Botulinum Toxin for the Treatment of Motor Imbalance in Obstetrical Brachial Plexus Palsy

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Background: Residual muscle imbalance is a common problem affecting obstetrical brachial plexus palsy patients. The goal of this study was to examine the efficacy of botulinum toxin type A (Botox) in improving this muscle imbalance.

Methods: The authors retrospectively reviewed obstetrical brachial plexus palsy patients treated with Botox for muscle imbalance as an isolated procedure. Outcomes were the change in Active Movement Scale scores from pre–Botox scores to scores at 1 month after Botox and 1 year after Botox.

Results: Twenty-seven patients were included, 19 treated for shoulder imbalance and eight treated for elbow imbalance. Active Movement Scale scores (mean ± SD) for shoulder external rotation improved from 0.6 ± 1.0 before Botox to 2.6 ± 2.14 ($p < 0.01$) at 1 month after Botox, and declined to 1.3 ± 1.2 ($p < 0.01$) at 1 year after Botox. Scores for elbow flexion were 3.3 ± 2.1 before Botox, unchanged at 4.4 ± 1.8 ($p = 0.07$) 1 month after Botox, and improved to 5.8 ± 0.5 ($p < 0.01$) at 1 year after Botox. Scores for elbow supination were 2.9 ± 1.7 before Botox and 3.4 ± 1.5 ($p = 0.2$) at 1 month after Botox, and improved to 3.9 ± 2.0 ($p < 0.01$) at 1 year after Botox.

Conclusions: Botox for shoulder movement imbalance produces improvement in external rotation that is not sufficiently sustained over time to be of clinical benefit. However, Botox for elbow movement imbalance produces a sustained and clinically useful improvement. (*Plast. Reconstr. Surg.* 131: 1307, 2013.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

The incidence of obstetrical brachial plexus palsy is estimated at 0.5 to 2 cases per 1000 live births.[1,2] Although the majority of infants demonstrate satisfactory spontaneous recovery,[1,3,4] it is essential to identify and operate on those infants who are otherwise likely to remain with significant functional deficits. This is the focus of management during the first months of life.

Although much attention is focused on the early triage of patients to either surgical or nonsurgical treatment modalities, the management of issues presenting or persisting at later stages can be no less challenging. Functional limitations remaining after both surgical reconstruction and nonsurgical management are often the result of restricted shoulder flexion, abduction and external rotation, and elbow flexion and supination.[5,6]

Movement restrictions are often the result of imbalance between muscle groups working across a common joint. Imbalance may develop when the brachial plexus lesion differentially weakens certain muscle groups, whereas others are less affected or unaffected. Muscle imbalance may cause movement restriction by three principal mechanisms.[5,7,8] First, sustained weakness of one muscle group in relation to the other may perpetuate power imbalance. Second, in the process of neuromuscular healing, agonist and antagonist muscle groups may develop aberrant co-contraction activity, resulting in minimal effective movement. Third, imbalance may lead to residual structural joint deformities, including contractures, subluxations, and dislocations.

Co-contractions can be identified on clinical examination and may be confirmed by electromyographic studies. The clinical hallmarks are

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dynamic imbalance in the face of available passive range of motion and palpable contraction of muscles. Although the pathophysiology is unclear, some have suggested that this may be the result of central apraxia caused by development of pathologic motor learning patterns during neurologic regeneration,[9,10] or it could be a manifestation of peripheral nerve synkinesis resulting from abnormal axonal outgrowth during regeneration at the level of the peripheral nervous system.[7]

