NEVADA STATE BOARD of DENTAL EXAMINERS

Post Meeting Documents

Public Comment & Records

September 23, 2016

Intent to Act Hearing &

Board Meeting

Public Comment made/submitted by:
Tina Tsou, Secretary for the Las Vegas Dental Association

STATEMENT TO NEVADA STATE BOARD OF DENTAL EXAMINERS

(Tina Tsou, September 23, 2016)

Good Morning. My name is Tina Tsou. I am the secretary for the Las Vegas Dental Association.

During the meeting of the Nevada State Board of Dental Examiners' Budget and Finance Committee held on August 18, 2016, multiple violations of the Open Meeting Law occurred. Complaints were then filed against this Board for violations of:

1. NRS 241.035, Subsection 3, and NRS 200.650 whereby a private conversation was recorded by a member of the public body;

2. NRS 241.020, Subsection 2, whereby a member of the public was prohibited from speaking on an agenda item during the meeting as allowed by Nevada Law and as Noticed in the Board's Agenda; and

3. NRS 241.033, Subsection 1a and 1b, whereby the character of licensees was discussed and slandered by a member of the public body without notice to such licensees as required by law.

These Open Meeting Law Complaints are still being reviewed by the Attorney General's Office. However, if the Board's public body is found to have committed a violation, it is possible that the actions taken by Board's Budget and Finance Committee during its meeting on August 18, 2016 may be voided. One of those decisions included a decision to increase the Board's budget for legal expenses in the Fiscal Year 2017.

During the Board's meeting on August 18th, it provided as an attachment to its Agenda wherein it listed "legal expenses" in the amount of $270,000 with the explanation "Includes Hunt, Drizin, and AG." However, the Dental Board paid John Hunt's firm alone $278,000 in 2015. Thus, these figures make no sense and are in direct conflict with the LCB Audit recommendation to reduce the use of outside counsel. Therefore, on behalf of the Las Vegas Dental Association, I am requesting that this Board provide the public with:

1. A breakdown of where the $270,000 in "legal expenses" budgeted for fiscal year 2017 is being allocated; and

2. An explanation as to why the Board has chosen to continue excessive expenditures for outside counsel when the LCB Audit recommended that the use of such counsel should and could be reduced to 20%.

Thank you!

Please respond to email address nevadadentists@gmail.com

Public Comment submitted in Opposition of the Regulation Changes regarding Botulinum Toxins, Dermal Fillers, and Other Facial Injectables

Debra Shaffer

From: Board of Dental Examiners
Sent: Friday, September 23, 2016 11:07 AM
To: Debra Shaffer
Subject: FW: Changes to Chapter 631

From: William Soren Mortensen [mailto:[redacted]
Sent: Thursday, September 22, 2016 5:28 PM
To: Board of Dental Examiners
Subject: Changes to Chapter 631

Dear Ms. Shaffer-Kugel,

As a board-certified dermatologist practicing in Nevada, I oppose the proposed changes to Chapter 631 of Nevada Administrative Code for a number of reasons.

First, the use of injectable products constitutes the practice of medicine, *within the scope of dermatology. According to the AADA Position Statement on Medical Spa Standards of Practice:*

> • *Procedures by any means, methods, devices, or instruments that can alter or cause biologic change or damage the skin and subcutaneous tissue constitute the practice of medicine and surgery. These include but are not limited to the use of: scalpels; all lasers and light sources, microwave energy, electrical impulses, and all other energy emitting devices; thermal destruction; chemical application; particle sanding; and other foreign or natural substances by injection or insertion.*

Second, the training received by dental hygienists is not adequate to perform this procedure. *Properly performing procedures using botulinum toxins or dermal fillers requires specific, long-term training, such as a medical residency in cutaneous dermatologic procedures.*

Third, the proposed rule endangers patient safety. *Our utmost concern is to ensure that these products are safely administered by licensed and qualified physicians or under the direct, on-site supervision of a licensed and qualified physician. The FDA's Consumer Health Information materials suggest that patients should discuss fillers with a doctor who can refer the patient to a specialist in the fields of dermatology or aesthetic plastic surgery.*

For these reasons, I oppose the proposed changes to Chapter 631 that would authorize dental hygienists to administer Botox and fillers.

Please let me know if you have any questions and we thank you in advance for your consideration of this action.

William Soren Mortensen, MD
Owner of Integrated Dermatology of Reno/Aistheta Reno Medical Skin Care Center

Debra Shaffer

From: Board of Dental Examiners
Sent: Friday, September 23, 2016 11:08 AM
To: Debra Shaffer
Subject: FW: Chapter 631 of NAC

From: R Strimling [mailto:[redacted]
Sent: Thursday, September 22, 2016 4:49 PM
To: Board of Dental Examiners
Subject: Chapter 631 of NAC

Dear Ms. Shaffer-Kugel,

As a board-certified dermatologist practicing in Nevada, I oppose the proposed changes to Chapter 631 of Nevada Administrative Code for a number of reasons.

First, the use of injectable products constitutes the practice of medicine, *within the scope of dermatology. According to the AADA Position Statement on Medical Spa Standards of Practice:*

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Second, the training received by dental hygienists is not adequate to perform this procedure. *Properly performing procedures using botulinum toxins or dermal fillers requires specific, long-term training, such as a medical residency in cutaneous dermatologic procedures.*

Third, the proposed rule endangers patient safety. *Our utmost concern is to ensure that these products are safely administered by licensed and qualified physicians or under the direct, on-site supervision of a licensed and qualified physician. The FDA's Consumer Health Information materials suggest that patients should discuss fillers with a doctor who can refer the patient to a specialist in the fields of dermatology or aesthetic plastic surgery.*

For these reasons, I oppose the proposed changes to Chapter 631 that would authorize dental hygienists to administer Botox and fillers.

