

Episode 54 – Botulinum Toxin use in Dentistry February 11, 2022

Overview of botulinum toxins

- Botulinum toxins are neurotoxins produced by the anaerobic, gram-positive bacterium *Clostridium botulinum* and are one of the most lethal substances known.
- Spores produced by the bacteria are heat- and drought-resistant and exist widely in the environment (e.g., in soil, water, on plants). In anaerobic conditions, the spores germinate back into vegetative cells (active bacterial cells that undergo metabolism) and then excrete the potent neurotoxins.
- There are 8 types of botulinum toxin (A, B, C_1, C_2, D, E, F, G). Type A is the most potent, followed by types B and F. Types A, B, E, and rarely F cause human botulism. Types C, D, and E cause illness in other mammals, birds, and fish.
- Forms of human botulism include foodborne, wound, infant, and inhalation botulism.
    - Foodborne botulism occurs when the toxins are ingested through improperly processed food in which the bacteria or spores survive, such as in home-canned and lightly preserved foods (e.g., fermented, salted, or smoked fish and meat products). Symptoms typically begin within 12 to 36 hours after consuming and include fatigue, muscle weakness, vertigo, blurred vision, drooping eyelids, dry mouth, difficulty swallowing or speaking, nausea, vomiting, and abdominal cramps (all symptoms of muscle paralysis). The illness can lead to respiratory and muscular paralysis and can be fatal if not rapidly diagnosed and treated with antitoxin.

    - Wound botulism is rare and occurs when the spores enter an open wound and reproduce in an anaerobic environment. Symptoms are similar to foodborne botulism, but may take up to 2 weeks to appear. Wound botulism has been associated with substance abuse, especially black tar heroin injection.

    - Infant botulism is the most common form of botulism that occurs after an infant ingests *C. botulinum* spores, which germinate into bacteria, colonize in the gut, and release toxins. Symptoms include constipation, loss of appetite, weakness, weak cry, and marked loss of head control. It typically occurs in infants under 6 months of age because as children age, they develop natural defences to prevent germination and bacteria growth in the intestines. The source of infant botulism may be honey or exposure to soil contaminated with the bacteria. This is rationale why it is recommended not to give honey to children under a year old.

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- Inhalation botulism is rare and occurs via accidental or intentional events (e.g., bioterrorism) which result in release of the toxins in aerosols. Symptoms present between 1-3 days after inhalation, are similar to ingesting botulinum toxin, and may result in muscular paralysis and respiratory failure.

- *C. botulinum* is the same bacterium used to produce pharmaceutical neurotoxin products injected for cosmetic and therapeutic purposes. [1] [2] [3] [4]

Cosmetic use of botulinum toxins
Botulinum toxins are used for cosmetic treatment of facial rhytids (wrinkles), including forehead, lateral canthus (crow's feet), and glabellar lines (frown lines).

Wrinkles are formed by dermal atrophy and repetitive contraction of underlying facial musculature. Injecting small quantities of botulinum toxin into specific overactive muscles causes localized muscle relaxation (flaccid paralysis) that smooths the overlying skin and reduces wrinkles. Botulinum toxin effects take about 2 weeks to fully develop and last approximately 3 to 4 months. Dynamic wrinkles, seen during muscle contraction, yield more dramatic results than static wrinkles, which are visible at rest. Botulinum toxin products authorized for cosmetic use in Canada are Botox Cosmetic®, Dysport Aesthetic™, and Xeomin Cosmetic™. [5]

Therapeutic botulinum toxin products [6] [7] [8] [9]

