

# Is the use of botox and dermal fillers by dentists a cause for ethical and dento-legal concern?

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## Key words

Botox, botulinum toxin, dermal fillers, facial aesthetics, ethics, legal considerations, cosmetic dentistry, therapeutic applications, side effects, complications, precautions, risks

## Executive Summary Clinical importance

- Botox and dermal filler treatments have become highly popular because of their quick, predictable and effective results in the management of facial wrinkles and rejuvenation, with lower procedure and recovery time in comparison with surgery.
- The exponential growth in the use of Botox and dermal fillers as a minimally invasive aesthetic and therapeutic in the medical and dental field, has signaled a need for greater focus on patient safety.

## Key points

- Botox is injected in muscles to relax (freeze) muscles with the purpose of smoothing dynamic wrinkles.
- Dermal fillers are injected under the skin to smooth lines (static wrinkles) or to add fullness to the face.
- Botox and fillers complement each other.
- Botox treatment is relatively safe and side-effects occurring in less than 1% of patients.
- Treatment with Botox is widely viewed as safe, effective, minimally invasive, non-surgical, reversible modality.
- Botox is a prescription only medicine.
- There is no restriction on who and how dermal fillers are used.
- Transient and benign side effects are usually well-localized, reversible and self-limiting complications.
- The frequency of serious side effects is 33 times higher for therapeutic than for aesthetic cases.
- Thorough medical history, aseptic and correct technique is key to preventing side effects.
- Lack of informed consent, dissatisfaction with the cosmetic outcome, arising from treatment and complications are the main reasons for litigation.

## Practical applications

- Botox and dermal fillers can have some serious risks and adverse events if not administered properly.
- Proper education and hands-on training is essential in learning proper techniques of administration.
- The best interests of patients should always take precedence over any consideration of profit or personal gain.
- Dentists need to ensure that they have appropriate indemnity before providing facial aesthetic or therapeutic procedures.

## Introduction

Botulinum toxin Type A (BTX-A) and dermal fillers, also referred to as soft tissue fillers, have become highly popular because of their quick, safe, and predictable results in the management of facial wrinkles and rejuvenation, with lower procedure and recovery time in comparison with surgery.<sup>1,2</sup> Non-surgical facial aesthetic procedures have become a billion dollar industry owing to the ever-growing demand to beat the ageing process and quest for staying young.<sup>1</sup> Although BTX-A has been mostly associated with facial aesthetic procedures, its benefits and uses go beyond aesthetic and include a wide range of medical and dental therapeutic applications.<sup>3</sup>

There are seven serotypes of botulinum toxins A-G. Botulinum toxin Type A (BTX-A) is the most potent.<sup>4,5</sup> BTX-A acts on nerve endings, blocking calcium channels and decreasing the release of acetylcholine. With the inhibition of acetylcholine, muscle contraction is reduced, with no effect on the central nervous system or systemic implications.<sup>1</sup> In addition, the release of neuropeptides, involved in the transmission of painful sensations from peripheral nerves, are also blocked.<sup>6</sup> The selective paralysis of certain muscles is the basis of BTX-A treatment, but paralysis of adjacent or other muscles can lead to the complications and/or patient dissatisfaction.<sup>1</sup> This process of relaxing or freezing muscles is influenced by the application, location, and dose used. The clinical effects appear from 2 to 10 days after the injection and the maximal visible effect occurs after 14 days of the injection. As 'dynamic wrinkles' result from contraction of muscles under the skin, when these motor muscles are unable to contract, they become smooth. This effectively weakens the muscle for a period of three to six months.<sup>4,5</sup> whilst allowing the sensory transmission to remain unhindered.<sup>7</sup> Patients may become partially or completely immune to repeated injections due to antibodies that neutralize the toxin.

