Long-term effects of Botox treatment on upper extremity in pediatric clients with cerebral palsy

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Long-term effects of Botox treatment on upper extremity in pediatric clients with cerebral palsy

Prepared by: Johannah Wong, OTS (wong2232@pacificu.edu)
Date: 10/20/2011
Review date: October 2013

CLINICAL SCENARIO:

Cerebral palsy (CP) is a disorder of movement, muscle tone or posture that is caused by injury or abnormal development in the immature brain, most often before birth (Mayo Clinic staff, 2011). In the United States 3.3 per 1000 8-year old children have cerebral palsy, the leading cause of motor impairments in children (CDC, 2011). Currently there are approximately 500,000 children in the United States who have cerebral palsy and an additional 10,000 children are born with cerebral palsy each year (My Child, 2011). There are three types of cerebral palsy: spastic, athetoid, and ataxic. Spastic cerebral palsy is the most common form, accounting for approximately 70% of all cases (emedicine.com, 2011). Symptoms of spastic CP include muscle weakness, loss of movement, tight muscles, abnormal gait patterns, and joint contractures. Symptoms may affect one or both sides of the body (Medlineplus, 2011).

Current treatments for children with spastic cerebral palsy include occupational and physical therapy, speech and language therapy, serial casting, orthotic devices, oral medications, intrathecal baclofen and botulinum toxin injections. Beginning in the 1990s, botulinum toxin injections (BTX-A) have been used to treat spastic muscles associated with cerebral palsy (NINDS, 2011). BTX-A injections chemically denervate spastic or hypertonic muscles by inhibiting acetylcholine release from the terminal junction resulting in a temporary reduction in tone (Wallen et al, 2007). Botox is a brand of botulinum toxin commonly used for injections.

This treatment is not FDA approved, and limited research has been completed on this treatment method, especially with children. According to Botox™ the safety of this treatment has not yet been established for the purpose of treating spasticity in pediatric patients (Allergan, 2011). It is still unclear how BTX-A injections influence body structures and neurological process in the long-term (Barrett, 2011). Are the long-term effects worth the short-term benefits?

FOCUSED CLINICAL QUESTION:

What are the long-term effects of Botox treatment on upper extremity in pediatric clients who have Cerebral Palsy?
SUMMARY of Search, ‘Best’ Evidence’ appraised, and Key Findings: Five research articles related to Botulinum toxin injections treating spasticity in pediatric patients with cerebral palsy were analysed by this writer.

- The study by Lowe, Novak and Cusick (2006) was deemed as the “best evidence” evaluated.

  The randomized control trial examined the effects of BTX-A injections for the purpose of improving upper extremity functions associated with cerebral palsy spasticity in children. The secondary purpose of this study was to determine if BTX-A injections in conjunction with occupational therapy results in greater functional improvements compared to BTX-A treatment only.

  The study included a large sample size (N=72) and participants were representative of the general population. All participants maintained participation in their previous standard treatment, as it is unethical to withhold all treatment from a participant for the sole purpose of research.

  The study examined 4 treatment combinations (OT only, BTX-A only, OT + BTX-A, no-treatment) to determine the best possible combination of spasticity treatment for children with cerebral palsy.

  The duration of the study was 6 months during which time all participants were assessed on multiple measures for the purpose of determining the duration and effectiveness of treatment.

  Statistically significant findings in both primary outcome measures at 3 months post baseline indicating benefits of BTX-A injections and occupational therapy compared to the control group.

- Findings reported by Lowe, Novak, & Cusick, (2006) support the use of BTX-A injections in conjunction with occupational therapy for improving upper extremity function of spastic limbs for up to 3 months.

- Fattal-Valevski, Sagi, Domenievitz, (2011) found that muscle tone was significantly reduced following BTX-A injections for up to 7 months, allowing for better opportunities for occupational therapy to work on positioning.

- A randomized control trial by Russo et al, (2007) found that BTX-A injections in addition to occupational therapy resulted in improvements in functional abilities related to tone for 3 months following injections.