	Botox®	**Dysport Therapeutic®**	**Xeomin®**	**Myobloc®**
Medicinal ingredient	OnabotulinumtoxinA (*C. botulinum* toxin type A)	AbobotulinumtoxinA (*C. botulinum* toxin type A)	IncobotulinumtoxinA (*C. botulinum* toxin type A)	*C. botulinum* toxin type B
Nonmedicinal ingredients	Human albumin Sodium chloride	Human albumin Lactose monohydrate	Human albumin Sucrose	Human albumin Sodium succinate Sodium chloride
Indications for use	Blepharospasm Strabismus Cervical dystonia Focal spasticity Hyperhidrosis Chronic migraine Bladder dysfunction	Cervical dystonia Focal spasticity	Blepharospasm Hemifacial spasm Cervical dystonia Focal spasticity Chronic sialorrhea	Cervical dystonia
Route of administration	Intramuscular Intradermal for hyperhidrosis Intradetrusor for bladder dysfunction	Intramuscular	Intramuscular Intraglandular for sialorrhea	Intramuscular
Dosage form	Powder 50, 100, & 200 units per vial	Powder 300 & 500 units per vial	Powder 50 & 100 units per vial	Solution 2,500, 5,000, & 10,000 units per vial

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	Botox®	Dysport Therapeutic®	Xeomin®	Myobloc®
Reconstitution	Sterile preservative-free 0.9% sodium chloride solution	Sterile preservative-free 0.9% sodium chloride solution	Sterile preservative-free 0.9% sodium chloride solution	N/A
Treatment dose	Varies according to brand, age of individual, type & severity of condition being treated			
Storage	Unreconstituted vial stored refrigerated at 2-8°C, or ≤ –5°C Reconstituted solution is stable for up to 24 hours at 2-8°C	Unreconstituted vial stored refrigerated at 2-8°C Reconstituted solution is stable for up to 24 hours at 2-8°C	Unreconstituted vial stored at room temperature up to 25°C Reconstituted solution is stable for up to 24 hours at 2-8°C	Vial stored refrigerated at 2-8°C
Company	Allergan Inc.	Ipsen Biopharmaceuticals Canada Inc.	Merz Pharmaceuticals	Solstice NeuroSciences, LLC
Authorized for use in Canada	1990	2012	2009	2004

Note: Due to unit differences in the potency assay, units are specific to each botulinum toxin product. Unit doses recommended for each product are not interchangeable with other botulinum toxin products.

Therapeutic use of botulinum toxins

Botulinum toxin injections are used as neuromuscular paralytic agents to treat a variety of medical conditions, including:

- Blepharospasm – The paralytic effect of botulinum toxin reduces the excessive, abnormal involuntary contractions (uncontrollable blinking) and spasms of the muscles around the eyes associated with blepharospasm, a type of dystonia.[1] [6]

- Strabismus – Strabismus (misaligned eyes) is commonly referred to as 'lazy eye' or 'crossed eyed'. The eye(s) may turn inward, outward, or be vertically misaligned. Strabismus causes blurred or double vision. Botulinum toxin administration is used to correct the imbalance in the muscles responsible for eye positioning. It is theorized botulinum toxin affects muscle pairs by causing atrophic lengthening of the treated muscle and subsequent shortening of the antagonist muscle. [6] [10]

- Cervical dystonia – Cervical dystonia is the most frequent type of focal dystonia.[2] It manifests around midlife, affects about twice as many females compared with males, and results from muscular hyperactivity in the shoulder and neck muscles. Symptoms may include pain, muscular hypertension, abnormal position of head and shoulders, tremors, and myoclonic jerks. Symptoms impact everyday activities, social interactions, and emotional wellbeing. Botulinum toxin is injected into the

[1] Dystonia is a neurologic movement disorder characterized by sustained or intermittent muscle contractions causing abnormal, often repetitive movements, abnormal postures, or both. [25]
[2] Dystonia can affect one body part (focal dystonia), two or more adjacent parts (segmental dystonia) or the whole body (general dystonia).