Furthermore, fillers inadvertantly injected into a facial artery is a known and feared complication that will cause facial necrosis (tissue death) that causes permanent scarring. I have personally seen this in Las Vegas on more than one occasion only from non-physician injectors, who do not have adequate training in not only facial anatomy, but what such complications may look like or how to treat this. Such complication can be treated, but requires significant physician skill and experience and prescribed medications. This is a serious and devastating complication that always requires physician care.
If an injector is incapable of handling potential complications, they should not be allowed to do it.

Sincerely, Robert Strimling, MD

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Debra Shaffer

From: Board of Dental Examiners
Sent: Friday, September 23, 2016 11:08 AM
To: Debra Shaffer
Subject: FW: Dental Examiners Vote

From: Mac Machan [mailto:[redacted]
Sent: Thursday, September 22, 2016 2:10 PM
To: Board of Dental Examiners
Subject: Dental Examiners Vote

Dear Ms. Shaffer-Kugel,

As a board-certified dermatologist practicing in Nevada, I oppose the proposed changes to Chapter 631 of Nevada Administrative Code for a number of reasons.

First, the use of injectable products constitutes the practice of medicine, *within the scope of dermatology. According to the AADA Position Statement on Medical Spa Standards of Practice:*

> • *Procedures by any means, methods, devices, or instruments that can alter or cause biologic change or damage the skin and subcutaneous tissue constitute the practice of medicine and surgery. These include but are not limited to the use of: scalpels; all lasers and light sources, microwave energy, electrical impulses, and all other energy emitting devices; thermal destruction; chemical application; particle sanding; and other foreign or natural substances by injection or insertion.*

Second, the training received by dental hygienists is not adequate to perform this procedure. *Properly performing procedures using botulinum toxins or dermal fillers requires specific, long-term training, such as a medical residency in cutaneous dermatologic procedures.*

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For these reasons, I oppose the proposed changes to Chapter 631 that would authorize dental hygienists to administer Botox and fillers.

Mac Machan

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Mac Machan, MD
[redacted]

September 21, 2016

Ms. Debra Shaffer-Kugel
Executive Director
Nevada State Board of Dental Examiners
6010 S. Rainbow Blvd., Ste. A-1
Las Vegas, NV 89118

Re: Opposition to LCB File No: RO86-16

Dear Ms. Shaffer-Kugel:

On behalf of the over 13,500 U.S. members of the American Academy of Dermatology Association ("Academy"), I am writing to oppose the proposed regulations of the Nevada State Board of Dental Examiners ("Board"), which would authorize dental hygienists to administer botulinum toxin, dermal fillers and other facial injectables. For the reasons stated below, we believe this proposal will jeopardize patients and we urge the Board reject the proposed language.

Use of Injectable Products Constitutes the Practice of Medicine

The proposed rules would allow dental hygienists to administer cosmetic products, including botulinum toxins (Botox) and dermal fillers. The Academy strongly believes the use of injectable products constitutes the practice of medicine, within the scope of dermatology. According to the *AADA Position Statement on Medical Spa Standards of Practice:*

> Procedures by any means, methods, devices, or instruments that can alter or cause biologic change or damage the skin and subcutaneous tissue constitute the practice of medicine and surgery. These include but are not limited to the use of: scalpels; all lasers and light sources, microwave energy, electrical impulses, and all other energy emitting devices; thermal destruction; chemical application; particle sanding; and other foreign or natural substances by injection or insertion.
>
> Any procedure that constitutes the practice of medicine, including but not limited to any procedure using a Food and Drug Administration (FDA)-regulated device that can alter or cause biologic change or damage, should be performed only by an appropriately trained physician or appropriately-trained non-physician personnel under the direct, onsite supervision of an appropriately-trained physician in accordance with applicable local, state, and/or federal laws and regulations.

American Academy of Dermatology Association
Excellence in Dermatology™

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With the growing public demand for cosmetic services, such as facial fillers and botulinum toxin, establishing scope of practice standards concerning who can safely administer these products is critically important. In addition to its cosmetic purpose, such injectables are a valuable treatment for scarring from injury, surgery and medical conditions, such as cystic acne. Other applications include correcting facial asymmetries resulting from congenital, accidental, or medical conditions, including HIV infection. Our utmost concern is to ensure that these products are safely administered by licensed and qualified physicians or under the direct, on-site supervision of a licensed and qualified physician.

Short-Term Training is Not Adequate to Protect Patient Safety

Properly performing procedures using botulinum toxins or dermal fillers requires specific, long-term training, such as a medical residency in cutaneous dermatologic procedures. Dental hygienists' education does not include the appropriate training to use botulinum toxins and dermal fillers. Additionally, a short term training program offered by manufacturers of these products do not adequately protect patient safety.

According to the American Dental Association, dental hygienists receive anywhere from two to four years of education, resulting in an associate's degree, baccalaureate, or master's degrees, in some cases. The focus of their education is on oral health, rather than the skin and facial tissue. Dental hygienists are not required to demonstrate competency in procedures involving skin and soft tissue augmentation involving products that can alter or damage such living tissue. Dental hygiene education programs offer clinical education in the form of supervised patient care experiences, courses in the basic sciences and dental hygiene, radiology and dental materials. Licensure generally requires a passing score on comprehensive written examinations that test clinical dental hygiene skills [1].

In comparison, following eight years of college and medical school and a one-year internship, dermatologists complete a dermatology residency program. Dermatologists receive in-depth education in anatomy and surgical and cosmetic procedures involving the skin and adjacent structures, which prepares dermatologists to safely and effectively perform cosmetic medical procedures using injectables and botulinum toxins. Included in this training is

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[1] Dental Hygienist Education and Training Requirements. Retrieved from http://www.ada.org/en/education-careers/careers-in-dentistry/dental-team-careers/dental-hygienist/education-training-requirements-dental-hygienist

proper technique, producing excellent outcomes and the management of adverse events.

