

## **Efficacy of Dynamic Splinting on Plantar-Flexion Tone and Contracture Seen in CVA and TBI Patients: a Controlled, Cross-Over study**

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### **Abstract**

The purpose of this study was to examine the efficacy of low-load, prolonged-duration stretch with dynamic splinting in reducing ankle contracture for stroke (CVA) and traumatic brain injury (TBI) patients. This controlled, cross-over study lasting six months was conducted at multiple outpatient facilities across the USA. Fifty volunteer patients (30 CVA and 20 TBI) who were one year or more post-incident took part in this study, and each presented with a pre-existing plantarflexion contracture.

All patients were treated with standardized therapeutic protocols (2/wk) for six months and ROM measurements were taken at enrollment, three and six months. Selected patients were “crossed-over” into *experimental* groups, as prescribed by their physicians (25 CVA and 15 TBI) for the final three months of this study, receiving additional treatment with dynamic splinting (DS) in dorsiflexion. The dependent variable was the maximal ankle dorsiflexion measured in PROM, and there was a significant change for the cross-over patients, ( $p = 0.007$ ). Preexisting excessive plantarflexion contracture was effectively reduced with DS for six months.

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### **Aim**

Cerebral Vascular Accident (CVA) is the third leading cause of death and the top leading cause of long-term disability in the United States.<sup>1</sup> This condition which affects over 1,000,000 patients per year, often shows the complication of hemiparesis and excessive neuromuscular tone (hypertonicity) in excessive plantar flexion as a frequent complication.<sup>1-5</sup> Over 1,500,000 individuals in America have suffered a Traumatic Brain Injury (TBI) and while the severity may vary, more than 70,000 TBI patients live with long-term or lifelong disability resulting from these injuries.<sup>6-11</sup>

Hypertonicity in plantar flexion is a frequent complication of TBI, and if not addressed with appropriate therapies and/or treatments, the tone can then cause contracture.<sup>2,11,12</sup> The source of hypertonia is considered to be attributed to infarct or damage to the upper motor neuron (UMN) which results in decreased inhibition.<sup>13,28</sup> In such a case, the gamma motor neurons will receive excess signals for muscle contraction and without inhibition from the UMN, the increased stimulation will yield tetany and hypertonia. Contracture is shortening of the connective tissue which results from hypertonia and decreased activation of antagonistic muscle.<sup>7,11,8-10,12-15</sup> or following immobilization of fractures.<sup>2,10,16,17</sup> Contracture has routinely been treated with interventions ranging from passive range of motion (PROM) stretching to botulinum toxin

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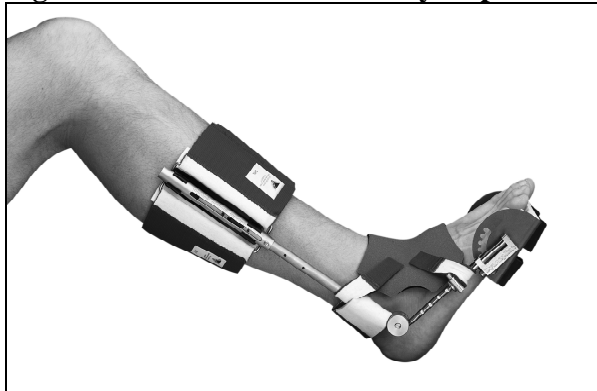
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injections which reduce the hypertonicity, allowing a more effective stretching protocol.

**Figure 1. Ankle Dorsiflexion Dynasplint**



Numerous studies have been conducted on the use of botulinum toxin type-A (BTX) for treating patients with hypertonicity following CVA or TBI.<sup>3,12,14,18-21,31</sup> In the study conducted by Pittock et al,<sup>21</sup> patients randomly received either placebo, 500, 1000, or 1500 U of BTX. The results showed that although the highest dose yielded the most significant benefit in reducing hypertonicity, limb pain, and need for walking aids, significant improvement also was seen in patients receiving 1000 U of BTX and some benefits were seen in patients receiving 500 U as well. Sixty-eight of the 234 patients (29%) reported a total of 130 adverse events (infection, seizures, lack of coordination, and injection site pain or stinging). However, BTX injections alone do not reduce contracture.