- A study by Satila et al (2006) found that individuals who received BTX-A injections experienced improvements in upper limb movement patterns related to decrease tone, but did not experience an increase in functional abilities following serial BTX-A injections.
CLINICAL BOTTOM LINE:
Results from the reviewed research indicate short-term benefits of BTX-A injections in addition to occupational therapy for the purpose of decreasing spasticity and increasing function of the upper extremity in children with cerebral palsy. There is a limited amount of research on this topic, specifically examining longer-term effects of BTX-A injection treatments. All studies reviewed in this paper found that significant differences between groups disappeared after 6 months, suggesting that occupational therapy provides the same health benefits in the long-term without the use of BTX-A injections. No research was located examining effects of injections for a longer duration. This intervention method must be administered by a well trained physician, can be very expensive and the safety of this treatment has yet to be determined for its use with children.

Limitation of this CAT: This critically appraised topic has not been peer-reviewed. The search was not exhaustive and was completed by a master of occupational therapy student. The author is not an expert in this area.

SEARCH STRATEGY:

Terms used to guide Search Strategy:

- **Patient/Client Group**: Children with cerebral palsy (spastic)
- **Intervention (or Assessment)**: Botox injections, spasticity treatment
- **Comparison**: N/A
- **Outcome(s)**: long-term effects

<table>
<thead>
<tr>
<th>Databases and sites searched</th>
<th>Search Terms</th>
<th>Limits used</th>
<th>Relevant Articles Retrieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Database</td>
<td>Search Terms</td>
<td>Language</td>
<td>Year</td>
</tr>
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</tr>
<tr>
<td>MEDLINE-OVID</td>
<td>“Botulinum Toxin”; “Cerebral Palsy”; “Upper Extremity”; “Children”</td>
<td>English language; full text, 2005-2011</td>
<td>(7 results; 0 used)</td>
</tr>
<tr>
<td>OT Search</td>
<td>“Botulinum Toxin”; “Cerebral Palsy”; “Children”</td>
<td>N/A</td>
<td>(5 results; 1 used)</td>
</tr>
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<td>Web of Science</td>
<td>“Botulinum Toxin”; “Cerebral Palsy”; “Children”; “Upper Extremity”</td>
<td>English; 2004-2011</td>
<td>(11 results; 0 used)</td>
</tr>
</tbody>
</table>

**INCLUSION and EXCLUSION CRITERIA**

- **Inclusion:**
  - Full-text
  - English
  - Published after 2005
  - Intervention included BTX-A injections for treating upper extremity spasticity
  - Population ≤ 18 years old, with spasticity related to cerebral palsy

- **Exclusion:**
  - Adult populations with cerebral palsy
  - Lower extremity BTX-A injection treatment for spasticity

**RESULTS OF SEARCH**

Table 1: Summary of Study Designs of Articles retrieved. Five relevant studies were located and categorised as shown in Table 1 (based on Levels of Evidence, Centre for Evidence Based Medicine, 1998)
Table 2: Description and appraisal of “Functional outcomes of intramuscular botulinum toxin type a and occupational therapy in the upper limb of children with cerebral palsy: a randomized control trial” by (Wallen, M., O’Flaherty, S., & Waugh, M.,2007)
Aim/Objective of the Study:
To determine if BTX-A treatment is an effective method of improving individualized functional outcomes and to determine if BTX-A injections in addition to occupational therapy is more effective than BTX-A alone in children with spastic cerebral palsy (Wallen, O’Flaherty & Waugh, 2007).

Study Design:
This study is a randomized control trial (RCT). Possible study participants were identified through the Physical Disabilities Clinic. Participant recruitment occurred through various pediatric therapy networks in the Sydney, Australia area. Assessment of eligibility for possible participants was determined by a rehabilitation pediatrician and a research nurse. Data collection occurred between June of 2000 and May of 2002. All children participated in assessments of both physiological and self-perceived measures.