In a 2007 paper, Drs. Hayes Gladstone and Joel Cohen note, "As with other cutaneous procedures, it is necessary to receive adequate training before using soft-tissue augmentation agents. In our opinion, physician injectors should first be made to demonstrate a detailed knowledge of anatomy and possible adverse events (such as sensitivity, infection and necrosis) through passing an American Board of Medical Specialties examination in one of the CORE aesthetic specialties after residency training in one of these disciplines." (See Exhibit A attached).

The Proposed Rule Endangers Patient Safety

As dermatologists, our utmost concerns are quality patient care and patient safety. Quality patient care includes evaluating a patient's needs and current condition, selecting an appropriate course of treatment in accordance with their medical history, and providing adequate information and follow-up care.

As stated above, short-term, basic training on how to use a product is in no way equivalent to a physician's training and understanding of a medical procedure and its implications for each patient. Ultimately, patient safety and quality of care are seriously compromised.

An analysis by the FDA's General and Plastic Surgery Devices Panel of six years of adverse event reports associated with the use of injectable dermal fillers concluded the following:

- There are a number of adverse events that are serious and unexpected such as facial, lip, and eye palsy, disfigurement, retina vascular occlusion, blindness, as well as rare but life-threatening events such as severe allergic reactions and anaphylactic shock.
- Some of the common adverse events that are expected to occur shortly after injection and resolve quickly have delayed onset and/or remain for a long period of time and turn into more serious problems.
- A number of the adverse events reported to the FDA and the device manufacturers imply that the administration of injectables were performed by untrained personnel or in settings other than health clinics or doctors' offices[2].

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[2] FDA General and Plastic Surgery Devices Panel. Dermal Filler Devices. November 11, 2008. Retrieved from **http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4391b1-01%20-%20FDA%20Executive%20Summary%20Dermal%20Fillers.pdf**

Further, a survey conducted by the Physicians Coalition for Injectable Safety found that 84 percent of physician respondents had seen at least one patient with complications from cosmetic injectables and 38 percent had seen complications arising from cosmetic injections administered by an unqualified or untrained provider.[3] Injectable fillers that are approved for injection in the dermis or mid-to-deep dermis require extensive knowledge of facial anatomy to ensure proper placement of the injections. Understanding which injectable product is appropriate for each anatomic site and its particular limitations is fundamental in avoiding adverse effects. Numerous studies have cautioned physicians on the use of dermal fillers, noting, "a physician's selection of facial filler(s) should be based on a solid understanding of the various filler products, appropriate patient selection, and the physician's proficiency in injection techniques." (See Exhibit B attached). Moreover, in discussing these devices, the FDA's Consumer Health Information materials suggest that patients should discuss fillers with a doctor who can refer the patient to a specialist in the fields of dermatology or aesthetic plastic surgery [4].

In order to protect the citizens of Nevada from adverse events and ensure quality patient care, the Academy urges the Board to reject the proposed amendment to chapter 631 of the Nevada Administrative Code. Two or four-year dental hygienist program does not provide a comprehensive education and training that is required to identify and respond to potential complications resulting from the administration of botulinum toxin, dermal fillers and other facial injectables. We appreciate the opportunity to provide written comments on this issue. For further information, please contact Lisa Albany, associate director, state policy, at **lalbany@aad.org** (202) 842-3555.

Sincerely,

Abel Torres M.D., FAAD

Abel Torres, MD, JD, FAAD
President
American Academy of Dermatology Association

cc: Members of the Nevada State Board of Dental Examiners

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[3] New Data Finds Greater Measures Needed For Consumer Safety And Education On Injectable Therapies. August 15 2007. Retrieved from **http://www.aafprs.org/media/press_release/150807.htm**

[4] Filling in Wrinkles Safely. Retrieved from **http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049349.htm**

Seminars in Cutaneous Medicine and Surgery

Adverse Effects When Injecting Facial Fillers

Hayes B. Gladstone, MD,* and Joel L. Cohen, MD†

Facial soft-tissue augmentation has become ubiquitous in cosmetic dermatology. In the appropriate patient and with appropriate training, fillers can temporarily eliminate rhytides, creases, and defects, thereby producing a rejuvenated appearance. Yet, even in the most experienced injectors, there can be complications. These adverse effects can be divided into early and late and range from bruising to necrosis. Understanding the anatomy, limitations of the filler and proper technique can reduce the risk of adverse effects. When a complication occurs, the practitioner should understand how to manage them from observation to surgical intervention.
Semin Cutan Med Surg 26:34-39 © 2007 Elsevier Inc. All rights reserved.

KEYWORDS collagen, calcium hydroxylapatite, 1-polylactic acid, foreign body granuloma

With the recognition of the importance of volume in facial rejuvenation, injectable fillers have become a very important option in the dermatologic surgeon's armentarium.[1] In experienced hands, fillers are safe and effective.[2] Yet, fillers are implants and essentially foreign bodies that may remain in some form for up to several years. Fillers need to be injected at a certain level of the skin. However, this is a blind procedure, as the physician is unable to see exactly where the filler is placed. With these characteristics, injectable fillers (which often are viewed as an entry procedure in one's practice) have the potential for a myriad of complications. Adverse effects are not uncommon. In one study of 286 patients injected with hyaluronic acid gel, there was a complication rate of approximately 5%.[3]

Anatomy and High-Risk Regions

Although injectable fillers theoretically can be used in any anatomic region, they are most commonly used for filling facial lines, depressions, and augmenting aging cosmetic units. The skin thickness also varies dramatically depending on the cosmetic subunit. Although the rich network of blood vessels may be a very favorable feature for other procedures such as rhytidectomies, it can increase the chance of bruising and hematomas when performing injections. More serious complications include emboli and resulting necrosis. There have been several reported cases of necrosis when injecting in the glabelar region.[4-7] Although the glabela must be respected as a high-risk area when injecting, necrosis also may occur in common injection sites. Cases of necrosis after performing hyaluronic acid injections in the nasolabial folds were recently presented.[8]

The facial cosmetic units also are characterized by the differences in skin thickness. There are wide variations of skin thickness and texture within the cosmetic units. There are 3 central facial cosmetic units in the "I" zone that are particularly susceptible to complications. A tell-tale sign of aging is in the periorbital region where there is a loss of volume and subsequent hallowing of the eyes. This depletion of soft tissue leads to the "double bubble"—the loss of a smooth continuous contour from the lower eyelid to cheek. The eyelids and periorbita have a very thin dermis, and injections into this layer will inevitably lead to lumpiness and potential granulomas whether the practitioner is injecting hyaluronic acid, calcium hydroxylapatite (Radiesse, Bioform Medical, San Mateo, CA) or polyl-lactic acid (Sculptra, Dermik Esthetics, Berwyn, PA).

