

## Botulinum Toxin Type A Injection May Restore Ankle Strategy Use in Stroke Patients: A Preliminary Report

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### Abstract

**Introduction:** Stroke causes upper motor neuron syndrome, and spasticity of foot ankle complex further leads to equine gait and posture stability disturbance. Botulinum type A (BTX-A) injection has been widely used in treating spasticity, yet few studies report its effect on posture control. This study aimed at applying BTX-A injection in treating ankle-foot complex spasticity and investigating its effect on ankle strategy use with sensory organization test.

**Material and method:** 9 stroke patients and 5 healthy subjects were recruited. BTX-A injection was applied over calf flexor muscle group under electrical stimulation guide. Strategy score (ST) and Composite score were assessed using standard sensory organization test (SOT) with SMART Balance Master. The higher ST and Composite score indicated that the subjects used more ankle strategy.

The individual test conditions were as following: EO: eyes open; EC: eyes closed; SV: swayed vision and fixed support; EOSS: eyes open and swayed support; ECSS: eyes closed and swayed support; SVSS: swayed vision and swayed support. For the patient group, SOT was performed before BTX-A injection, and at 4 weeks, 8 weeks and 12 weeks follow up. For control group, the assessments were performed once. Generalized estimating equation was implemented for data analysis, and set  $p < 0.05$  as statistical significance.

**Result:** Before BTX-A injection, Composite score of patient group was significant lower than control group. After BTX-A injection, there were no significant differences of Composite score comparing control group to patient group at 4 weeks, 8 weeks and 12 weeks follow up. Comparison within patient group revealed that Composite scores were significant higher after BTX-A injection at 4 weeks and 12 weeks follow up. For ST of individual test conditions, improvement trend of ST after BTX-A injection was noted in EO, EC, SV and EOSS condition. And the improvement in EOSS condition was most consistent.

**Conclusion:** BTX-A injection might restore the use of ankle strategy in stroke patients and might serve as the mechanism of the improvement in posture control.

**Keywords:** Stroke; Botulinum toxin type A injection; Sensory organization test; Ankle strategy; Posture control

### Introduction

Stroke is a major illness which causes impairment in cognition, sensory, perception, and motor function. The positive features of impaired motor function included stretch-sensitive phenomenon such as spasticity, hyperreflexia, co-contraction and spastic dystonia [1]. Among these symptoms, the spasticity of foot-ankle complex was most notably due to it directly lead to insufficient toe clearance during walking and result in stumbling and falling [2]. Equine gait was characterized as adducted hip, extended knee, plantar flexed and inverted ankle, and significantly interfere with balance, gait and walking speed [3,4].

Posture control altered after stroke, and many mechanisms were reported. Sensory integration impairment such as distorted

proprioception [5] and vestibular mechanism impairment [6]; motor movement impairment such as muscular weakness [7] and abnormal muscle tone with stiffening of the joints [8]. Other dysfunctions included loss of anticipatory activation during voluntary movements [9], delayed postural responses in the lower extremity muscles in standing displacements [10,11], decreased area of stability in stance [12], an uneven weight distribution in stance with less weight placed on the weaker leg [13] and difficulties in adapting postural movements to changing task demands [14]. Many studies had focused on the mechanism of posture control alteration after stroke, but few had discussed with the treatment.

Chemodenervation with botulinum toxin A (BTX-A) injection effectively reduced harmful spasticity while preserved useful motor function [15]. Current studies showed beneficial effects of IM BTX-A injection in several aspects. For anti-spasticity, it effectively reduced lower limbs spasticity, improved distal positioning in the upright situation, and decreased subjective rating of problem severity [16,17];

for clinical function, it improved walking distance, stepping rate, and reduced the use of walking aids [18]. Moreover, BTX-A was effective in reducing antagonistic and distant muscle activation that impeded volitional dorsiflexion [19,20]. The idea of applying BTX-A injection in modifying posture control appeared in recent ten years. Study in children with spastic cerebral palsy showed that BTX-A treatment led to change in motor coordination of lower limbs but also interfered with trunk stability [21]. Another study showed BTX-A injections improved intralimb coordination in spastic stroke patients with stiff-knee gait [22]. Improved posture control and base of support were also reported [23,24]. However, there were few studies elucidating the mechanism of BTX-A injection in modifying posture control.