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affected neck muscles. Localization of the involved muscles with electromyographic guidance[3] may be useful during administration. [6] [11] [12]

- Focal spasticity – Botulinum toxin is use to treat persistent arm and/or leg muscle spasms in adults (e.g., post-stroke, multiple sclerosis, traumatic brain, spinal cord injury) and children aged ≥2 years (e.g., cerebral palsy). [6] [13] [14]

- Hyperhidrosis – Botulinum toxin is used to treat severe underarm sweating by blocking signals to the sweat glands. [6]

- Bladder dysfunction – Botulinum toxin is used to reduce urinary incontinence caused by an over active bladder or neurologic disease in adults with multiple sclerosis or spinal cord injury who have an inadequate response to or are intolerant of anticholinergics. [6] [15]

- Chronic migraine – Botulinum toxin is used to prevent headaches in adults with chronic migraine by inhibiting the neurotransmitters associated with the inception of pain. The presumed mechanism for headache prevention is by blocking peripheral signals to the central nervous system, which inhibits central sensitization. Botulinum toxin is injected into up to 31 fixed sites in the head and neck muscles using a 30-gauge, 0.5-inch needle. [6] [16]

Botulinum toxin use in dentistry[4]

Botulinum toxin is used "off label" to manage conditions of the head and neck, such as temporomandibular disorders, bruxism, masseteric hypertrophy, and oromandibular dystonia, and to treat aesthetic dental conditions, such as excessive gingival display.

- Temporomandibular disorders (TMDs) – TMDs are musculoskeletal conditions associated with pain and dysfunction of the temporomandibular joint (TMJ) and muscles of mastication.[5] Symptoms include headaches, neck and/or facial pain, decreased joint movement, joint sounds, and periauricular pain. Treatment options for TMD include occlusal splint therapy, acupuncture, muscle relaxants, anti-inflammatory medications, and biofeedback. Research suggests botulinum toxin injection provides long-term relief of TMD by reducing the intensity, frequency, and duration of recurrent episodes. Injections are typically delivered extraorally into the temporalis and masseter muscles, and intraorally into the lateral pterygoid

[3] Electromyography (EMG) measures electrical activity in muscles during movement. EMG (also called needle EMG) involves placing a needle electrode into the muscle being tested. Intramuscular injections of botulinum toxin aided by EMG guidance allow for very accurate targeting of specific muscles.

[4] In May 2013, the Royal College of Dental Surgeons of Ontario Council approved botulinum toxin injection by dentists intraorally for therapeutic or cosmetic purposes, or extraorally for therapeutic purposes, as long as they are trained and competent to perform the procedures. Educational requirements include didactic and clinical components, and formal evaluation. The didactic component should include pharmacology & physiological activity of botulinum toxin; diagnosis of relevant conditions; indications for use; contraindications; head & neck anatomy; adverse reactions & their management. The clinical component should include hands-on or clinical simulation. Extraoral administration requires more extensive training due to potential serious & life-threatening adverse reactions to this neurotoxin. [49] [50]

[5] Primary muscles of mastication: temporalis, medial pterygoid, lateral pterygoid, and masseter muscles.

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muscles. The duration of efficacy for TMD is approximately 12 weeks, though this is affected by individual treatment response and condition severity. [17] [18] [19] [20]

- Bruxism – Bruxism is characterized by unconscious clenching or tooth grinding due to repetitive contraction of the masseter and temporalis muscles. Bruxism may lead to severe dental attrition, dental work failure, TMJ damage, headaches, masseteric hypertrophy, and periodontal disease exacerbation. Common treatment of bruxism includes occlusal splints, pharmacologic therapy, and relaxation therapy. [21]

  Research suggests injection of botulinum toxin into the temporalis and masseter muscles provides safe and effective treatment for bruxism by reducing frequency of bruxism episodes, masticatory forces, and pain, in a variety of individuals, including those with neurologic disorders (e.g., Rett syndrome,[6] intellectual disability, cerebellar hemorrhage, autism, traumatic brain injuries). [18] [22] [23]

- Masseteric hypertrophy – Masseteric hypertrophy may occur with chronic bruxism. The increased size of the masseter muscles results in the jaw appearing swollen and misshapen (square jaw, bulging at angle of mandible). Treatment may include nonsurgical interventions (e.g., occlusal splints, muscle relaxants, etc.) or surgical resection of the muscle, which can cause permanent shortening of the muscle. Research has demonstrated botulinum toxin injection into the masseter muscles decreased muscle hyperactivity, which can alleviate pain and reduce muscle enlargement. [18] [24]