Because of the variability of skin thickness in different anatomic facial regions, soft-tissue filler placement in the periorbital skin in not the only complicated site in the treatment of aging facial skin. Augmentation of the nose can also be quite challenging and lead to a higher rate of complications. The skin of the nasal dorsum is usually very thin in contrast to the sebaceous quality if the tip and supratip subunits. Injecting in the nasal dorsum for either augmentation or making existing humps less noticeable requires injections deeper than the conventional technique. Injections into the

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doi:10.1016/j.sder.2006.12.008

dermis in this cosmetic subunit will increase the risk of lumpiness and nodules. Similarly, the lip is another anatomic area which can have poor outcomes. The lip's thin mucosa is very unforgiving if the filler is too thick or the injection technique is not meticulous. Although the marionette lines do not share the same risks as these other sites, because they are adjacent to the commissure, the lip can become distorted. Augmenting the chin with calcium hyrdoxylapatite or fat could potentially lead to vascular compromise if too much of the product is injected at one time compressing the blood vessels aside from enlarging the chin to an abnormal degree.

Understanding the Fillers

Despite media hype, there is not one filler that satisfies all sites or a perfect injectable. Rather, each filler has a specific niche. It is important to understand where fillers should and should not be used—or at least with extreme caution–to decrease the risk of adverse events. Understanding the depth in which to inject each implant is crucial. If a filler such as calcium hydroxylapatite is injected into the papillary dermis, it will increase the risk of superficial papules. Fillers such as human collagen and the medium life hyaluronic acids such as Restylane (Medicis, Inc, Scottsdale, AZ) and Juvederm Ultra (24HV; Allergan, Inc, Irvine, CA) if injected with the proper technique are at lower risk, though in some regions may not provide a satisfactory result because of their lack of volume. While more viscous fillers such as calcium hydroxylapatite, polyl-lactic acid and fat can be very versatile, they will have a higher complication rate if injected into certain regions such as the lip.

Generally, "lighter" products such as the human collagens and the medium hyaluronic acids such as Restylane and Juvederm Ultra are very appropriate for the lips, marionette lines, nasolabial folds, fine rhytides, glabelar folds, the periorbita and for filling acne scars. The "heavier" injectables such as calcium hydroxylapatite, cross linked hyaluronic acid (Perlane, Medicis, Scottsdale, AZ), and fat are excellent for the nsaolabial folds, marionette lines, prejowl sulcus cheeks, the temporal fossa and scars. They need to be used judiciously in the periobita to avoid lumpiness, but can be very effectively with the right volumes and depth of placement. These "heavier" products are usually avoided in the glabelar folds. They can be excellent for augmenting specific structures such as the nose and chin, though fat transplants may lead to lumpiness in these areas. Essentially, the heavier implants are best for pan-facial rejuvenation.

Technique Considerations

As with other cutaneous procedures, it is necessary to receive adequate training before using soft-tissue augmentation agents. In our opinion, physician injectors should first be made to demonstrate a detailed knowledge of anatomy and possible adverse events (such as sensitivity, infection and necrosis) through passing an American Board of Medical Specialties examination in one of the CORE esthetic specialties after residency training in one of these disciplines.

Training for implant injections can be more complex given that, if there is an adverse effect, in many instances, it (or part) will remain for several months. Minor interventions may not work or be feasible, complications can be devastating to the patient. Moreover, although a practitioner may be very competent in injecting a certain cosmetic unit, if he or she chooses to offer other more complex sites such as the periorbital, then training for this site should be undertaken. Aside from being intimately aware of the particular product's limitations (such as reading articles in peer reviewed journals), observation and practical experience are the keys to excellence. Initially observing an experienced injector in interactive sessions, and then practicing on a cadaver head will lay a foundation.

For the first several injections, it is wise to have your injections proctored by an experienced injector. Although this scrutiny may cause anxiety in some novices, the advantage is the correction of technique so as not to develop bad habits that would lead to complications. When finally injecting on one's own, the initial patients should be those with which the practitioner already has a bond. Some physicians will decrease their fee for the first several patients as well as place on the consent that the patient understands that the practitioner has limited experience with this procedure. While these last two tactics will not necessarily decrease the legal risk of a complication, the patient may be more understanding. should one occur. It is important to maintain one's skills. For less-common areas such as the chin and nose, the practitioner may want to inject staff or offer discounts for established patient who has the appropriate condition.

Technically, it is most important what depth to place a specific implant. In brief, human collagen should be placed in the mid-dermis. Medium length hyaluronic acid products such as Juvederm and Restylane should be placed in the deep dermis.[9] Calcium hydroxylapatite is injected at the dermal-subcutaneous border.[10,11] Polyl-lactic acid and fat are injected into the subcutis.[12] Injecting a filler too superficially will lead to lumpiness, nodules and an unsatisfactory result. In many instances, it is impossible to distinguish the mid dermis and the deep dermis. Generally, it is better to err on placing the filler deeper. The downside of this deeper placement is that the augmentation effect may not be as apparent, though it may last longer given less mobility.