Muscle contractures typically present with limited passive range of motion. They may lead to joint subluxation, joint dislocation, or abnormal development of joint structure such as glenoid dysplasia.[11] Posterior shoulder dislocation is reported to occur in 8 percent of patients with obstetrical brachial plexus palsy before the age of 1 year.[12] Up to 25 percent of patients who had primary brachial plexus surgery will require secondary musculoskeletal balancing procedures to improve muscle balance, joint position, and limb posture.[13] Procedures include contracture release, open reduction of humeral head, various tendon transfers, tenodeses, arthrodeses, and rotational osteotomies.[11,14] These procedures achieve balance by structurally altering the mechanics of joint function. Botulinum toxin type A (Botox; Allergan, Inc., Irvine, Calif.) has been used for various therapeutic indications, including treatment of cerebral palsy spasticity and dystonia.[15] Botox injection into strong antagonist muscles of the shoulder and elbow joints has been reported to improve synergistic muscle balance in obstetrical brachial plexus palsy patients.[8] The rationale for treatment is that by temporarily weakening strong antagonist muscles and discriminating in favor of agonist muscles, Botox may contribute to better muscular balance either by strengthening agonist muscles peripherally or by promoting motor learning at the level of the central nervous system. Observations suggest that Botox shows long-term benefits that outlast its direct biological effect.[10]

Studies reporting the use of Botox in obstetrical brachial plexus palsy patients are scarce.[8] Although showing promise, evidence for the efficacy of these treatments is limited by the small number of studies and the absence of randomized controlled trials. This study examines retrospectively the use of Botox for treatment of obstetrical brachial plexus palsy patients in a larger cohort of patients with long-term follow-up.

PATIENTS AND METHODS

With the approval of the Research Ethics Board of the Hospital for Sick Children, health records were reviewed retrospectively for all patients in our institution with obstetrical brachial plexus palsy who had been treated with Botox. Clinical assessment was undertaken using the Active Movement Scale developed at the Hospital for Sick Children,[16] an eight-point assessment scale for active range of motion of the upper limb both against gravity and with gravity eliminated. The indications for the use of Botox were minimal improvement over time in Active Movement Scale scores for external rotation of the shoulder or flexion of the elbow in the face of improvement in other movements and clinical evidence of co-contraction limiting effective movement on physical examination. These indications were not based on a strict protocol but were individualized on the basis of patient need. Both surgically and nonsurgically managed patients remained under follow-up to a maximum age of 18 years. Management was provided by a multidisciplinary team including a plastic surgeon (H.M.C.), a physiotherapist (C.G.C.), an occupational therapist, and an orthopedic surgeon.

For the purposes of this study, patients were excluded if the use of Botox was combined with a primary or secondary surgical procedure or was undertaken within 8 months of such a procedure. We have presented unpublished data demonstrating that the plateau following either nerve surgery or spontaneous recovery occurs during the second or third year after.[17] Selecting an 8-month minimum interval between nerve surgery and Botox injection produced an average interval in our study population of 2 to 3 years between prior treatment and Botox. Choosing a longer interval would have reduced the sample size below the limits suitable for statistical analysis and would have precluded the possibility of a single-center study. Patients were also excluded if the minimum follow-up following Botox without further intervention was less than 5 months. For patients who had surgical procedures after treatment with Botox, the posttreatment change was assessed at a visit before the surgical treatment was provided, eliminating that potential confounder.

Data retrieved for each patient included demographic information; Active Movement Scale scores; and procedures including brachial plexus reconstructions, Botox injections, and orthopedic procedures. Outcomes were measured by assessing the change in Active Movement Scale scores for the relevant joint movements between the following pairs of evaluations: the last pre-Botox visit versus the first post-Botox visits (immediate posttreatment change); the last pre-Botox visit versus the 1-year post-Botox visit (1-year posttreatment change); and the first post-Botox visit versus the 1-year post-Botox visit (immediate posttreatment to 1-year posttreatment change). For those patients who received two separate Botox treatments, we used the first visit after the first Botox treatment for the immediate post-Botox analysis and the visit closest to 1 year after the second Botox treatment for the 1-year follow-up analysis.

Statistical Analysis

For each group of patients, Active Movement Scale scores were compared across evaluations by repeated measures analysis of variance, using PROC-Mixed SAS version 9.3 (SAS Institute, Inc., Cary, N.C.). We treated time as a categorical variable and used a compound symmetry correlation matrix to model the correlation within the patients. Statistical significance was determined as $p < 0.05$.

