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ORIGINAL RESEARCH

Dynamic Splinting After Treatment with Botulinum Toxin Type-A: a Randomized Controlled Pilot Study

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ABSTRACT

Introduction: Over 1.5 million Americans are diagnosed with a stroke each year, and excessive flexion or extension (hypertonia) of upper extremity joints are common secondary conditions. The purpose of this study was to compare the efficacy of botulinum toxin type-A and manual therapy, with the adjunct treatment of dynamic splinting on range of motion, spasticity, and elbow flexor hypertonia, in a randomized trial. ***Methods:*** Thirty-six subjects were recruited for this pilot study and all exhibited hypertonia in elbow flexion. Six patients were excluded due to noncompliance. Testing was done with pre/post active range of motion in elbow extension, and the Modified Ashworth Scale (extension) for spasticity. All patients received the current standard of care: botulinum toxin type-A injections and manual therapy. Experimental patients were randomly assigned adjunct treatment with Elbow Extension Dynasplint®. ***Results:*** Thirty patients completed the study (mean age [SD] 52±17 years). The percentage of change in active range of motion in elbow extension was greater for the experimental than for control subjects (33.5% vs. 18.7%). The Modified Ashworth Scale (extension) scores showed comparable changes of a mean 9.3% improvement for experimental versus 8.6% for the control subjects. ***Conclusion:*** This study confirmed the efficacy of botulinum toxin type-A in tone management and occupational therapy in contracture reduction. It also showed the value of dynamic splinting in maintaining gains in range of motion.

Keywords: botulinum toxin; contracture reduction; Dynasplint; range of motion; tone management

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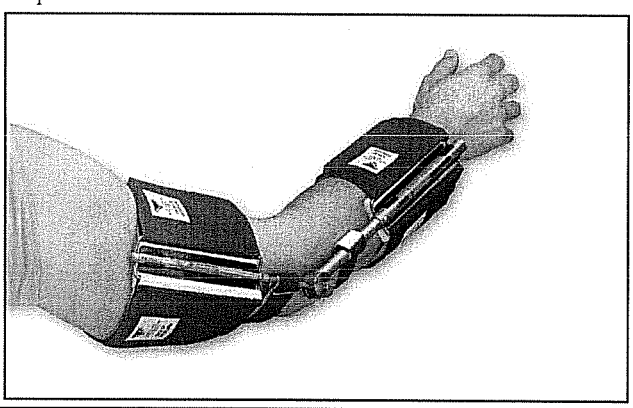
INTRODUCTION

Hypertonicity is defined by the National Institute of Health (2006) as "increased muscle tone or rigidity".[1] This differentiates hypertonicity from clonus, which is defined as a series of rapid muscle contractions. Hypertonicity commonly affects the upper extremities after cerebral vascular accident (CVA, or stroke).[1,2,3-5] Stroke is the leading cause of long-term disability in the United States, affecting over 1.5 million patients per year, often resulting in hemiparesis and hypertonicity.[1]

Botulinum toxin type-A (BTX) is an accepted modality for treating hypertonicity and spasticity.[3-8] An intramuscular injection of BTX disrupts the neuromuscular junction, blocking neural transmission by inhibiting the release of acetylcholine for muscle contraction.[3-8] In addition, occupational therapy uses manual stretching in joint-specific protocols and the therapist attempts to take the patient's joint to the end range of motion for as long as possible to reduce the contracture.[4-10] Previous investigators have described differences between dynamic splinting (DS) versus static progressive stretching (SPS) and serial casting.[11-14] DS uses consistent force through a bilateral spring-loaded tension system, which keeps the joint at end range. SPS uses constant limb position, which must be reset for each of several sequential positions for contracture reduction. This makes SPS similar to serial casting and they are also similar in occurrence of skin breakdown. The tension of DS may be overcome by recoil or spasm, which allows the joint to flex or extend thereby reducing the occurrence of skin breakdown. DS has constant force whereas SPS has constant position.

DS uses low-load, prolonged-duration stretch to remodel and permanently elongate connective tissue by using a calibrated, replicable, bilateral tension system.[12,13,15-17] As the contracture is progressively reduced, the force is increased to keep the joint at end range, and this modality has changeable torque settings from 16 kg/cm to 125 kg/cm, adapting to patients' size and degree of rigidity (Figure 1).[11-17] The purpose of this study was to compare the efficacy of BTX and manual therapy, with the adjunct treatment of DS (Elbow Extension Dynasplint® [EED]; Severna Park, MD, USA) on range of motion and spasticity in elbow flexor hypertonia.

Figure 1. Elbow Extension Dynasplint®.