Ankle-foot complex plays a key role in posture control and BTX-A injections could effectively modify ankle foot complex spasticity. This preliminary study aimed at applying BTX-A injection in treating ankle-foot complex spasticity and investigating its effect on ankle strategy use with sensory organization test.

## Material and Method

### Subjects

9 stroke subjects and 5 healthy subjects, aged 20-75 years, without significant perceptual or communication disturbances were recruited in this study.

**Inclusion and exclusion criteria of stroke subjects:** The inclusion criteria of stroke subjects included: (1) first-ever stroke; (2) hemiplegia resulting from stroke; (3) not a cerebellar or brain stem stroke; (4) no other peripheral or central nervous system dysfunction such as peripheral neuropathy or myelopathy; (5) no active inflammatory or pathologic changes in the joints of the lower limb in the most recent 6 months; (6) no acute medical problems such as infection (eg., pneumonia, urinary tract infection) or upper gastrointestinal bleeding; (7) be able to stand without device. The exclusion criteria in stroke subjects include (1) recurrent stroke, (2) muscle contractures over the affected limbs, (3) previous treatment with phenol or alcohol nerve blocks or motor point injections with neurolytic agents for spasticity at any time, or with BTX-A in the 6 months preceding the study, (4) use of aminoglycoside antibiotics or any other medicine that interfere with neuromuscular transmission; (5) pregnancy or breast feeding. No change in anti-spastic treatment was allowed during the course of the study in all stroke subjects and all stroke patients continued with active physiotherapy and occupational therapy after the injections.

**Inclusion and exclusion criteria of healthy subjects:** The inclusion criteria of the healthy subjects were that the subjects being able to walk without device. However, the exclusion criteria of the healthy subjects included history or physical findings of any trunk, back or lower extremity musculoskeletal disorders or mal-alignments. Functional abnormalities which could impair gait pattern, such as muscle weakness, sensory loss, pain, and impaired motor control were also excluded. The following foot deformities were excluded: hallux valgus, hallux rigidus, hammer toe, claw toe, rigid pes cavus, and severe pes planus.

### BTX-A injections

The 9 stroke subjects received BTX-A injection. The BTX-A used in this study was Botox Allergan (100 U/vial) that was diluted with normal saline to a concentration of 5 U/0.1 ml. The dosage was individualized according to the severity of muscle spasticity, muscle

mass, muscle number, muscle position and published clinical guidelines. The maximal total dose was 360 U. Intervened muscle included medial and lateral heads of gastrocnemius, soleus, tibialis posterior, flexor digitorum longus and flexor hallucis longus muscles [25-27]. A Teflon-coated, 21-gauge, open-lumen needle (Allergan, Irvine, CA) was used to stimulate the targeted muscle once per second (repetitive square wave pulses, 0.25 msec in duration) to locate the motor point of each injected muscle. The lowest threshold for motor response determined the site of injection.

### Posture stability assessment

The 9 stroke subjects received sensory organization test before the BTX-A injection, and 4 weeks, 8 weeks and 12 weeks after the BTX-A injection. The 5 healthy subjects received sensory organization test once for normal posture control evaluation.

**Balance measurement equipment:** For standing balance, the SMART Balance Master<sup>®</sup> (MP150, Biopac Inc.) was used to acquire postural stability measurement under defined conditions. This device consists of (1) Two 9 × 18-inch forceplates on which an individual stand. The 2 forceplates are supported by 4 force transducers (strain gauges) mounted. Symmetrically on a supporting center plate. The fifth transducer is bracketed to the center plate directly beneath the pin joint. (2) A visual enclosure, which is composed of a wall covered with gray-collar aluminum sheet and a small blue dot pattern, enclosing the subject on 3 sides, and a computer monitor located approximately 60 cm in front of the subject at eye level. (3) An overhead bar with safety harness. (4) A computer and software system. This system is automatically calibrated by an internal system that activated when the operating system is turned on. The forceplate data is sampled at 100Hz.