- Oromandibular dystonia – Oromandibular dystonia (OMD) is a type of focal dystonia characterized by involuntary and repetitive spasms of the facial, tongue, and masticatory muscles. It results in varying combinations of abnormal jaw, tongue, or lower face movements. OMD may impact individuals with Parkinson's disease, Meige syndrome,[7] and traumatic brain injuries. Symptoms of OMD include bruxism, dysphagia, dysarthria (difficulty speaking), soft tissue trauma, mandibular deviation, and TMJ subluxation. Symptoms may be task specific, triggered by speech or eating, or present at rest. OMD impacts chewing, swallowing, speaking, and quality of life, and marked pain has been reported. Pain is usually associated with headache and facial pain as a result of dystonic activity and forceful contractions.

  Management of OMD may include medication (e.g., anticholinergic and antiparkinson drugs, muscle relaxants, benzodiazepines, anticonvulsants, dopamine receptor antagonists), physiotherapy, dental appliances, and deep brain stimulation. Research suggests botulinum toxin injection is effective for managing OMD. [18] [21] [25] [26]

[6] Rett syndrome is a rare neurodevelopmental disorder that affects girls almost exclusively. It is characterized by normal early growth and development followed by slowing of development, constant repetitive hand movements, slowed brain and head growth, problems with walking, seizures, and intellectual disability. [51]

[7] Meige syndrome is a rare neurological movement disorder characterized by involuntary and often forceful contractions of the jaw and tongue muscles (oromandibular dystonia) and involuntary muscle spasms and contractions of the muscles around the eyes (blepharospasm). [52]

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- Hemifacial spasm – Hemifacial spasm[8] is a neuromuscular disorder characterized by frequent involuntary contractions (spasms) of the muscles on one side of the face innervated by the facial nerve. The first symptom is usually intermittent twitching of the eyelid muscle that can lead to forced closure of the eye and functional blindness. The spasms may gradually spread to muscles of the lower face causing the mouth to be pulled to one side. Eventually all of the muscles on one side of the face spasm almost continuously. Injecting botulinum toxin into the affected muscles is one of the most commonly used treatments for hemifacial spasms, given its high efficiency in controlling spasms. [21] [27] [28]

- Hemimasticatory spasm – Hemimasticatory spasm is a rare disorder of the trigeminal nerve that produces unilateral involuntary contraction of the jaw-closing muscles, causing brief or prolonged spasms, severe pain, and restricted mouth opening. Several case studies have reported positive response from botulinum toxin therapy by diminishing the effects of hyperfunctional or spastic muscles, improving function and mouth opening, and decreasing pain. [24] [29] [30]

- Trigeminal neuralgia – Trigeminal neuralgia (TN), also known as tic douloureux, is a painful disorder of the trigeminal or fifth cranial nerve. Typical presentation of type 1 TN is severe, sporadic, sudden burning or shock-like neuropathic pain affecting one side of the face (e.g., mouth, cheek, nose), lasting a few seconds to several minutes per episode. Some individuals experience quick successions of episodes lasting as long as 2 hours. Type 2 TN is characterized by constant less intense dull aching, stabbing, or burning pain. Both types may occur in the same individual, even at the same time. Pain can be triggered by light tactile stimuli in a trigger zone (e.g., brushing teeth, applying makeup, shaving, face washing, eating, drinking, light touch, or wind). Pain intensity can be incapacitating affecting quality of life. [31] [32]

  Treatment may include pharmacotherapy and surgery. Some individuals report pain reduction with complimentary therapies, such as acupuncture, biofeedback, vitamin therapy, and botulinum toxin injections. A meta-analysis by Wei et al. (2019) suggested botulinum toxin therapy was efficacious and safe in treating trigeminal neuralgia. However, further larger and well-designed randomized controlled trials are necessary to confirm this finding. [21] [33] [34] [35]

- First bite syndrome – First bite syndrome is acute intense pain in the parotid region occurring with the first bite of food and improving with subsequent bites. It is seen after surgery involving the infratemporal fossa, deep lobe of the parotid gland, and parapharyngeal space and is related to damage to sympathetic innervation of the parotid gland. Case studies have demonstrated botulinum toxin therapy decreased symptom severity and improved quality of life. [21] [36] [37]

[8] Xeomin® is authorized for use in Canada to treat hemifacial spasm in adults.