BTX-A used as a neuromodulator, is the most popular non-surgical aesthetic/cosmetic procedure performed world-wide (Estimated 7.3 mil. in 2021).<sup>2,8</sup> It is widely viewed as safe,

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effective, minimally invasive, non-surgical modality and largely devoid of serious side effects.<sup>4,9</sup>

Dermal fillers are frequently performed to complement BTX-A, making them the second most popular nonsurgical cosmetic procedure (Estimated 5.3 mil. in 2021).<sup>2,8</sup> The American Association of Facial Aesthetics has trained approximately 20,000 dentists in Botox and dermal fillers, which is more than the number of practicing dermatologists and plastic surgeons combined.<sup>10</sup>

Good facial aesthetics and a harmonious smile are considered essential factors for most patients' self-esteem,<sup>5</sup> and has given rise to a new social norm. The current demand for youthfulness and treatments to curb ageing, on the one hand, and the technological advances in the field of medicine and dentistry is driving the modern era of facial aesthetics and therapeutics.<sup>11</sup> Furthermore, contemporary dentistry is characterized by changes from a needs-based service where diseases and symptoms are primarily treated, towards improving oral health, towards a wants-based service where the primary focus is more on cosmetic/aesthetic services.<sup>12</sup>

The increasing demand for facial aesthetic treatment, amongst a wide range of ages, within the completely unregulated nature of the non-surgical aesthetic industry, potentially poses serious risks to patients safety.<sup>13</sup> In the UK, the oversight and lack of regulations, has resulted in the Department of Health cautioning that the "use of injectable fillers is a crisis waiting to happen."<sup>14</sup> Heydenrych and co-workers<sup>15</sup> has also reported that "the recent rapid growth in dermal filler use, in conjunction with inadequate product and injection control, has heralded a concerning increase in filler complications."<sup>15</sup>

In addition, the administration of aesthetic fillers is currently enduring an onslaught of factors compromising not only patient safety, but also the reputation of the field of facial aesthetics.<sup>15</sup> Rowland-Warman<sup>16</sup> has also pointed out that "there is a discord between device regulation and the regulation of professions and that the lack of regulation of dermal fillers poses a real threat to patient safety".

The application of BTX-A for dental treatment is gaining momentum and is viewed by clinicians (medical and dental) as relatively safe for use.<sup>17</sup> Irrespectively, there is a wide spectrum of views as to whether or not dentists should be getting involved in the provision of facial aesthetic procedures.<sup>18</sup> Currently, there are no guidelines as to what constitutes adequate training or verification of courses for facial aesthetic and therapeutic treatment with BTX-A and dermal fillers for dentistry. Patients mainly rely on the manufacturers declaration of safety and the practitioners assessment and application of the product to ensure treatment success and safety.<sup>16</sup>

A summary of key differences between BTX-A and dermal fillers is provided in Table 1.

The purpose of this article is to illuminate whether the

administration of BTX-A and dermal fillers by dentists in South Africa are a cause for legal and ethical concern.

## **Dento-legal considerations with BTX-A and dermal filler administration within the context of dentistry in South Africa**

### **• Legal and regulatory framework**

The dental administration of BTX-A is regulated, by virtue of the provisions of the Health Professions Act<sup>32</sup> (Act 56 of 1974), The Medicines and Related Substances Amendment Act<sup>33</sup> (Act 72 of 2008) and the Health Professions Council of South Africa (HPCSA) Guidelines.<sup>11,34</sup> The Medicines and Related Substances Amendment Act<sup>33</sup> (Act 72 of 2008) states that "a practitioner registered under the Health Professions Act<sup>32</sup> (Act 56 of 1974) may prescribe and apply, only within his/her scope of practice and subject to the indication for the use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care." Dentists who act beyond the scope of their training are subjected to disciplinary action such as suspension from practice, dismissal or criminal charges.