Participants were randomly placed into one of 4 groups (including a control group) by a third party who was separate from all stages of the recruitment and eligibility process. Occupational therapy intervention was administered by each child’s usual occupational therapist. Assessment measures were administered at baseline, 2 weeks post, 3 months post, and 6 months post baseline by a pediatric occupational therapist, rehabilitation pediatrician and a research nurse. The research occupational therapist was blinded to participant group allocation and was different from the therapists who were administering therapy services. Other research professionals were not blinded to group allocations.

Setting:
This study took place at the Children’s Hospital at Westmead, in Sydney Australia.

Participants:
Sample included 72 children (n=72) who had spastic cerebral palsy affecting one or both upper extremities and were receiving services from the Physical Disabilities Clinic at the Children’s Hospital. Participants were recruited by a rehabilitation pediatrician at the hospital. Eligibility for participation in this study included being 2-14 years of age, having a diagnosis of spastic cerebral palsy affecting one or both upper extremities, a Modified Ashworth Scale (MAS) of 2 or 3, family identified goals and had received spasticity management treatment for a minimum of 6 weeks prior to the start of the study. Children who had significant contractures, an absence of movement or fluctuating muscle tone were ineligible for this study.

The mean age of participants was 5 years, 11 months. 64 percent of the study participants were male. Of the 72 participants, 28 had quadriparesis, 11 experienced tetraplegia and 33 had hemiparesis. 96% of the upper extremities that were studied were the participant’s non-dominant arm. Group assignment to one of the four research groups was randomly drawn by an independent party. There were no significant differences between groups at baseline.

This study received approval by the Ethics Committee of The Children’s Hospital at Westmead. All families and caregivers of study participants provided written consent for study participation and publication.

Drop-outs reported:

•8 participants withdrew from this study prior to data collection at baseline.
Reasons noted for withdrawal: accepted to another study focusing on BTX-A injections, not satisfied with group allocation and unable to attend occupational therapy sessions.

**Intervention Investigated:**

**Control:**
Group 1: The control group received no research related care. This group continued with their pre-study therapy throughout the duration of the study.

**Experimental:**
Group 2: BTX-A injections only - Under local anaesthesia and nitrous oxide sedation, participants in this experimental group, received one set of BTX-A injections at baseline to identified muscles. This group continued with their pre-study therapy through out the duration of the 6-month study.

Group 3: Occupational Therapy intervention only - Beginning one week following baseline, participants in this group received one hour occupational therapy sessions, once a week for 12 weeks. Occupational therapy interventions included stretching, casting, splinting, motor training, environmental modifications and goal specific activity practice. Therapy was administered by each child’s usual occupational therapist. Therapy was not standardized, but focused on goal attainment of the individual’s goals. This group also continued with their pre-study therapy routine through out the 6-month study.

Group 4: Occupational therapy plus BTX-A injections - Participants in this experimental group received both BTX-A injections at baseline under local anaesthesia following the same protocol as the BTX-A injection only group (see group 2) and weekly occupational therapy sessions (see group 3). Participants in this group were instructed to continue with their pre-study occupational therapy sessions in addition to study related treatments.

**Outcome Measures:**
All outcome measures were administered by the three research professionals (research occupational therapist, rehabilitation pediatrician, and research nurse) involved in data collection for this study at the Children’s Hospital at Westmead.

*Primary Outcome Measures:*

<table>
<thead>
<tr>
<th>•Functional performance and satisfaction assessments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>•Canadian Occupational Performance Measure (COPM): This assessment is a semi-structured client or caregiver interview with a focus on the occupational performance areas of self-care, productive and leisure participation. This assessment also examines the client’s satisfaction with their occupational performance. Previous research determined an effect of 2 points on the 10 point scale was significant (Wallen, O’Flaherty, &amp; Waugh, 2007).</td>
</tr>
<tr>
<td>•Goal Attainment Scale (GAS): This assessment involves establishing goals and specifying a range of outcomes or behaviors that would indicate progress</td>
</tr>
</tbody>
</table>
toward achieving these goals. Specific outcomes are placed on a five point continuum where each point describes the degree of achievement to the goal (Willer, B., & Miller, G., 1976).