**Sensory organization test:** Body height and weight was measured for each subject. A harness was secured with straps to an overhead bar to protect the subject in case of fall. Subjects stand in bare feet on the platform with the medial malleolus at the rotation's axis, as indicated by a line on the forceplate. The lateral borders of the feet were placed 26.5 cm apart and equidistant from the center line of the force platform. The feet were pointed slightly outward to provide each subject with a comfortable foot placement. Subjects were evaluated for postural stability sequentially as Table 1.

Abbreviation	Condition
EO	eyes open and fixed support
EC	eyes closed and fixed support
SV	sway-referenced vision and fixed support
EOSS	eyes open and sway-referenced support
ECSS	eyes closed and sway-referenced support
SVSS	sway-referenced vision and support

**Table 1:** It shows the description of individual test conditions of sensory organization test and its abbreviation.

There were three consecutive trials for each condition. Each trial last for 20 seconds. The subjects were informed of the condition before the beginning of each trial. In the SV condition, the visual enclosure would be rotated simultaneously and proportionally with the spontaneous sway of the subject, thereby minimizing the sway-related visual feedback. In this circumstance, visual feedback conflicted with

somatosensory and vestibular feedback. In the SS condition, the support surface would be tilted around the ankle joint, and the somatosensory feedback from the ankle and foot would conflict with the visual and vestibular inputs. In addition, the visual enclosure and the support surface simultaneously tilted synchronously with the subject's spontaneous body sway during the SVSS condition. Thus, the subjects were challenged to stand in a progressively more difficult sensory environment.

**Strategy score:** Strategy scores(ST) is the difference between the maximal and minimal shear force produced by the subject, this difference is then divided by a constant which stands for the theoretical shear force difference in normal condition, and the result is also expressed as percentage. The higher score indicates that the subject uses more ankle strategy than hip strategy. A composite score, the mean of the average strategy scores for all trials of conditions EO and EC and the 3 trials of conditions SV, EOSS, ECSS and SVSS was calculated based on the formula from NeuroCom.

### Statistics analysis

In this preliminary study, generalized estimating equation(GEE) was implemented for the comparison of ST between control and patient group, and the comparison within patients group among various time points (pre-test, post injection 4 weeks, post injection 8 weeks and post injection 12 weeks). Generalized estimating equation was first described in Biometrics, 1986, developed by Scott L. Zeger and Kung-Yee Liang, and was suitable for longitudinal data analysis where time points were not independent [27-29]. All data were presented as means  $\pm$  SD. A p value of  $<0.05$  was considered as statistical significance.

## Result

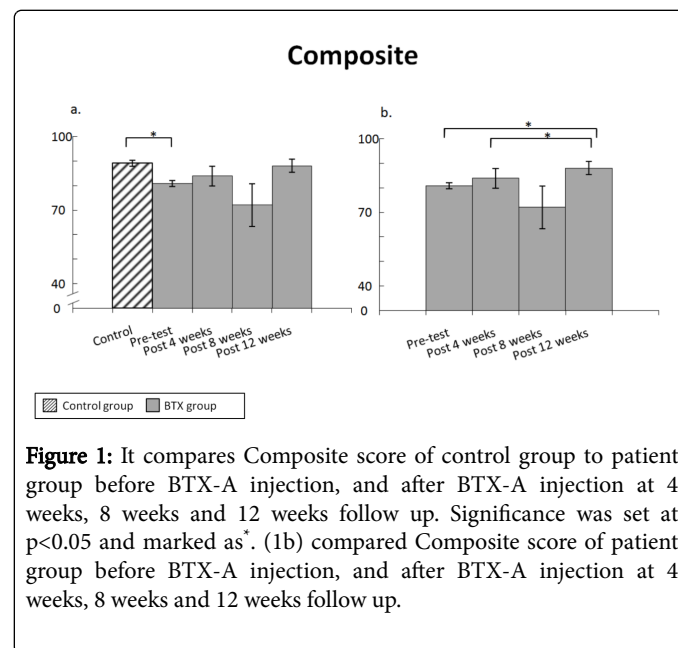
### Composite score

Figure 1A compared Composite scores of individual test conditions of control group to patient group from various time points. Before BTX-A injection, composite score of patient group was significant lower than control group. After BTX-A injection, there were no significant differences of Composite score comparing control group to patient group at 4 weeks, 8 weeks and 12 weeks follow up. Figure 1B shows the comparison of composite scores within patient group from various time points. Composite scores were significant higher after BTX-A injection at 4 weeks and 12 weeks follow up comparing to before BTX-A injection.