Dentists' suitability and competence is primarily deduced from a wider application of the existing legislation and regulations promulgated in the Health Professions Act and the Medicine and Related Substances Control Act. The legislative framework of these Acts "are not explicit in the determination of the scope of practice of dentists, in particular, and is construed to be inadequate to extend to the administration of BTX-A by dentists."<sup>11</sup>

The HPCSA is a Statutory Body governing/regulating the scope of dental practice, thus protecting the interest of the patient. According to the HPCSA Guidelines<sup>34</sup> (Addendum 2) scheduled substances used for cosmetic medical procedures may only be administered by a doctor or other qualified professional registered with the HPCSA who is adequately trained in the relevant anatomy, physiology and pharmacology, including the management of potential side effects and complications. What is not clearly established is whether dental surgeons fall within the ambit of adequately qualified medical professionals or not. The HPCSA<sup>34</sup> guidance is set out in Ethical Rule 21 – Performance of Professional acts: "A practitioner shall only perform, except in an emergency, a professional act for which he or she is adequately qualified and sufficient experienced".

The guidelines for the HPCSA for good practice in the health care profession require that a registered practitioner ensure that a procedure is within the scope of their practice and further, that they have appropriate training not just to administer, but also to mitigate, this medical procedure's potential adverse effects. The onus is therefore on the practitioner to ensure that they have adequate education, training and experience in the performance of a BTX-A procedure.<sup>11,25</sup> The HPCSA also makes it compulsory for all members of the medical and dental profession, including

**Table 1: Key differences between BTX-A and Dermal (soft tissue) fillers**

Characteristic	Botulinum toxin	Dermal (Soft Tissue) Fillers
<b>Product: Origin/ content [Brands]</b>	Botulinum toxin Type A (BTX-A): (neurotoxin) produced from bacteria <i>C. botulinum</i> [Botox™ (onabotulinumtoxin A) Allergan Inc. Ireland] [Dysport® (abobotulinumtoxin A) Ipsen Ltd , UK] [Xeomin;® (incobotulinimtoxin A) Merz Pharmaceuticals, Germany] [Jeuveau® (prabotulinumtoxin A)] Botulinum toxin Type B: [Myobloc® (rimabotulinum toxin Type B) Solstice Neurosciences Inc]	Hyaluronic acid: Biodegradable natural product [Restylane® Juvéderm XC® Ultra® (Plus), Perlan®, Belotera® Revanesse versa®] Poly-L-lactic acid: (PLLA) Biodegradable synthetic [[Sculptra® Calcium hydroxylapatite, Naturally occurring substance (Radiesse®) Polymethylmethacrylate (PMMA): Non-resorbable- permanent; Synthetic biocompatible (Bellafill®)
<b>Description</b>	Medicine (Injectable Drug)	Medical device (dermal injectable implantation)
<b>Dental Uses</b>	Peri-oral Aesthetics (Cosmetic) Softening expression lines, deep nasolabial folds radial lip lines, high lip line (gummy smile) Therapeutic: Mandibular spasm, clenching, masseter muscle hypertrophy, trismus and tension headaches, sialorrhoea, asymmetrical smile	Peri-oral Aesthetics (Cosmetic) Mild-deep dermal implantation Submucosal implantation for lip augmentation Black triangles between teeth Treatment of high lip lines
<b>Mode of action</b>	Neuromodulator - Relaxes (freezes) muscles to reduce wrinkles; Prevents muscles from contracting	Smooths wrinkles by filling in, adding, or restoring volume to soft tissue/fat loss resulting from ageing. PLLA is a collagen stimulator
<b>Key focus areas</b>	Relax or freeze dynamic wrinkles or expression lines upper face - around eyes & forehead	Static wrinkles or fine lines due to ageing - Lips, eyes, nose, mouth corners, cheeks, temple
<b>Application</b>	Injected into specific muscles	Injected beneath the surface of the skin
<b>Maximum allowed dosage</b>	Do not exceed a total dose of 360 units in a 3 month interval	Restylane: 6.0ml per patient treatment or 1.5 ml per lip treatment
<b>Aesthetic Purpose</b>	To slow down aging and to rejuvenate; Softens lines & prevents wrinkles caused by facial expression	Restore the look of fullness of the face that is common in youth
<b>Results</b>	Initial effect after 3 days, maximum effect after 10 days	Immediate
<b>Duration of effect</b>	3-6 months	6-12 months
<b>Side effects and complications</b>	Injection site reactions (bruising, swelling, pain), bacterial infection, fever, headache, antibody development, asymmetry, aesthetic disenchantment	Injection site reactions (bruising, swelling, pain), bacterial infection, fever, headache, antibody development, asymmetry, aesthetic disenchantment
<b>Rare adverse events</b>	Hypersensitivity, eyelid/brown ptosis, dysphagia, facial muscle weakness, blurred vision, salivary gland injury, nerve injury, botulism	Delayed hypersensitivity, salivary gland injury, nerve injury, tissue necrosis, vascular occlusion & stroke, blindness
<b>Relative Contraindications</b>	-Neuromuscular disorders (e.g. myasthenia gravis, Eaton-Lambert syndrome) -Allergies to any components of BTX-A -Patients on medications that can affect neuromuscular impulse transmission and exacerbate the effects of BTX-A (e.g. amino glycosides, D-penicillamine, quinine, and calcium blockers, cyclosporine, muscle relaxants, -Pregnant patients or lactating mothers -Psychologically unstable patients or who have questionable motives and unrealistic expectations -Individuals who are dependent on intact facial movements and expressions for their livelihood (e.g. actors, singers, musicians, and media personalities,	-Active infection near site of injection -Known allergy or hypersensitivity to the filler material and/or components (i.e. Gm+ bacterial proteins, lidocaine, bovine collagen) -Glabellar necrosis -Patients with bleeding disorders -Safety of Restylane® implantation in anatomical regions other than nasolabial folds or lips have not been establish -Safety of Restylane® in pregnancy and breastfeeding has not been established. -Restylane® should be used with caution in patients on immunosuppressive therapy