In terms of specific injection technique such as multiple serial puncture versus. linear threading, there have been no studies to suggest that one type of placement is superior. Multiple puncture is somewhat easier to control placement, though it can lead to unevenness unless there is overlap. When using this technique, the practitioner must also remember to reduce pressure on the plunger as the needle is exiting to avoid superficial deposition of filler The linear threading technique tends to require more experience, and can result in too much product in one area. Though most practitioners ultimately prefer this linear threading technique, most injectors typically utilize some combination of both methods.

Patient Assessment and Education

As with any other aspect of medicine, and in particular pertaining to cosmetic surgery, a strong patient-physician bond is important when administering fillers. In the best situation, the patient will have had other procedures performed at the office and a trust established with the physician. In the consultation, the patient's esthetic concerns need to be addressed in a detailed manner, since a filler may not be the solution to her/his concerns and another procedure may be a better option. The patient's expectations need to be realistic in terms of the specific effect of the filler and the overall facial effect. A detailed medical history should be taken. Patients with active infections should delay cosmetic procedures. Aspirin and nonsteroidals or coumadin need to be stopped before the procedure; if this is not possible, the patient should be made aware of the increased risk of bleeding and this should be written into the consent. While immunosuppression is not a contraindication for fillers, the higher risk of infection should be discussed. In those patients with immunologic diseases such as lupus or scleroderma, it is best to discuss with the patient's medical dermatologist or rheumatologist before proceeding.

The approximate duration of the fillers need to be discussed. The patient should be given a choice of different fillers, the benefits and risks of each, and should participate in the decision-making process. The use of anesthesia should be discussed, as well as the amount of discomfort the patient would be expected to have both during and after the procedure. For instance, the injection of calcium hydroxylapatite may cause a transient "achiness." Detailed postoperative care and potential minor adverse effects need to be reviewed. Of course, the risk of major and delayed adverse effects need to be discussed in a manner which educates the patient rather than creating additional anxiety. All potential adverse effects should be listed in the informed consent and reviewed with the patient before injection.

Complications

Early

Minor

Despite the best intentions and technique, there can still be minor complications such as bruising, swelling, tenderness, and skin discoloration. Bruising can be immediate or within a few hours. Occasionally, it may reveal itself the next morning. Ecchymosis is almost invariably minor, and generally limited to around the injection site. If a patient is on some form of blood thinning medications or some vitamin supplements (including vitamin E, ginseng, garlic, ginger, gingko, etc.), bruising can be quite profound. In some instances, ecchymosis covers the majority of the facial anatomy below the injection site and may require several weeks to fully resolve.

Anecdotally, homeopathic medications such as echinacea have been reported to reduce bruising. However, there have been no studies showing a difference in postinjection bruising in those who taking this medication. Ultimately, excellent technique will decrease the risk of bruising. Interestingly, the fanning technique which is favored by many practitioners has been reported to increase the likelihood of bleeding. Because injectables are a blind technique, even experienced individuals may pierce a small vessel and cause ecchymosis.

Transient swelling may occur simply because of the irritation of placing a foreign implant within the skin or because of an indelicate technique. This swelling may last from 24 to 72 hours. Similarly, temporary tenderness may occur because of the needle trauma or because of the physical imposition and subsequent volume displacement on the skin from an implant. Generally, both swelling and tenderness will more pronounced in the semi permanent fillers compared with the shorter-acting injectables. This postinjection "ache" most likely occurs due to volume displacement of the stretching of cutaneous nerves. Skin discoloration, particularly erythema along the injection site has been documented both in the hyaluronic acids and in calcium hydroxylapatite.[3,13] Although it is unlikely to be a hypersensitivity reaction, there may be mast cell release contributing to this discoloration. Fortunately, in the vast majority of patients, the erythema will resolve in 2 to 3 days.

Major

Because facial augmentation with injectables is a cosmetic procedure whose purpose is to improve appearance, any sequelae that actually worsens the patient's cosmesis is a significant complication. Many patients have asymmetry at baseline. While this quality can be corrected with fillers, it should be discussed during the consultation, and the patient should be aware that he/she may still have some asymmetry after the procedure. We recommend photographs be taken for documentation both before and after the procedure.

Gross unevenness after soft-tissue augmentation is certainly not acceptable. Lumpiness may resolve with massage. However with semipermanent fillers injected too superficially, the lumpiness may remain for several months (Fig. 1).

Figure 1 Lumpiness and deposits in the infraorbital region after a Restylane injection that was too superficial. (Color version of figure is available online.)

Although physicians strive to achieve a full correction, to overcorrect with a long-lasting filler is problematic. This result could remain for several months and be very difficult to disguise.

Hematoma is an uncommon occurrence, but it can result from the inadvertent laceration of small facial blood vessels. Because of the supratrochlear artery and anastomosing blood vessels in the glabelar region, there may be a higher risk for hematoma when injecting frown lines. Immediate hypersensitivity is rare, and has been associated with bovine collagen. Anaphylaxis could occur secondary to preservatives.[14] Although infection is rare, the trauma of injection could lead to an HSV infection and potential long term pigmentary changes or small punctuate scars (Fig. 2).

Delayed Complications

Minor

Occasionally, delayed small bumps may occur. This complication can occur with any filler, but is more likely with implants that need to be injected at least in the mid dermis or deeper such as the hyaluronic acid gels, calcium hydroxylapatite or polyl-lactic acid. Their etiology is unclear. Most commonly, it again may be due to a portion of an injection which was too superficial. These papules may have a bluish-tint known from the Tyndall effect of placing this foreign gel in a superficial plane (Fig. 3).[15] Although delayed hypersensitivity reactions can occur in implants with animal particles, it is exceedingly rare in those implants with nonanimal derivatives to cause hypersensitivity reactions. Initially, hyaluronic acid implants performed outside the United States seemed to have higher immunogencity risks, but this was most likely due to higher protein contents as well as impurities, and currently purification techniques have virtually eliminated this complication.