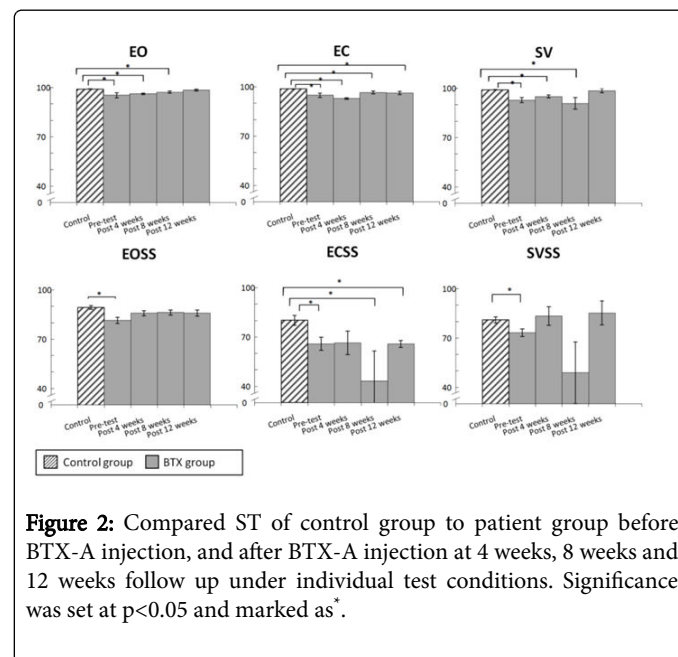
### Strategy score of individual test conditions

**Comparison between control and patient group:** Figure 2 illustrated the comparison of ST among control group and patient group from various time points under individual test conditions. (1) EO condition: ST of patient groups was significant lower than control group before Botox injection and after Botox injection at 4 weeks and 8 weeks follow up. There was no significant difference between control and patient group at 12 weeks follow up. (2) EC condition: ST of patient groups was significant lower than control group before Botox injection and after Botox injection at 4 weeks, 8 weeks and 12 weeks follow up. (3) SV condition: similar as EO condition, ST of patient groups was significant lower than control group before Botox injection and after Botox injection at 4 weeks and 8 weeks follow up. There was no significant difference between control and patient group at 12 weeks

follow up. (4) EOSS condition: before Botox injection, ST of patient group was significant lower than control group. After Botox injection, there were no significant differences between control and patient group at 4 weeks, 8 weeks and 12 weeks follow up. (5) ECSS condition: similar as EC condition, ST of patients group was significant lower than control group before and after Botox injection. (6) SVSS condition: similar as EOSS condition, before Botox injection, ST of patient group was significant lower than control group. After Botox injection, there were no significant differences between control and patient group at all evaluation points.



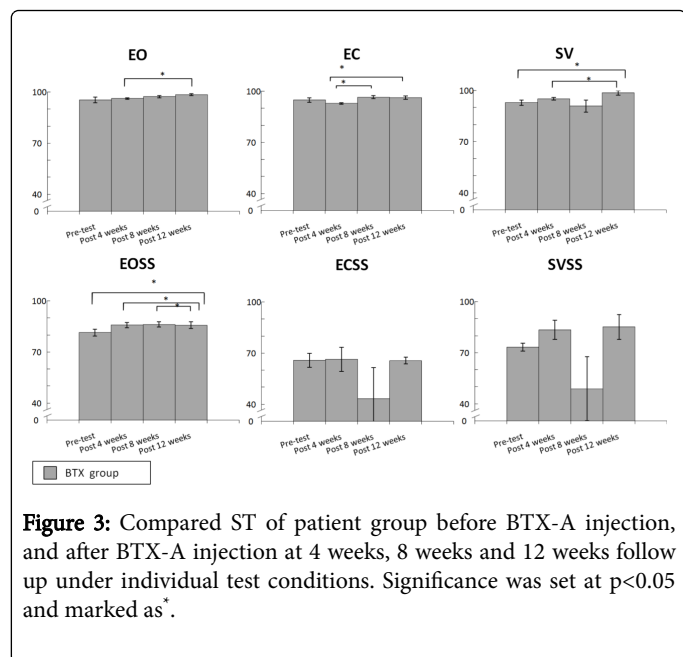
**Figure 1:** It compares Composite score of control group to patient group before BTX-A injection, and after BTX-A injection at 4 weeks, 8 weeks and 12 weeks follow up. Significance was set at  $p < 0.05$  and marked as\*. (1b) compared Composite score of patient group before BTX-A injection, and after BTX-A injection at 4 weeks, 8 weeks and 12 weeks follow up.