References: 1,4,5,9,19,21-31

dentists who administer BTX-A and dermal fillers, to continuously update their knowledge and skills by attending continuing professional development courses.

**• Classification of Botox and dermal fillers**

In South Africa, BTX-A is scheduled as a 'prescription-only medicine', meaning that the procedure can only be performed

by a registered health care practitioner, with adequate training in facial aesthetic procedures, after a clinical assessment to ensure treatment suitability.<sup>33</sup> (Act 72 of 2008) In contrast, dermal fillers are currently classed as a 'medical device' and are freely available for purchase and use by non-registered health care practitioners, with no need for a prescriber to assess clients beforehand.<sup>35</sup>

#### • **Scope of practice of the dentist**

The South African Health Professions Act<sup>32</sup> (Act 56 of 1974), section 33(1), read with section 61(2), of the Health Professions Act<sup>32</sup> (Act No. 56 of 1974) as amended by Act 29 of 2007, sets out the scope of practice of the dentist as follows:

- (a) "The physical clinical examination of the oral, maxillofacial and related structures of a person;
- (b) making a diagnosis of diseases, injuries and conditions of the oral, maxillofacial and related structures, including determining the relevance of systemic conditions, and/or giving advice on such conditions;
- (c) performing dental procedures and/or prescribing medicines aimed at managing the oral health of a patient, including prevention, treatment and rehabilitation;
- (d) performing any procedure on a patient aimed at fitting or supplying a dental prosthesis or appliance; and
- (e) performing any aesthetic or cosmetic procedure on a patient pertaining to the oral and perioral area."

Currently, uncertainty persists specifically in terms of the scope of practice of dentists in administering BTX-A.<sup>11</sup> Regarding whether the administration of BTX-A falls within the scope of dentists' practice – registered dentists are identified as 'appropriate practitioners' – and in terms of Section 58(2) of the Medicines and Related Substances Act<sup>33</sup> (Act 72 of 2008), they can procure, prescribe, dispense or administer, prescription-only medicines as part of their scope of practice in the field of dentistry.