Major

True granulomas are rare. They occur in approximately 0.1% of the patient population.[16] The majority will result from injections of semipermanent and permanent fillers. Granulomas, which are the body's response to a foreign material, will present most commonly as dermal nodules with mild erythema. They may appear singly or in small clusters. They may or may not be tender. Though they usually will appear within the first 6 months after injection, delayed granulomas fourteen months after injecting polymethylmethacrylate microspheres have been reported.[17] In most patients, they are fairly obvious and create significant anxiety.

Infection can be an early complication and is most likely due to common skin pathogens such as staphylococcus aureus. However, when infection arises later, they may be due to other less common bacteria. In contrast to granulomas, they will appears as fluctuant nodules, with more surrounding erythema and warmth and tenderness. The patient may also have a fever. Similar to other cosmetic procedures such as liposuction, mycobacteria may be the causative agent in delayed filler infections. Sterile abscesses may also occur without evidence of bacteria (Fig. 4).

Migration with permanent implants such as expanded polytetrafluorethylene have been well documented.[18] It is

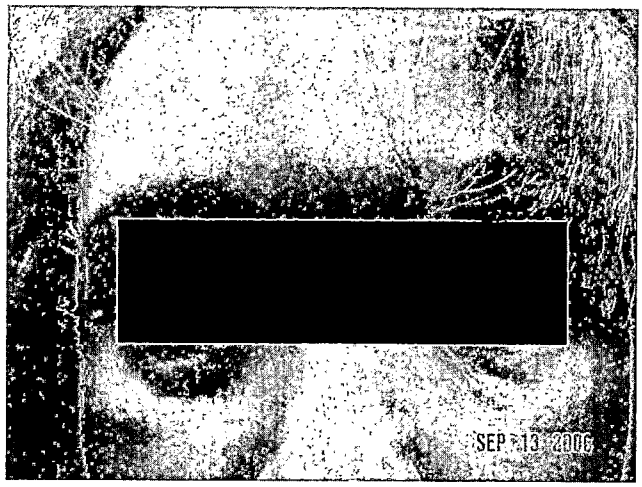

Figure 3 The Tyndall effect—a bluish hue from a Restylane injection into the papillary dermis. (Color version of figure is available online.)

Figure 2 Herpes simplex virus blisters and ulceration after soft-tissue augmentation of the lips. (Color version of figure is available online.)

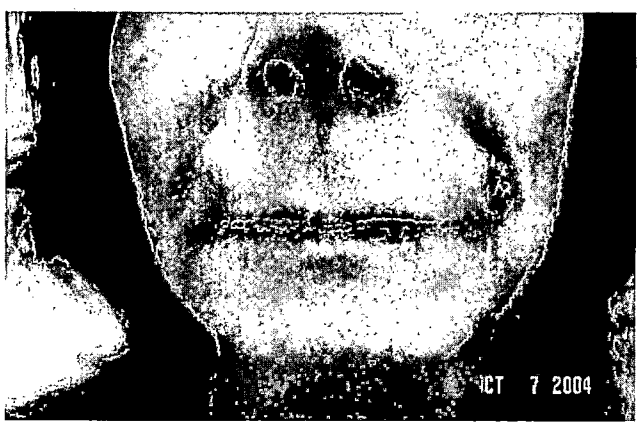

Figure 4 Sterile abscesses after a Restylane injection. Three cultures were negative. (Color version of figure is available online.)

much less frequent with temporary fillers which are reabsorbed. There is a potential higher risk with semipermanent and permanent implants such as calcium hydroxylapatite and silicone. Yet, in 3 studies with calcium hydroxylapaptite there have not been any cases of migration.[13,19,20] But some reports discuss migration of calcium hyroxylapatite superficially in the lip leading to the appearance of "popcorn lip." With the microdroplet technique for silicone placement, migration is much less likely. Migration can occur up to several years after the injection. An infection or delayed granulomatous reaction may trigger migration. In some patients who have dramatic changes in laxity and elastosis due to normal facial aging, it may appear that the implant has migrated when in fact the facial anatomy has changed somewhat over time.

Management of Complications

Avoidance

The best way to manage complications is to avoid them. Understanding which filler is appropriate for each anatomic site and its particular limitations is fundamental in avoiding adverse effects. For example, while calcium hydroxylapatite is a very versatile implant, its use for lip augmentation carries a risk of lumpiness and nodularity. While this effect will slowly diminish, management can be challenging since a corticosteroid injection into the lip to decrease the nodule also carries a risk of atrophy. This can lead to a "snowballing" effect of complications which can lead to a permanent lip deformity and a very unhappy patient.

Producing consistently excellent results and avoiding poor outcomes and complications begins before the actual injection. Marking patients before injection is a good habit which will ensure reproducibility. Expressions can change or the lighting angle may alter the appearance of the rhytide or defect.

Anesthesia, including nerve blocks, can potentially distort the site of injection due to the volume. While nerve blocks are certainly acceptable before filler injection, this type of anesthetic does not constrict local blood vessels. When injecting the nasolabial folds, a direct infiltration of 1 mL of 1% lidocaine with 1/100,000 epineprhine along the folds will constrict the blood vessels and decrease the risk of piercing a blood vessel and causing ecchymosis or inadvertent injection of the substance into the vessel. While there is initial distortion of the site, this dissipates in 15 minutes while the practitioner is treating other patients. In addition, because a smaller anatomic region will be "frozen," the patient will generally be happier with the overall treatment.

Evaluation

When a patient presents with an undesired effect, they should be seen promptly. It is important to explain that an adverse effect has occurred and to have a plan of action. The patient needs to be informed that the treatment plan may require multiple sessions. In addition, a discussion regarding the potential for any permanent blemishes from these interventions (such as a scar) should be had. Initially, the physician should determine whether this adverse effect will potentially resolve on its own and whether only reassurance is only necessary or whether it requires intervention. Yet, even adverse effects that diminish over a relatively short period of time may be unacceptable to the patient. For instance, superficial beading will generally resolve over the course of a month, but it can be very difficult to camouflage with cover-up. If there is an irregularity due to a semipermanent or permanent filler, then it will require some form of intervention. Though there is a risk of not resolving the problem and a repeat treatment may be necessary, the more conservative/less invasive treatment is generally preferred.