**Figure 2:** Compared ST of control group to patient group before BTX-A injection, and after BTX-A injection at 4 weeks, 8 weeks and 12 weeks follow up under individual test conditions. Significance was set at  $p < 0.05$  and marked as\*.

**Comparison within patient group:** Figure 3 revealed the comparison of ST within patient group among various evaluation points under six different conditions. (1) EO condition: after Botox injection, ST was significant higher at 12 weeks follow up than 4 weeks follow up. (2) EC

condition: after Botox injection, ST was significant higher in the comparison of 12 weeks follow up to 4 weeks follow up and 8 weeks follow up to 4 weeks follow up. (3) SV condition: ST was significant higher in the comparison of 12 weeks follow up to before Botox injection and 12 weeks follow up to 4 weeks follow up. (4) EOSS condition: after Botox injection, ST was significant higher comparing 12 weeks follow up to before Botox injection, and also to 4 weeks and 8 weeks follow up. (5) ECSS: there were no significant differences. (6) SVSS: there were no significant differences.



## Discussion

The posture stability is a sophisticated network, which relies on the input of somatosensory, visual and vestibular and the output of hip strategy, ankle strategy and stepping or reaching to maintain [30-34]. When standing on a firm surface and the sway amounts were small, body used ankle as a flexible inverted pendulum to remain balance. When standing on compliant surface where ankle torque use was forbidden or when body's center of mass shift quickly, body used hip strategy to exert torque at hip [34-36]. When confronted with instability, body tend to resume body's center of mass initial position with ankle strategy first. Elderly people with risk of falling tend to use reaching and hip strategy more than people with low risk of falling [34,37]. In stroke patients, hip strategies were mainly used and ankle strategies were used lesser [38]. Stepping was also more frequently used than other aged-match control [39]. However, stroke patients often fall even with these compensatory movement strategies [40,41].

This study revealed those 12 weeks after BTX-A injection, Composite score was remarkably improved in patient group, which indicated that patients were allowed to have more ankle strategy use. Examining individual test conditions, consistent ST improvement was noted in EOSS condition. The improvement trend was also seen in EO, EC and SV condition, however, some comparisons failed to show significance. In the ECSS and SVSS condition, which is considered to be the two most difficult conditions, ST remarkably decreased at the 8 weeks follow up. One patient fell in both ECSS and SVSS condition at the 8 weeks follow up evaluation and 0 score was given, and resulted in

relative low ST and large standard deviation. Ankle strategy was challenged mostly when referenced support swayed, which was correlated to our result that the most consistent improvement occurred under EOSS condition.

To our knowledge, this was the first study to applying sensory organization test in investigating the effect of BTX-A injection in ankle strategy use. The results were and positive and the improvement trend was inspiring, which suggested that BTX-A treatment might be an effective treatment to restore ankle strategy use in stroke patients and might prevent fall more efficiently than their current compensatory movement strategies.

However, several limitations existed in this preliminary study. The learning effect of sensory organization test has been a major concern in repetitive sensory organization tests. There was study revealed that learning effect existed when administering 5 times sensory organization tests over 2 weeks period and 1 month later, and a composite change more than 8 points were considered to be truly related to intervention [42]. However, this study only investigated equilibrium score and the learning effect of ST has not been reported. To decrease the potential concern about learning effect of ST, multiple baselines sessions may be applied in the future study. The sample size was relative small and more subjects are needed in the future study.

## Conclusion

BTX-A treatment might restore the use of ankle strategy in stroke patients and might serve as the mechanism of the improvement in posture control.

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