However, if a procedure is unrelated to dentistry and beyond the scope of practice, it can be argued that a dentist should not perform it, irrespective of the training or certification the dentist has obtained. Thus it would be illegal and unethical for a dentist trained or certified to administer BTX-A treatment for procedures that are either beyond the scope of dentistry or unrelated to dentistry."<sup>11</sup>

There is, however, need to clarify circumstances in which the use of BTX-A and related treatments is linked to the practice and scope of dentistry. The peri-oral area, including the lips, cheeks and jaw, falls within the scope of dentistry but parts of the face outside these areas do not.<sup>11</sup> The HPCSA guidelines dictate that dental BTX-A may only be practiced by a registered specialist who has received training from an examination body accredited by the Board.

Currently there are no rules, regulations and clinical guidelines specifically pertaining to dentists using BTX-A and fillers. Firstly, there is no express provision giving dentists a green light in

performing Botox procedures. Secondly, the provisions for dentist's scope of practice have not been clearly articulated to include administration of BTX-A.<sup>11</sup>

#### • **Complaints and litigation**

The Dental Protection Board, of which South Africa is a member, publishes statistics on complaints related to dental BTX-A for each member country.<sup>18,36</sup> The three most common types of complaints and litigation are the following:

- (i) Shortcomings in the consent process; particularly, failure to adequately inform the patient about the expected cosmetic outcomes, and potential negative outcomes of the procedure including warning the patient of the possible risks and side effects.
- (ii) Dissatisfaction with the outcome of the cosmetic procedure (often related to asymmetry and 'lumping' in the case of dermal fillers).
- (iii) Complications arising from treatment, such as hypersensitive reactions (leading, in one case, to anaphylaxis) postoperative pain, discomfort and bruising.<sup>18</sup>

Dentists venturing into aesthetic/cosmetic procedures should be aware of the possible complications, complaints and the legal hassles that may arise.<sup>37</sup> Litigation experience can be devastating for a dental practitioner. The best defence to a malpractice case is to avoid one altogether.<sup>38</sup> It is not always the actual treatment outcome that makes the patient take litigation against a dentist. The patient's perception of his relationship with his/her doctor is the most important factor in deciding whether or not the patient will file litigation against a doctor.<sup>37</sup> A patient is more likely to file litigation if the patient perceives that his/her doctor is lacking in empathy and communication skills. An open, truthful, and caring approach, when unfortunate complications occur, can avoid unnecessary litigation.<sup>39</sup> Furthermore, in the present era of consumer protection rights and activism, it is recommended to avail professional indemnity insurance to cover risk of allegations of dental negligence and its consequences.<sup>37,40</sup>

#### • **Malpractice**

Dental malpractice is defined as "any act or omission by a dentist during treatment of a patient that deviates from accepted norms of practice in the dental community, or found to be below the acceptable standard of care expected from a dentist, that results in serious personal harm sustained by the patient".<sup>11,41</sup> Dental malpractice arises when a dental practitioner neglects to administer appropriate treatment, excludes the correct action, or provides substandard treatment that culminates in harm or injury to a patient or results in the patient's death.<sup>11</sup> It is, in fact, medical malpractice when a dentist administers BTX-A outside the scope of his practice, whether intentionally or negligently, unless this procedure is conducted in an emergency situation.<sup>11</sup>

Legally, a dentist commits dental malpractice if he or she undertakes to do a task for which he or she lacks professional competence. Competence does not only involve attaining a qualification, but also involves continually staying abreast of

developments in the field, and ensuring that one has the necessary skills and training to perform new or updated procedures.