Treatment

In some patients with minor complications such as bruising, observation and reassurance are appropriate. If action needs to be taken for a complication, this should be promptly performed. For lumpiness, mild asymmetry or mild overcorrection, gentle massage may be effective. In cases of significant asymmetry, a simple additional injection should achieve symmetry.

In the past for beading and small papules, spot dermabrasion or laser resurfacing has been advocated.[21] While this intervention can be an appropriate measure, it would better to first initially attempt aspiration of the product—as long as it is not a permanent implant. Injecting the site with saline may increase the efficacy of aspiration. For granulomas secondary to superficial placement of hyaluronic acid, the injection of hyluronidase should remove the offending agent with a minimum of trauma.[22] Intralesional steroid injections also have been widely used for foreign body granulomas caused by implants.[16] Although this treatment is effective, it should be used judiciously and in weak concentrations (no greater than 10 mg/mL) because it can result in adjacent skin atrophy and erythema. It may require multiple injections over time which can not only increase patient anxiety, but also the risk of an adverse effect. Some unapproved long-lasting implants have seen higher rates of infection which can be difficult to manage. In one case study, polyacrylamide gel resulted in a delayed infection in which antibiotics were ineffective, though intralesional steroids resolved the lesions.[23]

In severe incidences of foreign body reaction, conservative measures are not effective, and surgery is the best option despite the subsequent scars.[24,25] In the tear trough, slit excisions and teasing out the granulomas should be effective. However, in larger areas a formal ellipse may be necessary and/or a soft tissue flap may be necessary. While the recovery time can be extensive, if the rules of facial reconstruction are followed, the scars can be camouflaged.

Although large delayed granulomas are the most challenging of the long-term adverse affects to treat, the most feared early complication is necrosis due to inadvertent injection into a vessel and embolization (Fig. 5). Although necrosis may result from this complication, it is more likely—given the robust facial vasculature—that compression of several small blood vessels is the culprit. If blanching or duskiness does occur, then massage, nitropaste and possibly heparin

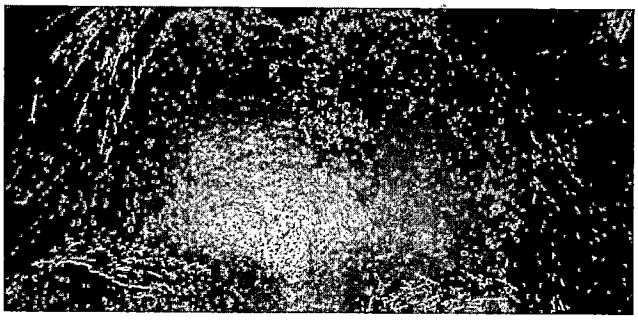

Figure 5 Partial forehead necrosis following a glabelar injection of hyaluronic acid gel. (Color version of figure is available online.)

injections may restore the local blood supply. Obviously, avoidance of overinjection would lessen the risk of this dreaded complication.

Summary

Volume restoration is an important aspect in facial rejuvenation. When used in indicated patients and with proper technique, implants can dramatically reverse facial aging. However, it is crucial to understand the limitations of each implant and the proper depth in which to inject them. Common complications include bruising, asymmetry and superficial papules. Delayed granulomas are more likely to occur in semipermanent fillers. Observation, additional filler, steroid injections, and surgical excision are customary methods to correct these adverse affects.

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Facial Dermal Fillers: Selection of Appropriate Products and Techniques

Steven H. Dayan, MD; and Benjamin A. Bassichis, MD

Over the last decade, there has been a shift in the way aesthetic surgeons approach facial rejuvenation. With recognition of the value of volume enhancement in achieving a more youthful appearance, as well as the ease of office procedures offering minimal downtime and predictable results, there has been a concomitant explosion in the soft tissue filler market. Given the vast array of filler products currently available, the decision of which facial filler to use in specific situations can be complicated and confusing. A physician's selection of facial filler(s) should be based on a solid understanding of the various filler products, appropriate patient selection, and the physician's proficiency in injection techniques. We present a review of the most widely used fillers, offering guidance on patient selection and effective injection techniques. (*Aesthetic Surg J 2008;28:335–347.*)

With the millennium came a conceptual shift in the approach to facial rejuvenation, from subtractive surgical methods toward additive volume restoration techniques. Understanding the importance of volume loss to aging features has recalibrated the manner in which the maturing face is treated. While surgical intervention remains vital, replenishing volume to attain a more youthful appearance is at the forefront of aesthetic science. Facial fillers, injectable therapeutic materials for soft tissue augmentation, are an ideal way of restoring facial volume and contour. Facial fillers appeal to a broad spectrum of patients, from those seeking minimal cosmetic enhancement to those seeking an effective complement to facial surgery. As such, facial filler injections are some of the most commonly performed cosmetic procedures.[1] With injectable product features including convenient office treatments; quick, reliable results; and minimal downtime, there has been an explosion in the number of commercially available fillers. While many filler materials have shown promise, others have been disregarded or even criminalized. Considering the numerous filler types and brands currently available in the United States and worldwide, deciding which facial filler to use, when to use it and why, can be a complex process. With a solid understanding of filler products, appropriate filler selection, prudent patient selection, and proper injection techniques, the aesthetic surgeon can expect satisfied patients with effective volume correction. Here, we will review the biology of the leading filler compounds and the components of successful filler treatments, including product selection and injection techniques.

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FACIAL FILLERS AND THE AGING PROCESS

During the aging process, the face loses fat and volume while the skin loses collagen and elasticity.[2] Accentuated by full cheeks and curves in youth, the aging face becomes framed by bony contours wrapped with thin skin, lending a deflated and fallen appearance (Figure 1).

Understanding the aging process is crucial to attaining optimal results with facial rejuvenation procedures. For those with thin skin and volume loss, tightly retracting the facial skin through surgical intervention may not be the best treatment.