MATERIALS AND METHODS

Participants

Volunteer patients who had previously suffered a CVA were recruited to participate in this study. These patients were qualified by the inclusion/exclusion requirements listed in Table 1, and briefed on the protocol of this study. All patients who chose to enroll gave their informed consent (as required by the University of Texas Health Science Center institutional review board, Houston, TX). Upon enrollment, all patients had their maximal active range of motion (AROM) measured, and Modified Ashworth Scale (MAS) score of extension was measured by the same therapist before and after the BTX injections. To measure the AROM, the therapist placed the patient's upper arm in anatomical position and instructed each patient to straighten their arm as far as possible; the therapist then took the AROM measurement. The patient was then instructed to flex their arm and the therapist moved the arm through passive range of motion while grading the rigidity according to the MAS.

The MAS measures spasticity, neuromuscular tone, and rigidity through the following scores and descriptions: (0)=No increase in tone; (1)=Slight increase in muscle tone, manifested by a catch and release or minimal resistance at the end of the range of motion, when the affected part(s) is/are moved in flexion or extension; (2)=Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the AROM; (3)=More marked increase in

Table 1. Inclusion/exclusion criteria.

Inclusion
Males and females aged 18-75 years, of all ethnicities
Patients who sustained stroke at least 6 months before entering study
Modified Ashworth scale score of 2 or more during elbow extension
Range of motion deficit of >24% in elbow extension
Exclusion
Patients with history of fracture to affected limb 3 months prior to enrolment
Patients taking aminoglycosides (known interaction with BTX)
Patients who had BTX injections within the previous 4 months prior to enrolment
Fixed, mechanical impingement blocking AROM
Patients with previous phenol injections to the study limb
Patients who had received serial casting of the study limb in the past 4 months
Patients with histories of other central neurological pathologies
Patients with baclofen pump implants
Patients who were pregnant, nursing, or may become pregnant
Patients who were not able to attend the scheduled twice-weekly therapy appointments

AROM=active range of motion; BTX=botulinum toxin type-A.

muscle tone through most of the AROM, but affected part(s) easily moved; (4)=Considerable increase in muscle tone, passive movement difficult; (5)=Affected part(s) rigid in flexion or extension.

Interventions

All patients received the current standard of care for elbow flexor hypertonia and that included BTX injections[2,4-10,18] and occupational, manual therapy.[2,3,17-21] The BTX injections were of uniform doses and injected into the biceps (150 U), brachialis (75 U), and brachioradialis (75 U) muscles, and the occupational, manual therapy occurred weekly for 16 weeks.

The occupational, manual therapy protocols used for each patient included the protocol proved by Vermuelen,[20] Hsu,[19,21] and Sun et al.[3] These methods included moist heat, patient education and re-evaluation of symptoms, joint mobilization (limited to progressive end-range joint mobilization), passive range of motion, AROM, proprio-neural facilitation to retrain sensorimotor deficits, and therapeutic exercise.

Experimental patients (selected with a randomized list) received the standard of care and additional, concurrent treatment with the EED (Figure 1). These patients were instructed on how to don/doff and safely operate the system by one consultant experienced with this modality. Tension was recommended to be increased one increment every 2 weeks, but this was based wholly on patient tolerance. The initial tension setting was #2 (16 kg/cm of torque), and the mean final tension setting was #6 (58 kg/cm of torque). The modality allows for greater time at each patient's end range of motion, and this has been proven effective in reducing contractures in several other joints.[11-17]

The EED device consists of hypoallergenic cuffs attached to bilateral tension bars to deliver a low-load, prolonged duration of force. It is prescribed for 6 to 8 hours of continual wear while sleeping. The dynamic, reproducible tension delivered by the EED allows the patient to make calibrated changes to adapt to increased AROM over time. Change in tension is prescribed twice a month based on patient comfort and tolerance. Tracking of all wear times and tension used was collected monthly by the attending clinicians.

Data Analysis

The population of patients who completed this study (n=30) was not adequate to power statistical analysis of variance, but Excel tables were kept to view the trends and mean changes in AROM elbow extension and the MAS score (extension). Values of the dependent variables were compared before BTX injections and after 14 weeks, which was designed to exceed the maximum duration of tone management from BTX alone.

Table 2. Patient demographics.

Variables	Experimental (n=15)	Control (n=15)
Male	7	10
Female	8	5
Mean age±SD, years	49.1±4	55.6±5
Ethnicity	A1, B4, C6, H4	A2, B4, C7, H2

A=Asian; B=African descent; C=Caucasian; H=Hispanic.

Table 3. Results: raw data.