Injection Technique

Under deep sedation or general anaesthesia, patients were placed in either supine or lateral decubitus position and prepared with povidone-iodine. For the shoulder, a total of 40 to 50 units of Botox was injected intramuscularly at two sites near the motor point for each of the pectoralis major, latissimus dorsi, and subscapularis muscles (Figs. 1 and 2). For the elbow, an intramuscular injection of Botox was performed into each of the three heads of the triceps muscle proximally near the presumed location of the motor points of the muscle (Fig. 3). A total of 20 to 25 units was injected into each head. Shoulder patients were placed in shoulder spica cast with the arm held in an external rotation position of approximately 35 degrees for 3 to 4 weeks to provide a sustained stretch of the internal rotators of the shoulder and to optimize the passive range-of-motion exercises that the caregivers were asked to provide once the Botox was deemed to be effective. Elbow patients were left unrestrained following the injections because contractures were less problematic in this group.

RESULTS

Forty patients were identified as having had one or more Botox injections between January of 2004 and April of 2011, a period during which over 600 new patients with obstetrical brachial plexus palsy were seen and 89 patients had brachial plexus reconstruction. Twenty-seven patients met the inclusion criteria; 10 were excluded because they were treated with Botox in conjunction with surgical procedures and three were excluded because they had a brachial plexus neurotization procedure within 8 months of Botox injection.

Of the 27 patients included in this study, 19 were treated for muscular imbalance of the

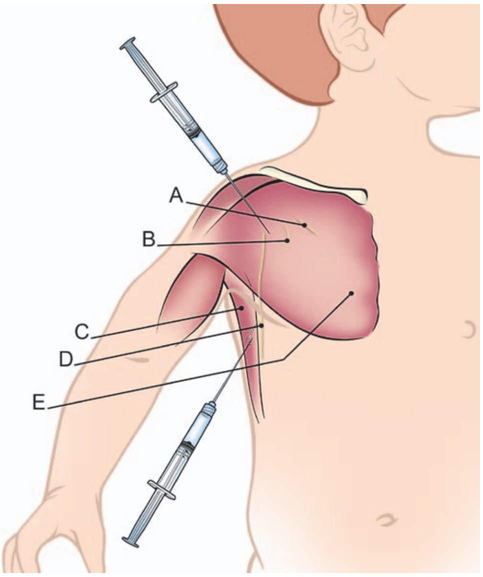

Fig. 1. Injection of Botox to the pectoralis major and latissimus dorsi muscles. *A*, lateral pectoral nerve; *B*, medial pectoral nerve; *C*, latissimus dorsi muscle; *D*, thoracodorsal nerve; *E*, pectoralis major muscle.

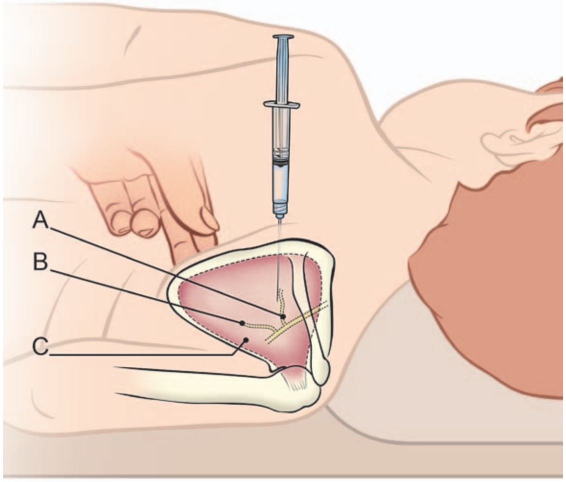

Fig. 2. Injection of Botox into the subscapularis muscle. *A*, upper subscapular nerve; *B*, lower subscapular nerve; *C*, subscapularis muscle.

