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CARIES CORNER

Fluoride Varnish: A Clinical Perspective on the ADA Laboratory Evaluation

We posed these questions to Domenick T. Zero, DDS, MS, the Director of the Oral Health Research Institute and a Professor in the Department of Preventive and Community Dentistry at the Indiana University School of Dentistry in Indianapolis.

All of the tested varnishes in the study demonstrated that they were capable of releasing fluoride. If this is the case, what distinguishes one from another?

Depending how you interpret the findings of this laboratory study, there does appear to be differences in the amount of fluoride released and the release rates for the products tested. With only two of the fluoride varnish products (MI Varnish [GC America] and Prevident [Colgate]) releasing most of their total fluoride into deionized water over the 6-hour experimental period. So if we assume that the test method will eventually prove to be a valid predictor of clinical effectiveness, then these two products could be considered better than the other products. However, other tested products, while releasing in most cases less than half of their total fluoride, had a more protracted fluoride release over the 6-hour test period.

There is currently no evidence as to which of the two parameters is more important. Furthermore, other laboratory parameters also can be considered in evaluating the potential clinical efficacy of fluoride varnishes. These include remineralization of early carious lesions directly underneath the varnish and adjacent to the varnish, and enamel fluoride uptake,[1,2] which can be considered more relevant to fluoride varnish efficacy, because they involve testing how fluoride varnish products interact with the target substrate, namely, the early caries enamel lesion.

Most of the fluoride in the study was released within the first hour after application. Is such rapid release more advantageous than, say for example, release over a period of days or weeks?

Since there currently is no clinical evidence supporting that the main mechanism of action of fluoride varnish is its ability for sustained release of fluoride into the oral environment, it is difficult to predict if a rapid release of fluoride may or may not be advantageous. Based on studies with dental materials (glass ionomer cements) with fluoride releasing ability, there does not appear to be a halo effect except immediately adjacent to the material. In my opinion the main benefit from applying fluoride varnish is the fluoridation of the demineralized tooth structure beneath and immediately adjacent to the fluoride varnish.

What should dentists look for when choosing a fluoride varnish?

The safest bet is to choose only clinically tested fluoride varnish products proven to prevent dental caries. However, this presents a problem because the only clinically tested product with 5 percent sodium fluoride that is currently available is the originally formulated Duraphat (Colgate), which is not available in single-dose packaging. Most of the popular products on the market are single-dose products.

While we can assume that fluoride varnish products containing the labeled amount of fluoride have the potential to be clinically effective, I still have concerns that differences in formulation can impact clinical efficacy. Currently marketed products have additives that could impact anti-caries efficacy positively or negatively. It is very well established from research on fluoride toothpaste that formulation is very important in optimizing fluoride availability and effectiveness. Based on the principles of evidence-based dentistry, we would need evidence from high-quality clinical trials establishing that these products are clinically effective or evidence that the laboratory models used to test fluoride varnishes are valid, and thus shown to be predictive of clinical efficacy.

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Editor's Note: These articles are intended to be an informational resource only. The views expressed are those of the authors and do not necessarily reflect the opinion or policy of the ADA. The article's contents are not a substitute for the dentist's own judgment and dentists are encouraged to consult with other professionals, as and when appropriate, regarding the information herein.

LABORATORY EVALUATION

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ADA Laboratory Evaluation Summary: Measuring Fluoride Release from Sodium Fluoride Varnishes

Note: This report is a summary. For the full laboratory report including all of the tables, a full description of the methods and a discussion of the implications for this evaluation, visit www.ada.org/ppr Volume 10, Issue 3, Laboratory Evaluation Full Report: Measuring Fluoride Release from Sodium Fluoride Varnishes.

Introduction

Fluoride varnishes are used in many countries for caries prevention and to treat dentin hypersensitivity associated with the exposure of root surfaces. While the U.S. Food and Drug Administration has only approved the latter use of fluoride varnishes, evidence-based reviews by the Cochrane Collaboration[1] and the American Dental Association (ADA)[2] concluded that fluoride varnishes are effective in preventing caries.