	Experimental patient results								Control patient results							
	AROM				MAS				AROM				MAS			
	Pre-BTX	Week 1	Week 14	% Difference	Pre-BTX	Week 1	Week 14	% Difference	Pre-BTX	Week 1	Week 14	% Difference	Pre-BTX	Week 1	Week 14	% Difference
	−30	−40	−20	33.3	3	2	3	0	−70	−35	−40	42.9	1	1	1	0
	−5	−5	0	2.8	2	2	1	20	−70	−52	−35	50.0	4	2	4	0
	−30	−20	−20	33.3	2	1	2	0	−40	−45	−74	−85.0	2	2	2	0
	−81	−70	−30	62.9	2	2	0	40	−39	−65	−70	−79.5	2	2	2	0
	−24	−15	−5	79.2	2	2	2	0	−75	−72	−80	−10.7	2	1	2	0
	−110	−85	−110	0	3	2	2	20	−80	−65	−64	18.7	2	1	2	0
	−115	−45	−12	89.6	3	2	3	0	−16	−13	−3	81.3	2	2	1	20
	−7	0	0	4.0	2	0	2	0	−40	−28	−34	17.0	2	2	1	20
	−143	−140	−80	44.1	3	2	2	20	−61	−45	−32	47.5	1	1	0	20
	−40	−30	−34	15.0	2	1	2	0	−27	−19	−24	11.1	3	2	1	40
	−41	−42	−36	12.2	0	0	2	−40	−60	−38	−34	46.9	1	1	1	0
	−80	−78	−75	6.3	0	0	1	−20	−32	−42	−30	6.3	1	1	2	−20
	−85	−60	−64	24.7	1	1	0	20	−21	0	0	13.2	1	2	1	0
	−109	−88	−83	23.9	3	0	0	60	−90	−108	−15	83.3	1	1	1	0
	−34	−35	−10	70.6	1	1	0	20	−80	−80	−50	38.5	2	1	1	20
$\bar{\chi}$	−62.27	−50.2	−38.6	33.5	1.93	1.2	1.5	9.33	−53.4	−47.13	−39	18.7	1.8	1.34	1.47	8.57
SD	43.56	37.34	35.03	29.6	1.03	0.86	1.06	23.7	23.97	27.87	24.54	48.7	0.86	0.062	0.92	12.9
SEM	11.25	9.64	9.05	7.6	0.27	0.22	0.27	6.13	6.19	7.19	6.34	12.6	0.22	0.16	0.24	3.45
n	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15

Percentage difference on MAS is on a scale of 5 (ie, change in score of +1 = 20%).
AROM=active range of motion; MAS=modified Ashworth scale; $\bar{\chi}$=mean.

RESULTS

Thirty patients completed the study; six patients were withdrawn from this study due to noncompliance with scheduled occupational therapy appointments. The patient characteristics are shown in Table 2. The experimental group displayed a mean 33.5% change in AROM compared with the control group, which displayed a mean 18.7% change in AROM (Table 3). The MAS scores (extension) showed comparable changes of a mean 9.3% improvement for the experimental group versus 8.6% improvement for the control group (Table 3).

DISCUSSION

BTX treatment is unquestionably effective in tone management and this study agreed with these findings. However, BTX is expensive and has limited duration of treatment. Occupational, manual therapy is ideal for contracture reduction, but two hour-long appointments each week limit the total amount of time that can be dedicated to contracture reduction. The EED was a beneficial adjunct because it delivered an additional 42 to 56 hours per week in range of motion therapy, worn while sleeping. In this 14-week study, the experimental patients received over 670 hours of additional end-range therapy from the EED modality.

The results of this study concur with the findings of Harvey et al., who examined multiple studies on stretching for permanent contracture reduction.[22] They found that studies that employed "high-quality, intensive programs" with stretching more than 20 minutes per day for 6 weeks, (totaling 16 hours) were more likely to achieve permanent contracture reduction. Daily dynamic stretching accomplishes a structured, daily home therapy, as recommended by Denham for optimal daily function in tone management and contracture reduction.[23] Tone management is addressed by Avela et al.,[24] who found that a prolonged, passive stretching decreased reflex sensitivity, and the amplitude of peak-to-peak reflex decreased by 84%.

The purpose of this study was to compare the efficacy of BTX and manual therapy, with the adjunct treatment of EED on range of motion and spasticity in elbow flexor hypertonia. The limitations of this study include a large rate of withdrawal from the study due to noncompliance in occupational therapy or scheduled medical appointments, and so it lacked power for statistical analysis. The patients were all from one region and the fact that this was not a multicenter study is also a limitation. However, the trends showed that patients gained greater AROM in elbow extension with decreased spasticity. To conclusively measure the efficacy of this system, a future double-blinded study could be designed to measure change in contracture reduction from EED use, and such a study could be designed to show if extended duration of tone management from BTX was achieved with use of EED.

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