- **Negligence**

Medical negligence is a form of medical malpractice which is failure on the part of the practitioner to exercise 'a reasonable amount of skill and care' during a medical procedure being undertaken, which renders them liable for delictual claims for damages.<sup>42</sup> BTX-A negligence refers to actions or inactions of a health care provider during administering BTX-A resulting in avoidable harm and complications. Negligence is a form of medical malpractice in four instances, namely: when the dentist acts outside the scope of his or her practice by administering BTX-A; when the dentist is incompetent in administering BTX-A in dentistry resulting in avoidable complications (that is when he or she administers BTX-A without having received the necessary training from an examination body accredited by the Board); and when a dentist administers excess dosage of BTX-A above the prescribed limits, and failing to advise the patient on the do's and don'ts after a procedure as well warning the patient about potential risks involved.<sup>11</sup>

Currently there is no legislation governing medical and dental malpractice cases, included cases where a BTX-A procedure as a non-invasive dental treatment goes wrong.<sup>11</sup> If BTX-A administration was administered by a dentist outside the peri-oral region, the dentists would be assessed against the standards of a practitioner who is authorized to administer BTX-A in these areas of the body, such as a plastic surgeon or dermatologist.<sup>11</sup>

### **Appropriateness of dentists carrying out facial aesthetic and therapeutic procedures with BTX-A and dermal fillers**

Facial aesthetic and dental therapeutic treatment with BTX-A and dermal fillers currently do not form part of the curriculum for undergraduate studies in dentistry in South Africa. Furthermore, there are no guidelines regarding what constitutes adequate training<sup>16</sup> or verification of courses at present. "The responsibility is the practitioners' to decide whether they are performing safely and to a high standard and are clinically equipped to deal with adverse events following training."<sup>13</sup>

However, the training, skills, and readiness of dentists to administer BTX-A and dermal fillers can be easily addressed through adequate training and exposure during post graduate years at various certified training institutions, either locally or abroad, potentially rendering a dentist a master in the field of facial aesthetic treatment.<sup>11</sup> It is unknown how many dentists are trained and certified to administer BTX-A and dermal filler in South Africa.

Although there is an increasing use of BTX-A and other types of cosmetic treatments in the dental field, there is an ongoing debate at present as to whether use of BTX-A for cosmetic purposes falls within the scope of dentistry. Dentists are generally in a more advantaged position than other medical practitioners when it comes to effectively carry out treatment and

procedures in the maxillofacial region.<sup>43</sup> This is largely due to their extensive undergraduate training in anatomy, physiology of the maxillofacial region. Benninger and co-workers<sup>44</sup> argue that the dental curriculum in the US adequately equips dentists to administer Botox. Students receive "an 11 to 12 week specific course of head and neck anatomy compared to their medical colleagues who receive on average 2 to 3 weeks of head and neck anatomy education during their first 4 years of prequalification training". Benninger et al highlights that dental students administer between 3000 and 4000 injections "at multiple sites intra and extra orally" during their four years of training in dentistry. Benninger et al argue that training in general dentistry provides the "fundamental knowledge and clinical skills" required for the administration of BTX-A.<sup>44</sup>

Dental Protection believes (and is on public record stating): "that dental health care professionals are better placed, in many respects, than many other potential providers to carry out non-surgical cosmetic treatments safely and successfully, not least because of their particular range of background knowledge and training, the standards of infection control and their ability to manage a medical emergency."<sup>45</sup> The DPL's expectations of dentists providing non-surgical cosmetic treatments such as BTX-A includes:

"Performing only those dental procedures for which they have been educated and trained and are competent; practice within their scope of practice; ensuring that they have appropriate professional indemnity insurance for all aspects of their practice; meeting the Board's recency of practice requirements; acting in accordance with the standards set out in the Code of Conduct including expectations about informed and financial consent; and completing ongoing continuing professional development that contributes to the development, maintenance and enhancement of knowledge, skills and performance; and adhering to relevant legislation and regulations in relation to approved use of botulinum toxin and dermal fillers, off-label use of botulinum toxin and dermal fillers, and advertising of therapeutic goods."<sup>45</sup>

The practitioner therefore bears the burden of proof to ensure that they have adequate education, training, experience in the performance of administration of BTX-A and dermal fillers. In addition, they should also have the capacity to manage potential side effects, reactions and complications that may result from the administration of such substances.