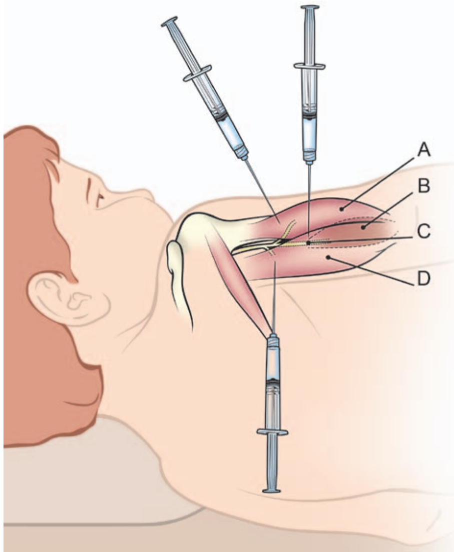

Fig. 3. Injection of Botox into the triceps brachii muscles. *A*, lateral head of triceps brachii muscle; *B*, medial head of triceps brachii muscle; *C*, radial nerve; *D*, long head of triceps brachii muscle.

shoulder with Botox injection to the internal rotator muscles (shoulder group), and eight patients were treated for elbow imbalance with Botox injection to the triceps muscle (elbow group). Data describing the demographic characteristics and course of treatment for each group are listed in Table 1. Botox injection was repeated in one elbow patient and three shoulder patients. There were no complications relating to the use of Botox. Six shoulder patients (32 percent) went on to a secondary surgical balancing procedure at a later stage after data collection, including contracture releases, open reduction of humeral head, and tendon transfers.

The shoulder group demonstrated a significant immediate (1 month) posttreatment improvement in external rotation and diminution in internal rotation (Table 2). At 1 year after treatment, the improvement in external rotation was significantly reduced but still present compared with before treatment, and internal rotation had returned to pretreatment values (Fig. 4). The average Active Movement Scale score for external rotation at 1 year after treatment was 1.3 ± 1.2 (mean ± SD), which does not represent clinically useful external rotation. Shoulder abduction and flexion were significantly improved at 1 year after treatment. The three patients who had a second Botox treatment did not show an incremental benefit from the second treatment.

The elbow group did not demonstrate significant immediate posttreatment improvement for any movement (Table 3 and Fig. 5). At 1 year after treatment, both elbow flexion and supination were significantly improved. The average Active Movement Scale score for elbow flexion at 1 year after treatment was 5.8 ± 0.5 (mean ± SD), which does represent clinically useful elbow flexion. Elbow extension and pronation were unchanged across the treatment.

Table 1. Study Sample Characteristics

	Elbow Group	Shoulder Group
No. of patients	8	19
Sex		
Male	1	7
Female	7	12
Affected side		
Right	3	9
Left	5	10
Prior plexus reconstruction, %	6 (75)	11 (58)
Age at plexus reconstruction, mo		
Mean ± SD	5.6 ± 2.7	6.7 ± 2.5
Range	3.5–10.6	3.2–11.1
Age at first Botox, mo		
Mean ± SD	36.2 ± 28.2	30.7 ± 24.8
Range	6–92.3	9.2–124.9
Time from plexus reconstruction to first Botox injection, mo		
Mean ± SD	31.1 ± 14.5	20.6 ± 8.5
Range	13.3–43.2	9.0–34.3
Post-Botox injection follow-up, mo		
Mean ± SD	34.6 ± 20.6	49.8 ± 16.7
Range	8.7–61	6.4–79.1
Patients having two Botox procedures, %	1 (12.5)	3 (16)
Secondary surgical balancing procedures, %	0 (0)	6 (32)
Time from Botox injection to secondary surgery, mo		
Mean ± SD	0	25.16 ± 15.4
Range	0	8.0–49.1