Serial casting is commonly used in treatment of TBI and CVA patients' excessive plantar flexion. Singer et al<sup>25</sup> examined the short-term benefits that brain injury patients received from serial casting. Sixteen patients (19 limbs) with deteriorating ankle range of motion underwent serial casting for 18 months. Maximal ankle dorsiflexion, was tested over the 18 month course. There was a significant difference between the initial calibrated goniometer PROM and the final measurement, but within just one week of the cast removal, 18% of the subjects experienced reduced maximal ankle dorsiflexion, PROM. This demonstrates that serial casting is

effective in short-term but suggests that patients require a secondary modality for permanent tone management and contracture reduction.<sup>11,20,22</sup>

While there have not been adequate investigations on the use of dynamic splinting (DS) of the lower extremity following CVA<sup>18-21,23,27,31</sup> or TBI,<sup>22,24-26</sup> one case study did measure the effect of DS on a TBI patient who had unresolved elbow contracture.<sup>15</sup> This report showed that the patient gained 52 degrees of elbow extension following nightly dynamic splinting for five months. The Dynasplint Systems have been shown effective in reducing contracture, which is orthopedic in origin<sup>10,16,17</sup> and the same biomechanical principle of low-load, prolonged-duration stretch to increase the total time at end range (of motion) should achieve a comparable physiological change in the contracture reduction in neurological patients.

Studies have suggested further research to determine the benefits derived from stretching in contracture reduction.<sup>8,10,11,13,15,20</sup> Blanton et al suggested a cross-over study to determine the difference between physical therapy and physical therapy with mechanical devices.<sup>11</sup> The purpose of this study was to examine the efficacy of low-load prolonged-duration stretch with DS in reducing ankle contracture for stroke and traumatic brain injury patients.

## **Methods**

### ***Subjects***

Fifty patients were enrolled in this study from multiple treatment centers in the United States (CVA = 30 and TBI = 20). All patients had been diagnosed with CVA or TBI more than 12 months before participating and each received a standardized physical therapy for unresolved contracture in plantarflexion. The standardized therapeutic protocols included: moist heat, patient education and re-evaluation of symptoms, joint mobilization (limited to progressive end-range joint mobilization), active range of motion, and therapeutic exercise. In addition to physical therapy, patients were instructed to perform daily ankle stretching at home.

The duration of this study was six months and the therapeutic protocols were continuous for that full duration. After three months, all patients had their maximal ankle dorsiflexion (PROM) re-measured by the originating therapist. Selected patients were re-categorized into *experimental sub groups* of TBI cross-over and CVA cross-over, based on physicians' prescription of the Ankle Dorsiflexion Dynasplint, (AFD, Dynasplint Systems, Inc., Severna Park, MD, USA). Control patients continued with the standardized physical therapy programs. Before starting this study, all patients signed an informed consent and patients' rights and privacy were maintained throughout this study in accordance with the Declaration of Helsinki.

### **Materials**

The AFD used is a biomechanical spring-tensioned device which applies force to the posterior region of the second metatarsals (ball of the foot) through a cushioned, hypoallergenic foot plate. A Velcro cuff surrounds the posterior gastrocnemius region (calf), providing stability. The counter force is applied across the anterior region of the inferior extensor retinaculum (bridge of the foot). (See Figure 1.)

The AFD uses a calibrated, replicable, bilateral tension device to produce the force needed to achieve the low-load, prolonged-duration stretch. As the contracture is progressively reduced, the force is increased to keep the joint at end-range, and the 12 increments are shown in the tension gage. (See Figure 1.)

### **Procedures**

When cross-over patients were individually custom-fit with the AFD, each was trained on how to don and doff the splint. Verbal and written instructions were provided for safety, general wear and care, and tension setting goals were set based on their tolerance. The device is worn at night, while resting or sleeping (6-8 hours), which could yield an additional 42-56 hours per week in ROM therapy.

After the patient spent the first week becoming accustomed to sleeping with the unit, tension was then increased one setting every two weeks, based on the comfort of the patient. This provided greater force in dorsiflexion as the ROM progressed. If the patient experienced additional "post-wear fatigue" or soreness following the increase in tension, then they were instructed to reduce the time worn for the next night. Tension was gradually increased from an initial setting at #1 (equaling 2.0 foot pounds, 27.7 KG/cm of torque) to the #8 setting in dorsiflexion (equaling 7.5 foot pounds, 103.7 KG/cm of torque).