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- Sialorrhea – Sialorrhea[9] (also known as ptyalism, hypersalivation, or 'drooling') is a salivary function disorder. It can occur as the result of excess saliva production (e.g., medication-induced by aripiprazole, clozapine, pyridostigmine) or, more frequently, accompany neurologic conditions that affect salivary clearance from the oral cavity. Sialorrhea is most commonly associated with cerebral palsy in children and Parkinson's disease in adults. Treatment options for sialorrhea include behavioural and physical therapies, anticholinergic drugs, acupuncture, radiotherapy, and surgical interventions (e.g., salivary duct ligation, salivary gland excision). Botulinum toxin injections have been shown to effectively reduce salivary output in adults and children, and most adverse effects are mild and transient (e.g., dry mouth, thickened saliva). Botulinum toxin is administered locally into the parotid and/or submandibular glands. The salivary glands are located using ultrasound imaging or surface anatomical landmarks.

  If treatment with botulinum toxin produces chronic xerostomia, dose reduction may be necessary since it can cause further complications, such as periodontal disease, caries, and dysphagia. An appointment with an oral health professional is recommended prior to sialorrhea treatment with botulinum toxin to determine if caries prevention strategies are necessary. [8] [38] [39]

- Dental implants – Osseointegration of immediate loaded implants can be hindered by excessive functional forces in individuals with parafunctional habits. It can also result in implant failure by loosening or fracturing implant components and preventing osteointegration. Muscular relaxation through prophylactic use of botulinum toxin injections to the masticatory muscles may be beneficial by allowing unhindered implant osseointegration. [24] [40]

- Dental surgery – Administering botulinum toxin before and after periodontal surgery in individuals with pathologic clenching may benefit healing by reducing periodontal trauma caused by clenching and bruxism. [41]

  Muscular relaxation of the masticatory muscles via botulinum toxin injections may be beneficial for fracture healing by reducing muscular overloading (e.g., for zygomatic fracture fixation surgery, surgical reduction of mandibular, condylar bone fractures). [24] [40]

- Orthodontic treatment – Orthodontic treatment may be prolonged in individuals who experience bruxism or have a deep or crossed bite if the vertical component of muscular force is greater than the force of the fixed or removable appliance. These cases often require the use of removable functional retainers in combination with regular fixed appliances in an attempt to control the component of vertical force. The use of botulinum toxin may decrease orthodontic treatment time by reducing clenching and bruxism forces. [40]

[9] Xeomin® is authorized for use in Canada to treat chronic sialorrhea associated with neurological disorders in adults.

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- Excessive gingival display – Hyperfunction of the lip elevator muscles can cause the maxillary lip to ascend too far apically resulting in excessive maxillary gingival display (gummy smile). Botulinum toxin injection limits excessive muscular contraction to help manage the condition with results lasting approximately 6 months. [42] [43] [44]

- Dentofacial aesthetics – Botulinum toxin injections may be utilized in individuals where lip elevation is bilaterally uneven to control the height of the misaligned side. [40]

Mechanism of action

Botulinum toxins interfere with neural transmission by blocking the release of acetylcholine at the neuromuscular junction and in cholinergic sympathetic and parasympathetic neurons. Injecting the toxin weakens overactive muscles and controls hypersecretion of glands supplied by cholinergic neurons. [45]

Intramuscular administration of the toxin acts at the neuromuscular junction causing temporary muscle paralysis by preventing the release of acetylcholine from presynaptic motor neurons. After synaptic transmission is blocked, the muscles become clinically weak and atrophic. The affected nerve terminals do not degenerate, but the blockage of neurotransmitter release is irreversible. The effects in the targeted muscles lessen over time with the sprouting of nerve terminals and the formation of new synaptic contacts. Neuromuscular signaling and muscle contractility are usually restored after 2 to 3 months. [2] [5] [45]