This study was designed to establish a standard test method to measure the rate of fluoride release from fluoride varnishes. Since the amount of fluoride released depends on the surface area of varnish exposed to solution (e.g., saliva) per unit volume of applied varnish, ADA researchers established a method that could provide samples with a consistent, reproducible thickness and exposed surface area of fluoride varnish for testing.

Fluoride release from seven commercially available fluoride varnishes containing 5 percent sodium fluoride (NaF) is documented in this study.

Materials and Methods

The ADA laboratory purchased products based on a survey conducted by the Dental Trade Alliance of the top selling, commercially available products on the market (Table).

ADA researchers developed a test method that involved coating Silicon Carbide (SiC) paper strips (Buehler 240 grit, 50 µm grain size) with the varnish and measuring the release of fluoride into water. After applying the varnish and immediately weighing, the researchers placed the strips in plastic tubes containing 30 mL of deionized water. The test samples were agitated for a total of six hours at room temperature (22 ± 2°C). The fluoride release was measured after 1, 2, 4, and 6 hours.

Table. List of Evaluated Products.*

Varnish Brand	Package volume (mL)	Manufacturer
Duraflor	0.5	Medicom www.medicom.com 1 800 361-2862 (North America)
Durashield CV	0.4	Sultan Healthcare 800-637-8582 www.sultanhc.com
Kolorz Clearshield	0.4	DMG America 800-662-6383 www.dmg-america.com
MI Varnish	0.5	GC America 800-323-7063 www.gcamerica.com
Prevident	0.4	Colgate 1-800-2-COLGATE www.colgateprofessional.com
Profluorid	0.4	VOCO 888-658-2584 www.vocoamerica.com
Vanish	0.5	3M ESPE 800-634-2249 www.3mespe.com

* All varnishes were 5 percent sodium fluoride (NaF) by weight and were individually packaged.

Results

The rate of fluoride release decreased over time for all of the products tested. In fact, for all of the products, with the exception of Vanish (3M ESPE), greater than 50 percent of the total 6-hour fluoride release occurred within the first two hours after application (Figure).

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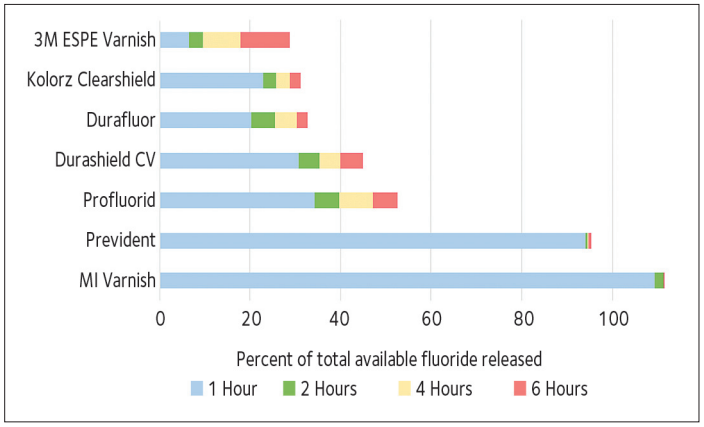
However, only three products (Profluorid, VOCO; Prevident, Colgate; and MI Varnish, GC America) released greater than 50 percent of their total available fluoride over the 6-hour test period. MI Varnish (GC America) and Prevident (Colgate) not only released much more fluoride than the others, they released almost all potential fluoride in the first hour.

Figure. Percentage of Fluoride Released Over Time at Room Temperature (22 ± 2°C) (n=5).



Conclusion

All of the tested fluoride varnishes were capable of releasing fluoride, most of which was released in the first hour (except Vanish, 3M ESPE). After 6 hours, most of the fluoride varnishes continued to release only small amounts of fluoride.

However, while MI Varnish (GC) and Prevident (Colgate) released all or almost all of their total available fluoride after 6 hours, the remaining five products released only about 29 percent to 53 percent of their total available fluoride over this time.