**Secondary Outcome Measures:**

- Upper limb function, functional skills: specifically self-care and range of motion

- Quality of Upper Extremity Skills Test (QUEST): This 36 item outcome measure is designed to evaluate movement patterns and hand function in children with cerebral palsy. It assesses dissociated movement, grasp, protective extension and weight bearing (DeMatteo et al., 1993).

- Pediatric Evaluation of Disability Inventory (PEDI): This standardized, normative assessment is used to measure capability and performance in the occupational areas of self-care, mobility and social function for children 6 months to 7-years of age (Pearson Education, 2011).

- Tardieu scale: This is a rating scale of spasticity in which the evaluator moves the selected limb through the range of motion at various velocities to determine the amount of spasticity present (We Move, 2011).

**Main Findings:**

Table 3. Mean change scores for each experimental group for COPM (Performance and satisfaction) at baseline, 3 months and 6 months.

<table>
<thead>
<tr>
<th></th>
<th>Control Group(a)</th>
<th>BTX-A only(b)</th>
<th>OT only(c)</th>
<th>BTX-A + OT(d)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Performance</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>3.2</td>
<td>3.1</td>
<td>3.5</td>
<td>2.4</td>
<td>0.016</td>
</tr>
<tr>
<td>3 months</td>
<td>1.2</td>
<td>2.3</td>
<td>2.1</td>
<td>2.9</td>
<td>0.002(a vs. d)</td>
</tr>
<tr>
<td>6 months</td>
<td>1.7</td>
<td>2.7</td>
<td>2.7</td>
<td>3.4</td>
<td>0.098</td>
</tr>
<tr>
<td><strong>Satisfaction</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>4.0</td>
<td>3.9</td>
<td>3.6</td>
<td>3.1</td>
<td>0.419</td>
</tr>
<tr>
<td>3 months</td>
<td>1.4</td>
<td>2.8</td>
<td>2.5</td>
<td>3.5</td>
<td>0.005(a vs. d)</td>
</tr>
<tr>
<td>6 months</td>
<td>2.1</td>
<td>2.7</td>
<td>3.3</td>
<td>3.6</td>
<td>0.287</td>
</tr>
</tbody>
</table>


Results from this Kruskal-Wallis analysis show that significant differences were found between the control group and the BTX-A plus OT group in both performance and satisfaction scores at 3 months. No significant differences were found between any groups at 6 months post baseline.
<table>
<thead>
<tr>
<th></th>
<th>Control group(a)</th>
<th>BTX-A only(b)</th>
<th>OT only(c)</th>
<th>BTX-A + OT(d)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal Attainment Scale</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>32.9</td>
<td>42.3</td>
<td>42.2</td>
<td>51.0</td>
<td>0.000 (a vs. d)</td>
</tr>
<tr>
<td>6 months</td>
<td>40.6</td>
<td>52.5</td>
<td>51.4</td>
<td>51.7</td>
<td>0.054</td>
</tr>
</tbody>
</table>


Results from this Kruskal-Wallis analysis show that significant differences were found between the control group and the BTX-A plus OT group on the GAS at 3 months. No significant differences were found between any groups at 6 months post baseline.

**Original Authors’ Conclusions:**
The study showed that BTX-A injections in conjunction with occupational therapy resulted in clear and earlier functional gains in comparison to other experimental groups. The evidence provided by this research suggest that the greatest amount of functional improvement can be elicited by the involvement of occupational therapy in children’s treatment immediately following BTX-A injections. “The combination of OT and BTX-A injections enhances the self-reported, individualized, functional outcomes of children with cerebral palsy” (p. 9)

**Critical Appraisal:** The main limitation of this study concerning the research question of this paper is that this study did not directly examine the long-term effect of BTX-A injections. Based on the results of this study, it is implied that the beneficial effects of BTX-A injections last only a few months.

**Validity:**
The authors included relevant background literature supporting the clinical question. The study design was appropriate for addressing the question while maintaining proper ethical issues and allowed the researchers to compare the experimental group to both occupational therapy treatment and to no intervention.

**Sample:** Study sample size was based on the standards set by a previous study from the Canadian Association of Occupational Therapists. It determined that each group required a sample size of 19 participants to determine an effect of 2 points on the COPM 10 point scale. The sample also included inclusions and exclusion criteria to determine study population. Drop outs were reported within the research.