### **Ethical considerations**

Ethical considerations encompass four fundamental principles: non-maleficence, beneficence, autonomy, and justice.<sup>46</sup> While ethical compliance requires that all four of these principles be satisfied, in reality one or more element is often given preference over the other. This may be due to conflicting views between a patient and clinician, with one party being more dominant. In cosmetic dentistry, ethics is usually fairly straightforward and situations can often be clearly judged as 'right' or 'wrong'.<sup>47</sup> Furthermore, in cosmetic dentistry, however, subjectivity can outweigh objectivity. Clinicians in their daily practice are faced

with problems and challenges regarding treatment management. The role of a dentist in providing cosmetic procedures or aesthetic treatment is threefold: professional, clinical and profit-based. In some situations two or more of these roles may be in conflict with each other. In such a case, the dentist must ensure that they honour all four principles of ethics in their duty of care.<sup>11</sup> A key ethical principle to adhere to is that “the best interests of patients should always take precedence over any consideration of profit or personal gain.”<sup>48</sup>

- **Benevolence – Duty of care**

A duty refers to ‘an obligation to do what is in the patients’ best interest’ or ‘avoidance of doing something that may cause harm or is not in the patients’ best interest’. If we have a duty to another person it means we are obligated to that person in some respect and for some reason while he or she holds a corresponding right or claim against us.<sup>11</sup> According to Pillay<sup>11</sup> “the broad principle of duty of care to the patient entails taking into consideration the best interests and wellbeing of the patient; acting with objectivity, integrity and competence; providing secure access to care; treating the patient with respect; involving the patient in the management of his or her health; upholding the patient’s privacy; obtaining informed consent, and preventing conflict of interest.”

To meet their obligations towards duty of care, dentists are required to have adequate skills (competencies) to perform a procedure, knowledge of how to manage possible complications, and the ability to address them properly.<sup>37</sup> Standard of care must be based on current best evidence available. Aseptic and universal infection control precautions should be followed.<sup>37</sup>

Finally, dentists need to ensure that they have appropriate indemnity before providing elective treatment to improve facial aesthetic or dental therapeutic procedures with BTX-A.<sup>40</sup>

- **Non-maleficence – preventing and mitigating complications and adverse effects**

While BTX-A is widely viewed as safe, effective and largely devoid of serious adverse events,<sup>49</sup> it is not without its side-effects and risks. (Table 1) Botulinum toxin is a lethal poison with life-threatening consequences when not administered properly within the prescribed limits or used incorrectly.<sup>11</sup> There are two classes of Botox-related adverse events – transient and benign events and potentially serious events. Benign side effects are well-localized, reversible and self-limited complications which develop within a few days of the injection, and they usually disappear without any treatment.<sup>43</sup> The serious events are sequelae due to the systemic spread of toxin.<sup>9</sup>

An important aspect of duty to prevent harm is the use of extreme caution in the administration of medicines or drugs, including BTX-A or dermal fillers, which may have adverse effects or contraindicated for patients or using drugs that may alter the effects of BTX-A.<sup>9,50</sup> (Table 1) In addition, dental practitioners who use BTX-A and dermal fillers for aesthetic or therapeutic procedures on patients are required to have the capacity to manage the potential adverse effects, allergic reactions and

complications.<sup>11,15</sup> The cosmetic use of BT rarely causes severe side effects. The frequency of serious side effects is 33 times higher for therapeutic than for aesthetic cases.<sup>9</sup>

- **Patient autonomy - Patient assessment, Informed consent and record keeping**

Patient autonomy, by itself, is not a rationale for treatment.<sup>51</sup> If the patient has expressed a desire for a particular aesthetic or therapeutic procedure, there is no ethical violation as long as the procedure lies within the realm of accepted treatment and the dentist's scope of practice. In addition, the patient must understand the risks, limitations and potential benefits.<sup>48</sup> Making an informed decision is the right of every patient, but it is the responsibility of the dentists to ensure that the patient is given all of the information necessary to exercise this right –including information about expected results, post-treatment instructions to prevent complications, risks, benefits, costs and other treatment options.<sup>51,52</sup>