Additional studies are necessary to determine the optimal rate at which fluoride releases from the varnish.

While more research is needed concerning the clinical effect of fluoride release, this study, based on the consistency of the results, offers a standard method for measuring rate of fluoride release from varnishes containing 5 percent sodium fluoride.

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CLINICIAN'S CORNER

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A Discussion about Dermal fillers, Botox and Dentistry

ADA Professional Product Review editor Dr. David Sarrett invites three experts to share their insights.

Today, the quest for a youthful appearance is stronger than ever. The American Society of Plastic Surgeons reported[1] that cosmetic minimally invasive procedures increased 3 percent, to more than 13.4 million procedures in 2013. The top two minimally invasive procedures in 2013 were botulinum toxin type A (Botox) (6.3 million injections) and soft tissue fillers (2.2 million procedures), representing increases of 3 and 13 percent, respectively from 2012. Some dental offices provide these services; however, state laws regarding who can administer Botox and dermal fillers vary widely. (See "State Regulations" sidebar below.)

For this article, the PPR editor Dr. David Sarrett (DS) poses questions to three clinicians about the use of these products: Dr. Gary D. Hack (GH) is Associate Professor at the University of Maryland School of Dentistry, Dr. Louis Malcmacher (LM) is president of the American Academy of Facial Esthetics and Dr. Joe Niamtu (JM) is a board-certified oral and maxillofacial surgeon.

DS: The U.S. Food and Drug Administration (FDA) approves injectable dermal fillers (also known as "wrinkle fillers" or "soft tissue fillers") as medical devices. Generally, these products are injected into the skin to help fill facial wrinkles and restore a smoother appearance. How do they work?

GH: As we age, our faces naturally lose subcutaneous fat; therefore the muscles of facial expression are functioning closer to the skin's surface, and so wrinkles become significantly more apparent. By directly injecting a naturally derived material — the most widely known is hyaluronic acid — or synthetic material into the wrinkle or crease, such as the deep lines from the corners of the nose to the corners of the mouth (nasolabial folds), the skin is plumped up to the point where the wrinkle, depression, or fold is significantly reduced. This improvement can last from 3 months to 2 years or longer depending on the type of filler used, how well the patient takes care of his or her skin, and how the patient's face continues to age. Dermal fillers can be used to plump thin lips and can be very helpful in treating patients with early signs of aging. Botulinum toxin injections reduce muscle movements that can result in skin wrinkles, which are known as dynamic wrinkles. Botox injections have nothing to do with the plumping or smoothing effect that dermal fillers have. Many people get both Botox and dermal fillers because the combination can produce a significantly younger-looking face.

JN: Botox, Dysport and Xeomin are all FDA-approved neurotoxins used for cosmetic and therapeutic uses. All of these products are derived from botulinum toxin A, produced by laboratory grown *Clostridia botulinum* bacteria. Neuromodulators block the release of acetylcholine at the myoneural junction. They are injected in facial muscles to decrease their function, paralyzing the muscles for about 90 days. Weakening the brow depressors improves frown lines, weakening the frontalis muscle improves horizontal forehead wrinkles, and injecting the lateral orbicularis oculi muscles improves crow's feet wrinkles.

DS: What made you decide to incorporate Botox into your practice? How has this changed your practice?

LM: Botox is well known for its esthetic uses and with all of the esthetic dentistry we do Botox completes the esthetic result by treating the soft tissue in the maxillofacial areas. Botox has been in the literature as being used for TMJ and orofacial pain for over 20 years but received little attention by clinicians. Like most clinicians, I continued to be frustrated when treating patients with TMJ/orofacial pain. Along with other faculty from the American Academy of Facial Esthetics (AAFE), we have used and taught Botox for dental and facial esthetics. [Anecdotally], patients reported relief from their TMJ, headaches and orofacial pain following receipt of Botox injections. Because 85% of TMJ and orofacial pain comes from muscles and Botox reduces the contraction intensity

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of muscles, the AAFE developed protocols with trigger point therapy and found Botox to be an effective intervention. It completely changed the way we plan treatment for both esthetic and therapeutic therapy because it gives us a minimally invasive therapy option that may be used prior to resorting to irreversible dentistry. This is better for us as clinicians and certainly better for our patients.