Patients were required to submit monthly tracking forms to their therapist noting the duration of wear of the AFD. Patients who did not comply at least 90% of the time by completing each month's report and seeing the prescribing physical therapist and/or physician were dropped from the study for noncompliance. For this reason, four CVA patients and one TBI patient were eliminated from this study.

Assessment of the maximal ankle dorsiflexion PROM was done by the same prescribing physical therapist that treated each patient. The therapists were instructed to measure degrees of dorsiflexion from a neutral position of 0 degrees in dorsiflexion with a calibrated goniometer.<sup>33</sup> For example, if a therapist measured 30 degrees of plantar flexion it would be recorded as: -30° dorsiflexion.

### **Statistical Analysis**

Data Collection was done by each physical therapist and was transferred to the biostatistician for analysis. A one way Analysis of Variance (ANOVA) was performed for analysis of data using the, *GraphPad InStat* software, and other calculations were made using Microsoft Excel. The dependant variable was the PROM (in degrees from neutral of dorsiflexion).

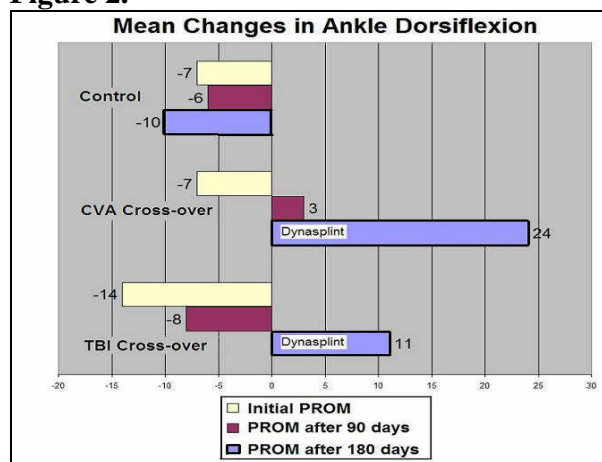
## Results

Ten control patients (5 TBI and 5 CVA), and 35 cross-over patients (21 CVA and 14 TBI) completed the study. There was a statistically significant change in the PROM for the cross-over patients after wearing the AFD for 180 days ( $p = 0.0007$ ,  $F=4.795$ ). (See table 1.) There were no adverse reactions reported while wearing the AFD in this study, and the splint discomfort was reduced with gradual increase in the dynamic tension of this device. No statistically significant difference was seen between the two cross-over groups (Mean difference  $12.69^\circ$ ,  $p > 0.05$ ). (See Figure 2.)

**Table 1. Results by Pathology**

	Initial PROM			PROM 180 days		
	N	Mean	SD	N	Mean	SD
Control	10	-7.9	28.7	10	-10.1	29.9
CVA X-Over	21	-7.4	29.1	21	24.2	23.9
TBI X-Over	14	-14.1	31.8	14	11.5	29.7

**Figure 2.**



## Conclusion

The purpose of this study was to examine the effect of low-load, prolonged-duration stretch with DS in reducing ankle contracture for CVA and TBI patients. The evidence confirms findings in previous case studies that DS is beneficial in reducing contracture.<sup>8,10,12,16</sup> In this study DS used for up to 56 hours per week,

while resting or sleeping, has been effective in increasing patients' PROM resulting in more time available for clinicians to focus on higher rehabilitation challenges including motor skill reacquisition and weight bearing therapies. Unlike serial casting, this tool for contracture reduction does not limit activities of daily living and physical therapy.

The cross-over component of this study showed efficacy of this modality when combined with physical therapy as suggested by Blanton et al.,<sup>11</sup> and the use of a secondary modality which increases the time in ROM therapy, was effective as predicted by Singer et al.<sup>22</sup>

Limitations of this study include that the patients were not randomly assigned to the different groups. Therefore bias by the prescribing physician and towards patient compliance history with home therapy protocols may be confounding variables in this controlled, cross-over, case series study. A future investigation could include randomization and a single-blind experimental design to resolve these limitations. A study of this modality following BTX injections could also be beneficial in measuring potentially effective, concurrent protocols for tone management and contracture reduction in CVA and TBI patients. Such a study might also determine if DS extends the effect of BTX injection treatments.

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#### Conflict of interest:

Dr. Lai and Mr. Jones have no conflict of interest and neither received compensation for this manuscript. Dr. Willis is employed by Dynasplint Systems, Inc., but he has no ownership or stock in this company.

#### Equipment Used:

##### Ankle Dorsiflexion Dynasplint® Systems

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