**Potential Biases:**

• Sample/Selection Bias: All participants were volunteers of the study, referred to the study by the research personnel at the Children's Hospital.
• Intervention/Performance Bias: (a) Co-intervention was not prevented during this study. Participants were instructed to continue their pre-existing treatments throughout the study. Thus, participants in the non-occupational therapy experimental groups may have been receiving some amount of occupational therapy during the 6-month study period. (b) Participants received their research occupational therapy sessions from their usual occupational therapist resulting in a possible bias. Variation between therapists and treatment methods may influence results of the study.

Outcome Measures:

- Canadian Occupational Performance Measure has been shown to have test-retest reliability of 0.89 for performance and 0.88 for satisfaction.
- Client Goal Attainment Scale has shown to correlate significantly with most other measure of treatment outcome.

PEDro score: 8/10
Random, concealed allocation; blind therapists, blind assessors; baseline comparability; adequate follow-up; between-group comparison;

Interpretation of Results: This study was well designed and conducted in a manner to effectively determine the effects of BTX-A injections in comparison and conjunction with occupational therapy. The results form this randomized single-blind control trial provides evidence that BTX-A injections have significant benefits in treating upper extremity spasticity associated with cerebral palsy in children. This research further supports the results of the additional studies reviewed in this CAT. In addition to providing additional support for the other articles it expanded on them by broadening the comparison of treatment options. The other studies reviewed in this CAT examined the difference between occupational therapy only and BTX-A injections in conjunction to occupational therapy. This study included 4 experimental groups, allowing for a more specific comparison of treatment options. However, like the other studies in this paper, this study also failed to find long-term benefits of using BTX-A injections for treating cerebral palsy related spasticity.

Summary/Conclusion:
This specific article found that BTX-A injections in addition to occupational therapy produced the greatest functional gains at 3-months post injections in comparison to the other experimental groups. The results from this study support the use of BTX-A injections for the purpose of short-term functional gains. Longer-term studies should be conducted in the United States to determine the physiological impact of BTX-A injections on children.