JN: I was an early adopter and have been using Botox for over 15 years. I was and continue to [communicate] with the doctors who developed botulinum toxin for cosmetic usage and became familiar with it early on. My practice is limited to cosmetic facial surgery and injectables (facial fillers and neuromodulators), which have become very popular as non-surgical, minimally invasive treatments and are a [necessity for] cosmetic practice. Botox treatment for facial wrinkles is the most popular cosmetic intervention in the world. I am a Diamond Level Botox provider, which places me in the top 3 percent of all providers in the United States. (Note: Allergan, the pharmaceutical specialty manufacturer offers a "Partner Privileges" incentive program to providers. The various levels mentioned throughout this article refer to that program.)

GH: My interest in this topic is from an educational and research point of view. Given that many dentists now use Botox and dermal fillers in their private offices, I want to ensure that the dental profession develops and maintains the highest standards in training dentists to perform these procedures. Moreover, I am investigating the role that neuromodulators like Botox play in reducing head and neck pain. I am particularly interested in what positive impact these medications may have on reducing pain in the newly described anatomic structures, the Sphenomandibularis Muscle and the Myodural Bridge. Lastly, I am developing methods to enhance and extend the cosmetic effects of botulinum toxin injections.

DS: Some reports indicate that dentists are ideal providers of Botox. Why is that?

GH: A 2013 survey[2] found that a majority of dentists support offering botulinum toxins such as Botox to their dental patients. Most of the survey respondents reported that dentists are one of the most suitable professionals to provide these injections, as dentists routinely deal with the head, neck and jaw as much or more than other medical specialties. In addition, there is a good fit between "refresh" Botox injections, which are typically two or three times a year, and routine dental cleanings, whitening or recall appointments. Botox therapy is similar to teeth whitening, as both procedures are temporary and need to be refreshed periodically. Not only are dentists experienced injectors, they are also extremely knowledgeable about the muscles of mastication and facial expression, which are routinely treated with botulinum toxins. A 2013 task force[3] concluded that this is an area that dentists can definitely work in and deliver care safely, given their background and training. It is, however, imperative to insure that dentists providing this therapy have an intimate understanding of the pharmacodynamics of these injectables.

LM: AAFE has trained nearly 10,000 dental professionals in the use of Botox and dermal fillers for both esthetic and therapeutic pain uses since 2008. Dentists now have a proven track record of outstanding patient outcomes using Botox and dermal fillers. The excellent facial esthetic outcomes and resolution of facial pain with Botox and dermal fillers likely from the same kind of precision that dentists are already familiar with. What is even more interesting is that dentists have discovered uses of Botox and dermal fillers that solve frustrating treatment including gummy smiles, deficient interdental papilla (black triangles), lip and smile line discrepancies, as well as addressing bruxism, TMJ and orofacial pain cases. Botox and dermal fillers have completely changed the way we now plan treatment for these patients.

JN: Like any treatment that is popular or remunerative, lots of politics are involved concerning who should or shouldn't provide those treatments. Many states allow general dentists to administer neuromodulators and many do not. In my state of Virginia, general dentists are only allowed to use Botox, Dysport or Xeomin for TMJ or perioral related usage, but not for cosmetic purposes, which is only permitted for oral and maxillofacial surgeons. Competing specialties may say that general dentists should not be providing cosmetic treatments in the upper face that is so removed from dentistry. Proponents make the point that many of the providers who administer neuromodulators have less training in facial anatomy and administer fewer facial injections than do dentists. States have to draw the line somewhere, so they can either limit the usage to certain specialties that are classically trained in cosmetic procedures or broaden the scope. In cases where the states allow any licensed provider (family practice, Ob/Gyn, urology, nurses, etc.) to provide cosmetic Botox injections, dentistry should be included.