Limitations

The most significant limitation of botulinum toxin is its effects are not permanent and treatment has to be repeated. The effects of therapy may last approximately 3 to 6 months depending on the individual, amount injected, injection site, and the condition being treated. The use of botulinum toxin may not be appropriate therapy for all cases and other treatment modalities should be considered first. [40]

Serious warnings

- All botulinum toxin products have a boxed warning indicating effects may spread from the injection site causing symptoms consistent with botulism, such as generalized muscle weakness, drooping eyelids (ptosis), double vision (diplopia), and difficulties swallowing (dysphagia), speaking (dysarthria), and breathing. Symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life-threatening and death has been reported. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can occur in adults, particularly in those with underlying conditions that would predispose them to these symptoms.
- Follow the recommended dosage and frequency of administration.
- Botulinum toxin products are not interchangeable; potency units are specific to each preparation and cannot be compared or converted to any other botulinum product.
- The product should only be administered by clinicians with appropriate qualifications and experience in the treatment and the use of required equipment. [6] [46]

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Contraindications

The use of botulinum toxin is contraindicated in:

- Individuals who are hypersensitive to any botulinum toxin or any ingredient in the formulation or component of the container.
- Presence of infection at the proposed injection site(s). [6]

Precautions

Precautions for administering botulinum toxin include:

- Neuromuscular disorders, including motor neuropathy, myasthenia gravis, Lambert-Eaton syndrome or amyotrophic lateral sclerosis (ALS)
- Pregnancy and lactation because animal studies have shown reproductive toxicity and it is not known if the drug is excreted in human milk.
- Individuals with unrealistic expectations.
- Professionals (e.g., actors) who rely on the acuity of their facial muscles. [47]
- As with any procedure that may induce bleeding, botulinum toxin should be administered with caution:
    - If bleeding disorders of any type exist
    - In individuals on anticoagulant therapy or taking medications at anticoagulant doses (e.g., warfarin, heparin, acetylsalicylic acid, clopidogrel). [8] [40]

Drug interactions

- Certain medications can interfere with neuromuscular impulse transmission and potentiate the effects of botulinum toxins, such as aminoglycoside antibiotics (e.g., streptomycin, tobramycin, neomycin, gentamycin), polymyxins, tetracyclines, lincomycin, spectinomycin, and tubocurarine-type muscle relaxants. Some studies suggest calcium channel blockers and quinine may increase potency of botulinum toxins so caution must be used with individuals taking these drugs. [6] [8] [40]
- Excessive weakness may be exaggerated by administration of a muscle relaxant before or after botulinum toxin injection. [48]
- When botulinum toxin is used to treat chronic sialorrhea, irradiation to the head and neck (including salivary glands) and/or co-administration of anticholinergics (e.g., atropine, glycopyrronium, scopolamine) may increase the effect of the toxin. [8]
- Administering different botulinum toxin products at the same time or within several months of each other may cause severe muscle weakness. [6] [7]

Side effects

Possible side effects include:

- Pain, tenderness, erythema, and/or bruising at the injection site.
- Transient local drug effects following injection into adjacent muscles.
- Malaise (generally feeling unwell), lasting up to 6 weeks after injection. [6]

Take home messages

- The use of botulinum toxin injections for various medical and dental conditions is safe, effective, and supported by a large body of evidence.
- As popularity of botulinum neurotoxin use increases, oral health professionals should be familiar with medical and dental indications, evidence for safe and

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effective use, treatment benefits, mechanism of action, modes and frequency, side effects, and contraindications to enhance interprofessional collaboration and client education and referral.

- Oral health professionals play an essential role in early identification of signs and symptoms of medical and dental conditions that may benefit from botulinum therapy to provide appropriate referral for evaluation, prompt diagnosis, and timely treatment. This emphasizes the importance of thorough medical history review, and comprehensive extraoral and intraoral examinations.

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