Table 5: Characteristics of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention investigated</th>
<th>Comparison intervention</th>
<th>Outcomes used</th>
<th>Findings</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Study Purpose</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Lowe, K., Novak, I., & Cusick, A., (2006). | To determine if children receiving occupational therapy would experience functional benefits from a single BTX-A injection 6 months post injection. | Occupational therapy only | • Quality of Movement at 6 months (Quality of Upper Extremity Skills Test)  
• Quality of Movement, function and spasticity at 1 and 3 months (Canadian Occupational Performance Measure, Pediatric Evaluation of Disability Inventory, Family/therapist Goal Attainment Scale, Modified Ashworth Scale)  
• Children who received BTX-A injections showed self-perceived functional performance improvements at 1 and 3 months.  
• At 6 months, there were no significant differences between groups. (intervention group and OT only group made equal functions gains (self-perceived and functional assessments).)  
• Only short-term benefits associated with BTX-A injections. |
| Russo, R. N., Crotty, M., Miller M., Murchlan, S., Flett, P., & Haan, E., (2007). | To explore the effect of localized BTX-A injections in conjunction with occupational therapy to treat upper extremity spasticity associated with cerebral palsy | Occupational therapy only treatment sessions | • Body structures (Modified Ashworth Scale; Assessment of Motor and Process Skills)  
• Functional self-report and activity participation (Goal Attainment Scale; Self-perception profile for children; social acceptance for young children)  
• Self-competence (Pediatric Evaluation of Disability Inventory: self-care domain)  
• Functional benefits obtained through BTX-A injections for up to 3 months.  
• No differences between groups after 6 months.  
• All groups made equal gains in 6 months. |
<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Objective</th>
<th>Participants</th>
<th>Measures Administered</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fattal-Valevski, A., Sagi, L., &amp; Domenievitz, D., (2011).</td>
<td>To investigate (1) the duration of effectiveness of BTX-A injections for the purpose of improving upper extremity function of children with spastic cerebral palsy, (2) the correlation between the duration of BTX-A effects and the likelihood that the patient would have additional treatments.</td>
<td>N/A; All study participants received BTX-A injections at some time.</td>
<td>Body structures and functions (Range of Motion; Modified Ashworth Scale; Manual Ability Classification System) • Personal functional goal attainment (Parent questionnaire)</td>
<td>Muscle tone is decreased after BTX-A injections with a longer than clinically proven duration of effects. Individuals who experienced functional improvements were more likely to request additional treatment injections.</td>
</tr>
<tr>
<td>Satila, H., Kotamaki, A., Koivikko, M., &amp; Autti-Ramo, I., (2006).</td>
<td>To assess the effects of single or serial BTX-A injection treatments for the purpose of improving upper extremity function related to spasticity over the course of two years.</td>
<td>N/A; All study participants received BTX-A injections (ranging from 1 to 4 injections) during the course of the study.</td>
<td>Upper limb movement patterns, fine motor and bimanual functions (1-grip strength, 2-Upper Limb Physician’s Rating Scale, 3-Melbourne Assessment) • Caregiver perception (4-Pediatric evaluation of Disability Inventory: Caregiver assistance scale) • Self-care abilities (5-Modified Goal Attainment Scale, 6-Pediatric evaluation of Disability Inventory: functional skill scale)</td>
<td>Reduction in muscle tone following BTX-A treatment that did not result in improved quality of bimanual, fine motor, or grip functions. Spasticity returned in all children within 6 months of treatment.</td>
</tr>
</tbody>
</table>
This study, and the other studies reviewed in this CAT have found that beneficial spasticity-related effects of BTX-A last approximately 12 weeks. This treatment method must be administered by a well-trained physician and can be expensive depending on the setting thus limiting its access to many patients with cerebral palsy. In addition to its potentially limited access, its safety has not yet been determined for use with children. Thus, the potential harm is not yet known. Additional research is needed to determine the long-term effects of this treatment.

BTX-A injections are used in the United States to treat cerebral palsy related spasticity in children. This type of injection cost approximately $500 dollars per injection and is not covered by all insurances. All research articles that have been discussed in this paper found that the benefits that were present 3 months following BTX-A injections disappeared after 6 months. Yet this method of treatment is commonly used to treat spasticity in children with cerebral palsy. As children mature through adolescence, the body demands that muscles increase in size to cope with the increased mechanical demand associated with an increase in body size and motor functions. Although beneficial in the short-term, the muscle weakening that occurs from BTX-A injections may therefore be detrimental in the longer-term (Barrett, 2011).

BTX-A injections were found to be of greatest benefit when administered in addition to continuous occupational therapy. However, in all studies discussed, these benefits were only significantly greater at 3 months. 6 months following injections children who had been receiving occupational therapy only were showing the same functional gains as those children who had received therapy in addition to Botulinum Toxin injections. Thus in the long-term children do not experience any greater functional benefits from having chemical injections. Botulinum toxin type A is considered to be one of the most potent poisons, and its use has been associated with respiratory tract infection, bronchitis, pharyngitis, muscle weakness, urinary incontinence, falls, seizures, fever, and unspecified pain (Friedman & Goldman, 2011). The safety, efficacy and dosage of botulinum toxins have not been established for the treatment of limb spasticity of cerebral palsy or for use in any condition in children (FDA, 2010). Medical professionals must provide adequate educational information to caregivers of children with cerebral palsy so they can make appropriate decisions about their child’s treatment.

If children can make significant functional gains without the use of toxic chemical injections, it stands to reason that until there is indisputable proof that this treatment is safe for children it should be prescribed with great caution in severe circumstances. From an occupational therapy perspective, in which progress and health are established through the doing of occupations, the use of BTX-A injections to improve function related to spasticity should be used with extreme caution. At this time, research shows that children can make the same gains by participating in client-centered occupational therapy without the use of injections.

REFERENCES

Allergan. (2011, August). What could one point mean to your patient?. OT Practice, 16(14) 7-12.


