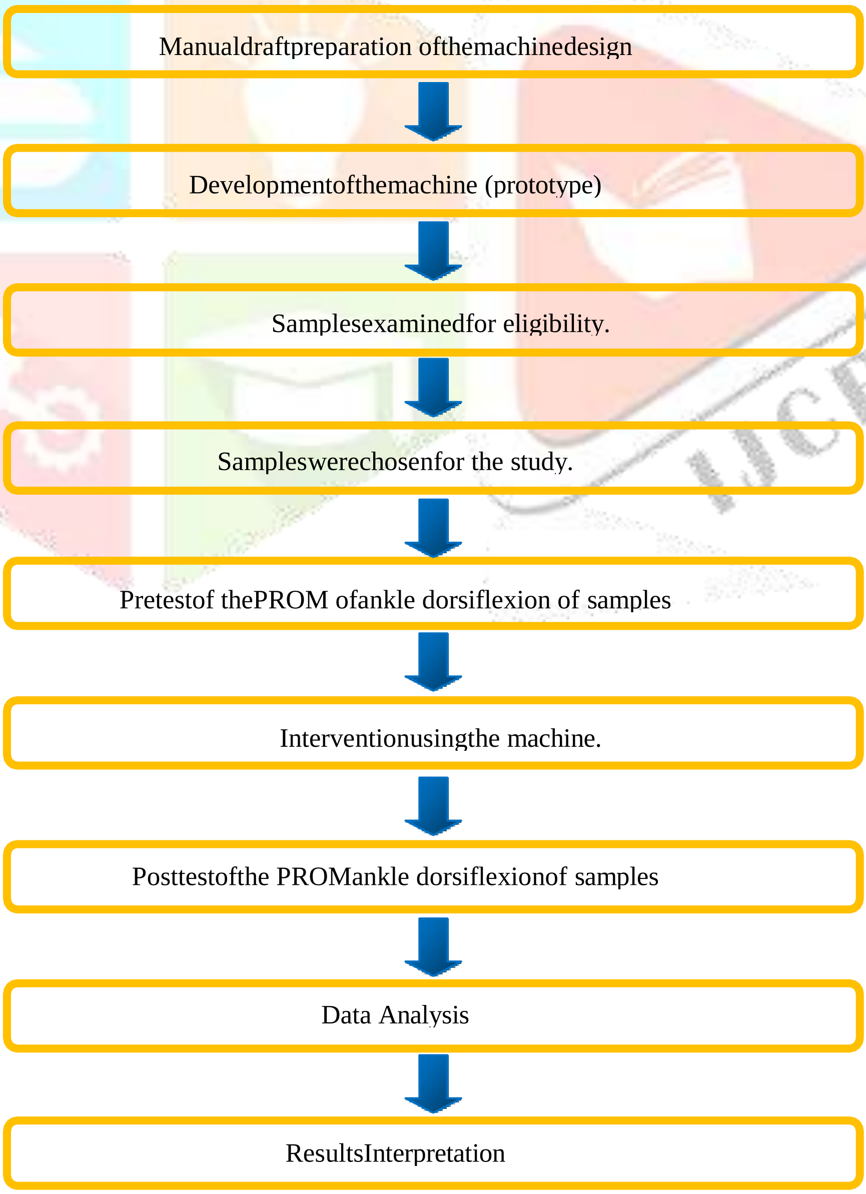

Figure.4: schematic representation of research design

IV. RESULT

The aim of this study was to develop a low-cost unilateral ankle continuous passive motion (CPM) machine (prototype) to find the effectiveness of the prototype in improving the passive range of motion of dorsiflexion movement in the ankle joint of patients belonging to the subacute phase of stroke. The previous chapter laid out the methodology employed for the current study. This present chapter looks into the analysis of the results obtained.

4.1 Descriptive statistics of the age group of the participants

Table 1 shows the age distribution of the participants. The age of the participants ranges from 45 to 60. With a Mean of 53.8 and a Standard Deviation of 5.2.

Table 1:Descriptive statistics of the age group of patients.

(n = 10)	**Range**	**Mean**	**S.D.**
Age(Years)	45 to 60	53.8	5.2

Table 2 shows the final results of comparison between the pretest and posttest scores. There was an improvement in dorsi flexion from the pretest to the posttest which is indicated by the p-value (significant value)of „0.005" (< 0.05 is significant) which indicates that the passive range of motion of ankle dorsi flexion has a significant improvement from the pretest to the posttest.