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DS: What type of training or certification is necessary?

LM: Education must include the relevant anatomy, pharmacology, physiology, diagnosis, treatment planning, proper injection techniques, possible adverse results, how to avoid and correct complications. Top quality training includes one-on-one mentored live patient treatment. It is very important to learn the use of Botox and dermal fillers from an anatomically based approach because these are pharmaceuticals and like any pharmaceutical, proper dosing based on the relevant anatomy is critical in achieving optimal patient outcomes.

JN: Like any other procedure, you need to be safe and proficient and have the same or similar training as competing specialties. If these procedures are taught in dental school, then it is core training. Otherwise, potential providers need to gain proficiency by post graduate training. We need to properly train anyone in dentistry who is going to do this and set the bar as high as or higher than competing specialties.

GH: A thorough understanding of the anatomy and neurophysiology of the face, and the relevant biochemistry is essential. This training should include instruction in the anatomy of the head and neck, neurophysiology, patient selection, pharmacological effects and contraindications, management of complications, informed consent, and hands-on training in the administration of these agents.

DS: Besides the obvious esthetic purposes, are there clinical and/or therapeutic uses for Botox in dentistry?

GH: The elimination of deficient interdental papillae can be achieved with the proper use of dermal fillers. Some orthodontists[4] are using Botox to lessen muscle hyperactivity, thereby helping to prevent teeth from shifting from their established position after the braces are removed. Periodontists also can benefit from using botulinum toxin. Gingival attachment loss due to excessive muscle pulls on the frenulum, can be reduced with appropriate Botox therapy. Similarly, prosthodontists can use Botox injections to control excessive muscle activity that can cause denture destabilization.

JN: [Although the vast majority of the Botox injections I do address cosmetic concerns], I also treat patients for hypertrophic masseter muscles, patients with TMD and increased bite force by injecting masticatory muscles and migraine headache patients. Botulinum toxin A has also been used to treat apthous ulcers.

LM: The AAFE is involved in a lot of interesting work in this area. One of the most exciting new areas is a study on the use of Botox for sleep-related bruxism and reducing the patient's apnea/hypopnea index in obstructive sleep apnea cases.

DS: How can a dentist determine if Botox is right for his/her practice?

GH: Minimally invasive procedures, such as Botox treatments, can achieve very satisfactory results for patients, and many dentists want to add this effective modality to their armamentarium of cosmetic treatments.

LM: Botox and dermal fillers [can be] right for every dental practice that provides restorative, esthetic, implant, endodontic, periodontic, orthodontic and oral surgery services. If you provide any of these treatments, which every dentist does, then there are Botox and dermal filler uses that are not only available but many times are the preferred treatment of choice because of their ability to provide minimally invasive results faster, easier, and better than conventional methods. Botox and dermal fillers are now able to offer dental patients minimally invasive options like never before.

JN: Providing Botox treatments may sound appealing to some dentists who begin treatment only to see that there is also a significant downside. Cosmetic patients can be quite finicky and may return to the office demanding a refund because their wrinkles did not go away. Others may complain of asymmetries, bruising, headaches and other problems. Although serious complications are rare, it is possible to over-treat areas and end up with droopy brows and eyelids and even eyelids that can be totally closed. I have seen a lot of complications from other providers in all specialties and have experienced them myself. A bad outcome with an elective procedure like Botox could cause a patient to lose confidence in the dentist or even leave the practice. Being a Botox provider sounds great, but it's not a panacea and some dentists find the problems with unreasonable patients and treatment complications to be more of a distraction than an attraction. Whether to offer neuromodulator or injectable filler treatment in a dental practice is solely a personal decision.

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DS: Are there particular patients who should not receive Botox?

GH: Patients who are pregnant, actively nursing, or who have preexisting neuromuscular conditions such as myasthenia gravis, Lou Gehrig's disease (amyotrophic lateral sclerosis), or Lambert-Eaton syndrome should not receive Botox. Likewise, patients with breathing disorders like asthma or emphysema should not receive Botox treatments.