Table 2. Shoulder Group Active Movement Scale Scores*

				p		
Movement	Pre-Botox Score	Immediate Post-Botox Score	1-Yr Post-Botox Score	Pre-Botox vs. Immediate Post-Botox Scores	Pre-Botox vs. 1-Yr Post-Botox Scores	Immediate Post-Botox vs. 1-Yr Post-Botox Scores
Abduction	5.1 ± 1.6	4.8 ± 1.7	5.6 ± 1.7	0.47	<0.01	<0.01
Adduction	7 ± 0	6.8 ± 0.7	7 ± 0	0.33	1.00	0.53
Flexion	5.2 ± 1.7	4.53 ± 1.9	5.6 ± 1.7	0.08	<0.01	<0.01
External rotation	0.6 ± 1.0	2.6 ± 2.1	1.3 ± 1.2	<0.01	0.04	0.01
Internal rotation	7 ± 0	6.2 ± 1.7	7 ± 0	0.04	1.00	0.05

*Active Movement Scale scores are expressed as mean ± SD.

DISCUSSION

Our goal in Botox therapy for obstetrical brachial plexus palsy is to improve muscle balance and thereby function by selective chemodenervation of overpowering muscle groups. Muscle imbalance is most often identified in patients with limited external rotation of the shoulder or with limited flexion of the elbow joint; thus, they constitute the two primary indications for treatment in our study and others.[8] Other described indications include therapy adjunctive to either spontaneous recovery of obstetrical brachial plexus palsy or primary brachial plexus reconstruction,[18–20] as treatment adjunctive to closed reduction of the humeral head in cases of glenohumeral subluxation or dislocation,[14] as an adjunct to surgical release of contractures of the internal rotators and adductor muscles of the shoulder,[21–23] and for limited extension or supination of elbow because of what has been described as muscle co-contraction.[24,25] We have chosen to exclude 10 patients treated in small numbers from among these other indications in an attempt to focus on the two groups of patients for whom we had sufficient data for statistical analysis. Similarly, patients who had Botox administered in proximity to primary brachial plexus surgery or secondary surgical reconstructive surgery (<8 months before or after surgery) were also excluded because any treatment effect could have been the result of the surgical intervention and not because of Botox. Although these exclusions may constitute a selection bias, it was our hope to determine the short- and long-term outcomes of Botox therapy in isolation.

Shoulder external rotation was significantly better both at 1 to 2 months and at 1 year after treatment, although long-term (1 year) scores were significantly lower than the short-term scores. Although the initial gain in active movement to a score of 2.6 ± 2.1 Active Movement Scale units may be beneficial functionally (e.g., allowing better reach behind the head), it may be attributed both to the effect of Botox and to the effect

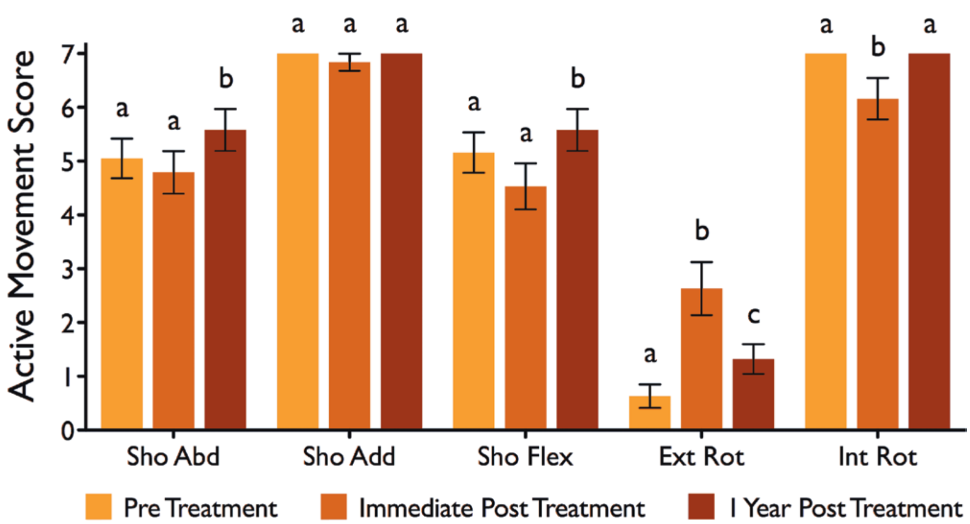

Fig. 4. Shoulder group Active Movement Scale scores. Means with common lowercase letter are not significantly different ($p > 0.05$). *Sho Abd*, shoulder abduction; *Sho Add*, shoulder adduction; *Sho Flex*, shoulder flexion; *Ext Rot*, external rotation; *Int Rot*, internal rotation.