Table 2: Descriptive statistics for Ankle Dorsi flexion PROM

Patients(n=10)		**Mean**	**S.D.**	**"t"**	**p-value**
Dorsiflexion	Pretest	10.4	1.2	-3.7	0.005
	Posttest	12.7	2.5		

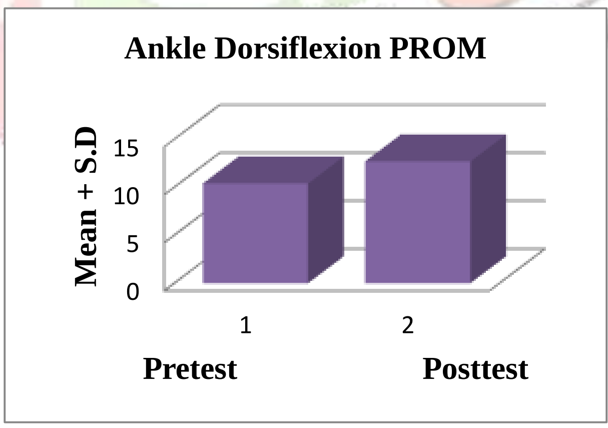

Figure 5: Pretest and posttest comparison between passive range of motion of ankle dorsiflexion

V. DISCUSSION

This study aimed to develop a low-cost ankle continuous passive motion machine and to compare the pretest and posttest scores of the passive range of motion of ankle joint dorsiflexion movement in an experimental group. Based on the results of this study, the alternate hypothesis of the study was accepted and null hypothesis was rejected.

Based on the results obtained, continuous passive motion to the spastic ankle joint using the CPM machine has improved the passive range of motion of ankle dorsiflexion motion. Table 2 from the data analysis chapter shows a significant increase in the mean posttest values compared to the mean pretest values.

This result was achieved because of various reasons such as the ankle was stretched using a constant velocity with the continuous passive motion machine throughout the intervention[14]. the ankle was stretched at an equal rate per second using the continuous passive motion machine throughout the intervention, this in fact prevented the cause of occurrence of the stretch reflexes which caused as a result of repetitive stretches[15][16]. , the joint was held by the continuous passive machine at the extreme end range which provided the ankle joint to feel the stretch[17] ,the continuous passive motion using the machine lead to the reduction in the ankle joint spasticity to some extend which resulted in the improvement of passive range of motion of the patient[18] and also the subjective factors like the interest and motivation of the patient had also contributed to the current outcome like, for people who believe that recovery depends on their own efforts and active participation in the rehabilitation process achieve much better results than those who are less convinced[19].

This study shows the proof that the ankle continuous passive motion machine can act effectively and bring out positive results from the intervention. Our study is different from the previously mentioned studies by being able to provide positive results by using a low-cost ankle CPM machine.

VI. CONCLUSION

For a stroke patient, the ankle dorsiflexion passive range of motion will be affected due to the presence of spasticity. Based on the study results it is concluded that the passive range of motion at the ankle joint of stroke patients of sub acute phase can be improved using the newly developed, low-cost ankle continuous passive motion machine (CPM) ,the machine can also help to reduce health care costs associated with longer therapy sessions.

VII. LIMITATIONS

More number of sample size could have been chosen for the study.

VIII. RECOMMENDATIONS

The ankle CPM can be used for edemamobilization, ankle fracture stiffness, burn contractures at the ankle joint, Achilles tendon (TA) tightness in children with cerebralpalsy, acute stroke phase flaccidity mobilization, active ROM of the ankle in foot drop cases, spasticity of the ankle joint. According to the conditions and comfort of the patient, further modifications of the machine can be done.

IX. ACKNOWLEDGEMENT

First and foremost I am grateful to the GOD for all the blessings and opportunities provided for me and also thank in gratitude for the knowledge, strength, peace of mind, and good health provided to me to complete this study. I acknowledge The Almighty’s presence in my life and I am humbled by the grace shown to me. I would like to thank my dearest family for the support, guidance, and encouragement they have showered upon me throughout, which helped me to complete this study. Without them, it would not have been possible.

I am deeply grateful for the valuable guidance and mentorship provided by my mentor and research guide **Mr. Kurinji Chelvan S, MOT(DD)., PGDCBR., MBA.**, Principal, College of Occupational Therapy, NIEPMD for his insightful advice, feedbacks and helpful recommendations. I also thank him for helping me to work on my thesis with full freedom and complete this study successfully. My heartfelt thanks to my co-guide **Ms. Abhipsha Biswal, MOT (Orthopaedics)**, Lecturer at College of Occupational Therapy, NIEPMD for providing valuable guidance, suggestions, and encouragement throughout this study.

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