JN: There are warnings with certain medications as well as distant spread of the toxin. Providers should be well versed in the indications and contraindications of any medication they administer.

LM: Patients with allergies to injectables, patients who are fearful of needles and patients with autoimmune disorders should not receive Botox or dermal fillers. I always tell dentists that if they have any questions about a patient, call the patient's physician and ask if the patient is an appropriate candidate for Botox and dermal fillers.

DS: What are the risks and potential side effects?

JN: Headaches, eyelid ptosis, blurry vision from extraocular muscle involvement, lip incompetence, smile irregularities from inadvertent lip elevator injection, swallowing difficulties from neck injection, and animation asymmetry are some of the more common side effects. Although they are not permanent, they can produce very unhappy patients and there is no reversing neurotoxins. You have to wait until they wear off and that can be a long three months.

LM: The primary risks and side effects are related to the actual injection procedure of Botox and dermal fillers such as bruising, edema, bleeding, and infection. The main side effects will come from improper Botox dosing which can include a droopy eyebrow or droopy eyelid. Because Botox only lasts three months, these situations are temporary and usually only last two weeks or so. Too much dermal filler can give the patient an unnatural appearance and also can cause vascular compression or occlusion. Dermal filler complications can be reversed with hyaluronidase, an enzyme that breaks down the dermal filler. All of these side effects are easily avoided with a good understanding of the anatomy and great training of the injection technique.

GH: Patients generally experience minimal discomfort with Botox injections. Sequela that can occur at any site due to percutaneous injection of a neurotoxin can include pain, edema, erythema, ecchymosis and headache. Injection discomfort can be decreased by use of topical anesthetics such as EMLA cream (a topical anesthetic cream of lidocaine and prilocaine) before injection, and the use of a small gauge needle. Ice applied immediately after injection can reduce pain as well as edema and erythema associated with any neurotoxin injection. Ecchymosis can be minimized by avoiding aspirin, aspirin-containing products, and NSAIDs (nonsteroidal anti-inflammatory drugs) for 7-10 days before injection with neurotoxins.

DS: Anything else you'd like to add?

LM: Yes, and this is really important. With 1 out of every 3 patients exhibiting bruxism, we now have available bruxism monitoring that can tell us the patient's bruxism episodes index (BEI), which is the number of times a patient bruxes their teeth per hour of sleep. Using this objective data, clinicians can quantify bruxism to properly dosage Botox to eliminate bruxism. This is a major advancement in bruxism therapy. I don't start a case without measuring a patient's bruxism so that I can ensure a good long-term prognosis for restorative and implant cases.

GH: A precise knowledge and understanding of the functional anatomy of the facial muscles is absolutely necessary to correctly use botulinum toxins in clinical dental practice. In addition to cosmetic treatments, botulinum toxins now plays a very significant role in the management of a wide variety of medical conditions such as headaches, and hyper-salivation. Why shouldn't dental professionals broaden their horizons and use all the tools available to them? Botulinum therapy is a conservative, minimally invasive treatment that can expand cosmetic as well as therapeutic options for the benefit of dental patients. Patients are motivated to accept these procedures and are willing to have them performed by their dentist.

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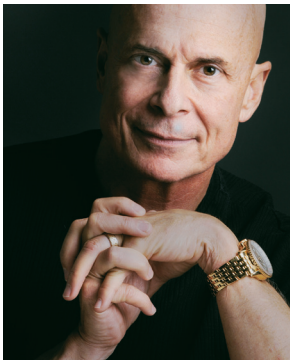
Dr. Gary D. Hack is an Associate Professor at the University of Maryland School of Dentistry (UMSOD) and Director of the Clinical Simulation Facility, and has been a faculty member at UMSOD for the past 30 years. He is the co-discoverer of two anatomical findings: the Sphenomandubularis muscle and the Myodural Bridge, which are now both described in numerous anatomy textbooks. He has been awarded several patents for his inventions related to the treatment of dentinal hypersensitivity, and has recently filed a provisional patent on a new skin treatment to enhance and extend the wrinkle-reducing effect of botulinum toxin treatments. He can be reached at ghack@umaryland.edu.