Table 3. Elbow Group Active Movement Scale Scores*

Movement	Pre-Botox Score	Immediate Post-Botox Score	1-Yr Post-Botox Score	*p*: Pre-Botox vs. Immediate Post-Botox Scores	*p*: Pre-Botox vs. 1-Yr Post-Botox Scores	*p*: Immediate Post-Botox vs. 1-Yr Post-Botox Scores
Flexion	3.3 ± 2.1	4.4 ± 1.8	5.8 ± 0.5	0.07	<0.01	0.03
Extension	7 ± 0	6 ± 1.9	7 ± 0	0.08	1.00	0.08
Supination	2.9 ± 1.7	3.4 ± 1.5	3.9 ± 2.0	0.2	0.03	0.24
Pronation	6.5 ± 1.4	6.4 ± 1.8	6.5 ± 1.4	0.9	1.00	0.85

*Active Movement Scale scores are expressed as mean ± SD.

of prolonged splinting. The subsequent decline in Active Movement Scale scores suggests that there is limited sustainable benefit. The restored power of the normally or nearly normally innervated internal rotators ultimately overpowers the reinnervated external rotators. The failure of three patients who had a second Botox treatment to show additive benefit from a second treatment supports our clinical impression that the formidable muscle imbalance between the powerful internal and weak external rotators of the shoulder cannot be sustainably reconciled by Botox, even if the treatment is repeated.

Scores for shoulder abduction and flexion showed significant improvement at 1 year when compared with pretreatment scores. Similarly, Desiato and Risina[22] demonstrated improvement in immediate and delayed Active Movement Scale scores for shoulder abduction (but not external rotation) in a prospective study of 50 obstetrical brachial plexus palsy patients treated for internal rotation contractures with Botox and a rehabilitation regimen. This may have been the result of improved muscle function following treatment. Alternatively, this gradual improvement may reflect the natural course of healing in these patients rather than an effect of Botox.

In addition to the goal of improving shoulder movement and range of motion, the long-term goal is to improve glenoid-humeral balance and reduce the rate of secondary orthopedic procedures. All patients are offered Botox treatment on the grounds of having severe imbalance and therefore higher risk for glenoid-humeral incongruence. Desiato and Risina[22] reported that 68 percent of patients treated with Botox did not require secondary orthopedic surgery during a follow-up period of 49.8 ± 16.7 months (range, 6.4 to 79.1 months). Ezaki et al.[14] reviewed 35 cases of obstetrical brachial plexus palsy patients with either shoulder subluxation or dislocation treated by closed humeral head reduction, Botox injection to the internal rotators, and casting. Overall, 69 percent of patients did not require later surgical reduction. The rate of shoulder patients not requiring secondary surgical