The standard of care also includes a dentist being able to keep patients’ medical and dental records updated, complete, distinct, precise and readable.<sup>37</sup> This includes ensuring that the personal information of their patients are kept confidential; failing to do so represents medical malpractice.<sup>11</sup> Specified informed consent is vital due to the concerning increase in vascular complications which carry risk of skin compromise and loss of vision.<sup>15</sup> Informed consent should be signed for both adverse events, their treatments and costs.<sup>15</sup>

The practice of treating patients without disclosing potential risks is akin to securing consent of the patient by misrepresentation.<sup>11</sup> South African courts regard medical misrepresentation of facts, to be a serious criminal offence.<sup>28</sup> Consent forms are the most protective for the dentists in instances where unpredictable reactions occur after appropriate treatment. However, it does not provide immunity for the dentists from all guilt should an adverse event occur.<sup>53</sup>

- **Veracity, advertising and marketing of BTX-A**

Veracity requires that the dentists presents a treatment plan and delivers care in a truthful manner without false, misleading or deceptive information.<sup>48</sup>

Botox<sup>TM</sup> is a prescription only, Schedule 4 medicine which results in the advertising and promotion thereof being governed under the Medicines and Related Substances Control Act, Act 101 of 1965. In accordance with this Act, direct to consumer advertising of a scheduled product is not allowed and would be seen as illegal.<sup>16</sup> (To enable medical practitioners to however continue promoting their businesses and services, whilst also complying with the regulatory advertising requirements for medicines, it is recommended that reference in advertisements to individuals, scheduled 4 items be deleted and substituted with phrases such as ‘wrinkle reducing injections’ or other words and phrases with similar meaning, but without referring to specific products such as Botox<sup>TM</sup>).

## Conclusions

Cosmetic interventions are an evolution in medicine and dentistry in line with the needs of patients. Due to increasing demand for facial rejuvenation and harmonization, and the growth in training and specialization courses, the use of BTX-A and dermal fillers in dentistry is gradually becoming a reality. BTX-A and dermal fillers has undoubtedly broadened the aesthetic and therapeutic horizons of dentistry. BTX-A is a minimally invasive, reversible, safe, satisfactory, and efficient tool for facial aesthetic treatments. In addition, it has numerous off label therapeutic uses.

There is no law in South Africa that expressly restricts dentists from administering BTX-A and dermal fillers. However, the safety and wellbeing of patients must be the principal consideration, and the patient's right to choose their treatment and practitioner is vital to patient autonomy. The key pillars (elements) of successful and safe BTX-A and dermal filler interventions are consent to treat and the information needed to make this decision, competency and appropriateness in administering such products, and ability to prevent and deal with complications and complaints, and ensuring appropriate level of practitioner indemnity.

From a clinical and technical point of view, dentists are in a more advantaged position when it comes to providing treatment and administering injections in the oro-facial region due to their knowledge and training in anatomy, physiology and

pharmacology, their technical skills and expertise in the control of infection, and their competency to cope with a medical emergencies. Dentists should therefore be recognised through HPCSA standards and guidelines as well as their education and training policy considerations, so that they practice as equals with their medical colleagues in administering BTX-A and dermal fillers in the facial region.

This privilege however should come with very specific ethical and legal obligations to maintain a high level of standard of care and safety measures, including attending certified education and training courses and continuing professional development to comply with regulations and standard of care.

It seems likely that the use of BTX-A and dermal fillers by dentists will increase in the years ahead. A thorough understanding of the techniques, appropriate training from a reputable and authoritative source, and an awareness of the risks and how to prevent and manage them effectively, including having adequate and appropriate professional indemnity, is no less important for facial aesthetic procedures than for conventional dentistry.

## References

The full list of references 1-53 is available from:  
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