Dr. Louis Malcmacher maintains a cosmetic and general practice in Bay Village, Ohio, and is president of the American Academy of Facial Esthetics (www.facialesthetics.org). He is an internationally recognized lecturer and author. He has experience in total facial esthetics and has taught many healthcare professionals in the areas of smile design esthetics and facial injectable therapy. He has lectured at major medical and dental meetings throughout the US, Canada, Europe, and the Middle East. Dr. Malcmacher is a master of the Academy of General Dentistry, a fellow of the International Association of Dental Facial Esthetics, a fellow of the World Clinical Laser Institute, and a visiting lecturer at several universities. He can be reached at drlouis@facialesthetics.org.



Dr. Joe Niamtu is board certified oral and maxillofacial surgeon, author and educator. Besides teaching cosmetic surgery seminars for doctors of all specialties at his continuing medical education facility in Richmond, Virginia, he lectures internationally on cosmetic facial surgery, has written six textbooks and has numerous publications on various cosmetic facial topics. A fellow of the American Academy of Cosmetic Surgery and the American Society for Laser Medicine and Surgery, Dr. Niamtu has served on the board of directors of the Cosmetic Surgery Foundation and chaired numerous committees with the American Academy of Cosmetic Surgery, where he currently is chair of the communications committee. His practice is limited to cosmetic facial surgery (www.lovethatface.com). He can be reached at niamtu@niamtu.com

Disclosures. Dr. Malcmacher is president of the American Academy of Facial Esthetics.

Editor's Note: These articles are intended to be an informational resource only. The views expressed are those of the authors and do not necessarily reflect the opinion or policy of the ADA. The article's contents are not a substitute for the dentist's own judgment and dentists are encouraged to consult with other professionals, as and when appropriate, regarding the information herein.

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State Regulations

Can you administer dermal fillers or Botox in your office? It all depends on your state dental practice act and decisions of your dental board. Check with your state dental association for the most current information. Even if these treatments are allowed in your state, your malpractice policy may not cover these procedures, so it would be prudent to check your policy provisions concerning coverage.

FDA Oversight and Recommendations

All FDA-approved injectable dermal fillers are Class III (high-risk) medical devices and manufacturers are required to submit a premarket application that includes clinical data supporting safety and effectiveness, for the FDA's review prior to marketing the dermal filler in the United States. The FDA provides the following recommendations1 for health-care providers, including:

- Do not inject soft tissue fillers if you do not have the appropriate training or experience.
- Make sure that you are familiar with the anatomy at and around the site of injection, keeping in mind that blood vessel anatomy can vary among patients.
- Before injection, thoroughly inform the patient of all risks of the procedure and the specific product you intend to use.
- Note that the approved indications for use of soft tissue fillers vary depending on the product. The FDA may not have reviewed use of soft tissue fillers in some locations in the body.
- During injection, take extra care when injecting soft tissue fillers, such as, injecting the product slowly and applying the least amount of pressure necessary.
- Know the signs and symptoms associated with injection into blood vessels, and have an updated plan detailing how the patient will be treated should this occur. This may include on-site treatment and/or immediately referring the patient to another health care provider for treatment.
- Immediately stop the injection if a patient exhibits any signs or symptoms associated with injection into a blood vessel, such as changes in vision, signs of a stroke, white appearance (or blanching) of the skin, or unusual pain during or shortly after the procedure.
- Tell patients that they should seek immediate medical attention after the procedure if they experience signs and symptoms associated with injection into a blood vessel.
- Educate facility staff and employees on how to quickly assist patients calling with signs and symptoms of filler complications on how to receive appropriate medical care.
- Report to the FDA and the manufacturer if you become aware of any adverse event associated with the use of soft tissue fillers, including unintentional injection of soft tissue filler into a blood vessel.[1]

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