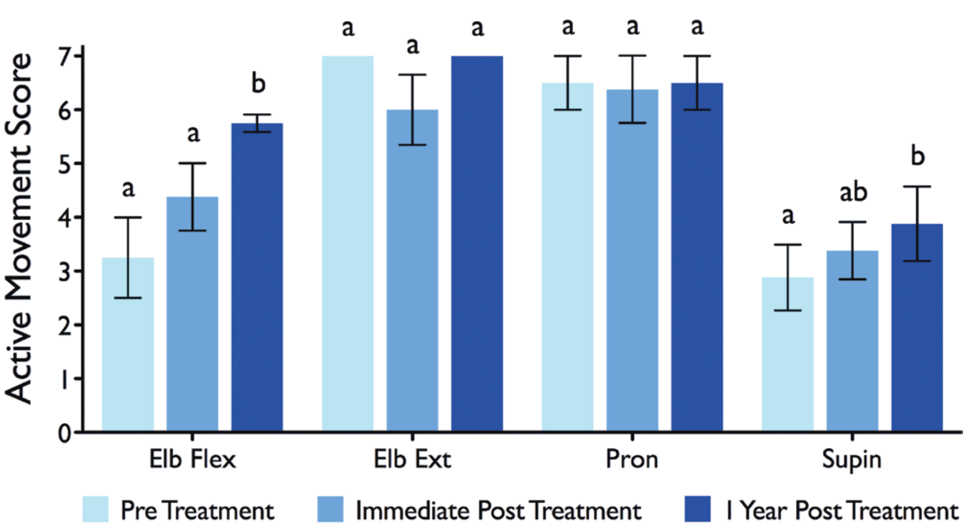

Fig. 5. Elbow group Active Movement Scale scores. Means with common lowercase letter are not significantly different ($p > 0.05$). *Elb Flex*, elbow flexion; *Elb Ext*, elbow extension; *Pron*, pronation; *Supin*, supination.

balancing procedures in our study (68 percent) was similar to both studies above. Direct comparison with these studies is limited, however, by the lack of complete data pertaining to the degree of glenoid-humeral incongruence in our patients who did not have routine shoulder imaging at this age. A complete description of our indications for shoulder reconstruction and the results obtained is published elsewhere.[26] It is interesting that all three studies demonstrate that of a group of patients identified as having sufficient shoulder imbalance and contractures to warrant Botox treatments, over two-thirds achieved satisfactory balance and stability with Botox and casting, to the endpoint of avoiding surgical balancing procedures. In the absence of a randomized control group, it is impossible to identify whether Botox had a favorable contribution to this outcome in these studies.

The elbow group demonstrated significant improvement in flexion and supination scores at 1 year after Botox injection. This group was not splinted, as opposed to the shoulder group, so that any gains were most probably the result of Botox injection alone. Only one patient showed a falloff in elbow flexion scores following Botox injection and had a second injection, after which the score fell off again. None of the patients required secondary orthopedic procedures for the elbow, suggesting that they eventually attained satisfactory elbow function.

This may be the largest published study group of patient with obstetrical brachial plexus palsy receiving Botox to the triceps muscle. Rollnik et al.[25] reviewed a series of six patients who were treated two to three times over a period of 8 to 12 months with Botox to the triceps muscle. They reported significant improvement in elbow range of motion and in muscle strength, although Botox had to be repeated two to three times during a treatment period of approximately 1 year. We have no explanation why their patients required numerous Botox injections as opposed to our elbow patients, because the technique and the mean age of the patients were similar. Perhaps the different scoring scales (range of motion and muscle strength as opposed to Active Movements Scale) may play a part in this.

DeMatteo et al.[18] reported a series of five patients who had single Botox injection to the triceps, with significant improvement in Active Movement Scale scores at 1 month after injection but not at 4 months after injection. Their study group included two patients who had brachial plexus surgery 3 and 5 months after Botox injection and three patients of whom two had surgery 5 months before Botox injection. It is therefore limited by the possible confounding effect of the reconstruction procedures, whereas our study offers better temporal isolation of the Botox treatment.

Basciani and Intiso[24] treated 22 obstetrical brachial plexus palsy patients with elbow flexion contractures with Botox and serial casting, and demonstrated functional improvement (using a nine-hole peg test) but no change in Medical Research Council or Mallet scores for elbow extension. We had no experience with patients treated for this indication.

The most important criterion for selecting patients for Botox treatment is the clinical evidence of muscle group imbalance. It is essential to evaluate whether the cause of imbalance is differential weakness or co-contraction of muscle groups. Some patients with limited elbow flexion because of co-contraction may be mistakenly diagnosed as having power imbalance. We offer Botox to those elbow patients who demonstrate simultaneous contractions of both flexor and extensor muscles resulting in inadequate effective flexion. In selected cases where it is difficult to differentiate between muscle weakness and co-contraction as the cause for impaired movement, Botox may be useful to diagnose between these two options.

We offer Botox therapy to shoulder patients for imbalance in muscle power even in the absence of co-contractions. In these cases, the goal is to favor the weaker muscles and to allow them an opportunity to strengthen and develop under more balanced conditions.

As mentioned previously, our study is limited by the lack of a randomized control group that could demonstrate the natural history of change in Active Movement Scale scores over time. We cannot rule out that the improvements in elbow flexion and shoulder external rotation are the result of the natural course of healing following nerve injury or brachial plexus reconstruction. Although the timeframe for neurotization to reach maximal healing is not certain, we chose 8 months as an arbitrary cutoff point because it allowed us to include sufficient patients for analysis. Nevertheless, two reasons that the observed changes in movements are unlikely to be the result of neurotization alone are, first, the actual average time elapsed between brachial plexus reconstruction and Botox was much longer than 8 months (20 months for shoulder and 31 months for elbow); and second, Botox therapy was offered to those patients who failed to show progress in the face of general progress in other scores.

Deep sedation or general anaesthesia was used in our patients to increase the probability of injection of the correct site near the motor point of the muscles and to reduce the risk of complications such as pneumothorax. Other centers with a more substantial experience in the use of Botox in other patient populations may well be able to provide these injections safely without sedation.

Both shoulder and elbow groups showed evidence of long-term effects following Botox, outlasting the expected time of the direct Botox effect (4 to 6 months). Other studies have reported similar observations, suggesting this may be the result of either central nervous system motor learning by cortical reorganization,[9,10] or of better balance of neuromuscular units on a peripheral level.[7] Although there is little evidence to determine which of these neurologic adaptations is occurring, it is reasonable to assume that Botox is helpful in breaking abnormal motor patterns, thus allowing an opportunity for adaptation toward better balance that may persist thereafter.

It is unclear whether long-term benefits of Botox are age related. Young age has been reported to be related to better long-term results by Desiato and Risina[22] and Basciani and Intiso.[24] We could not perform age-stratification analysis because we had an insufficient number of patients for statistical purposes. Although it is likely that younger children may have a better capacity for change of neurologic pathways, there is little evidence for this because very few studies include older children or adults.

Clinically meaningful, long-term benefits were seen in the elbow group but not in the shoulder group, as demonstrated by a substantial change in Active Movement Scale score at 1-year follow-up and by much lower rates of secondary balancing procedures. It is our assumption that the degree of imbalance across the elbow joint is significantly milder than the imbalance across the shoulder joint. Thus, Botox may have a better chance of promoting sustainable muscle equilibrium in the elbow than in the shoulder. Prospective studies may be required to address issues such as the efficacy of Botox independent from other procedures, its long-term outcomes, and whether it reduces the risk of secondary orthopedic shoulder surgery.

CONCLUSIONS

Botox for shoulder movement imbalance produces improvement in external rotation that is not sufficiently sustained over time to be of clinical benefit. However, Botox for elbow movement imbalance produces a sustained and clinically useful improvement in elbow flexion.

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Plastic Surgery Level of Evidence Rating Scale—Diagnostic Studies

Level of Evidence	Qualifying Studies
I	Highest-quality, multicentered or single-centered, cohort study validating a diagnostic test (with "gold" standard as reference) in a series of consecutive patients; or a systematic review of these studies
II	Exploratory cohort study developing diagnostic criteria (with "gold" standard as reference) in a series of consecutive patient; or a systematic review of these studies
III	Diagnostic study in nonconsecutive patients (without consistently applied "gold" standard as reference); or a systematic review of these studies
IV	Case-control study; or any of the above diagnostic studies in the absence of a universally accepted "gold" standard
V	Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

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