Performance of an inappropriate surgical procedure may produce an artificial-looking, "wind tunnel" appearance. Replenishing facial volume or augmenting a surgical procedure with filler technologies would be a better approach in these patients. The placement of injectable fillers in the treatment of lines, wrinkles, and areas of volume depletion can achieve excellent aesthetic results with limited or no downtime and without the potential morbidity of surgery.

Selecting the Most Appropriate Filler

A wide variety of filler materials and brands are currently available, with a seemingly endless flow of new and emerging products (Table 1). But many of the "latest and greatest" products do not prove to be safe or effective, and they eventually fall by the wayside. Sometimes it is only after the products have been in the marketplace for months to years, and after many patients have been treated, that physicians come to the realization that the products have failed to deliver the anticipated results. Understanding the biology of current filler compounds that have been approved by the U.S. Food and Drug Administration (FDA) facilitates the best treatment selection. We include silicone in our discussion, although its

Figure 1. The aging face has lost volume and skin elasticity.

cosmetic use is off-label, because of its history as a filling agent and the continued interest of some physicians in its potential as an effective treatment.

PRODUCTS

Hyaluronic Acids

Of the available hyaluronic acid (HA) fillers, Restylane (Medicis, Scottsdale, AZ) was the first to receive approval by the FDA (in December 2003) for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.[3] In a study by Narins et al,[4] Restylane was found to be superior to Zyplast (Inamed Aesthetics, Santa Barbara, CA) in 60% of patients 6 months posttreatment with a smaller volume of Restylane required to reach full correction as compared with Zyplast. Other HA fillers currently approved by the FDA for cosmetic use include Captique (Allergan Inc, Irvine, CA), Juvederm (Allergan), and the animal-derived Hylaform (Allergan). Restylane has an HA concentration of 20 mg/mL with a particle size of 400 μm,[3] making it a more viscous product than the FDA-approved animal-derived HA with 6 mg/mL HA. It had originally been postulated that Restylane's physical volume was the sole cause for the volumetric improvement. However, a recent study revealed that Restylane operates as an effective dermal filler by physically stretching dermal fibroblasts, which induces de novo collagen formation while inhibiting the breakdown of existing collagen.[5] These data contribute to anecdotal reports of a cumulative Restylane effect in which subsequent treatments require less material than initial treatments to achieve the desired soft tissue correction.

Juvederm, a similar non–animal-based HA with a slightly higher concentration of HA (24 mg/mL) and more extensive cross-linking, was approved by the FDA in June 2006. The additional cross-linking is thought to increase longevity, and recent reports have shown this product to persist up to 12 months.[6] Whereas the HA particles in Restylane are uniformly shaped, Juvederm particles are randomly shaped. This is postulated to be responsible for Juvederm's smooth gel-like consistency. Some physicians describe this product as flowing from the syringe with more ease and fluidity and causing less bruising. Much like the rivalry between Coke and Pepsi, there are those who prefer the alternate brand. Additionally, Juvederm was approved by the FDA in thinner (Ultra) and thicker (Ultra Plus) versions for greater injection subtlety and variety. With greater particle size and a slightly higher percentage of cross-linking than Ultra, Juvederm Ultra Plus is designated for deeper, volumizing injections.

Perlane (QMed, Eatontown, NJ), a thicker, larger-particle version of Restylane, was approved by the FDA in January 2007. Perlane differs from Restylane only in its particle size (940 vs 1090 μm), although the concentration of HA remains constant in both products (20 mg/mL).[7] As larger particle size suspensions, Perlane and Juvederm Ultra Plus have less total surface area subject to attack by the body, and are theoretically more resistant to degradation. Because these products are thicker, Juvederm Ultra Plus and Perlane are designed to be injected deeper into the dermis or subdermis for volume correction and contouring capabilities.

The hydrophilic nature of HA allows it to maintain its shape using the body's own moisture. One gram of HA can bind up to 6 L of water.[8] As a component of the extracellular matrix, intrinsic HA functions include space filling, lubrication, shock absorption, and protein exclusion. Over time, the injected hyaluronic gel is slowly absorbed by the surrounding tissues and disappears by a process called isovolumetric degradation.[9] As the HA gradually degrades, each molecule binds more water and, eventually, the same volume can be maintained with less HA. This provides a natural appearing volume correction and cosmetic persistence until the product is almost completely degraded.

The chemical and molecular composition of natural HA is conserved throughout all living organisms; therefore, HA fillers do not possess species or tissue specificity. This means that there is a negligible potential of eliciting humoral or cell-mediated immune reactions. Restylane, Perlane, and Juvederm are HA dermal fillers derived from bacterial fermentation in cultures of a Streptococcus species. Because these products are not of animal origin, there is almost no risk of contamination with animal allergens, pathogens, or xenogenic disease during the manufacturing process.[10] Restylane, Perlane, and Juvederm lead the market in HA fillers. Other HAs have not demonstrated similar longevity or reliability and are rarely used. Predictable and natural results coupled with minimal risk and downtime have contributed significantly to their growing worldwide popularity.

Table 1. Facial fillers

Filler	Function	Uses	Pros	Cons	Comments
Collagen-based products (Cosmoderm and Cosmoplast)	Human-derived, bioengineered collagen injected to fill facial wrinkles	Anywhere; effective contouring agent (lips, fine etched lines)	Immediate results with no downtime; formulated with lidocaine for patient comfort	Limited longevity (lasts 3 months)	An FDA-approved collagen dermal filler that does not require a skin test
Hyaluronic acid (Restylane, Perlane, Juvederm, Captique)	Non–animal-derived hyaluronic acid engineered to resist degradation for wrinkle filler and volume replacement	Volume and contouring (periorbital, nasolabial, lips, cheeks, etc.)	Results are immediate and last 6–18 months; reversible	May be visible or palpated if injected superficially; less effective for treating lipoatrophy or very large volume correction	Stimulates de novo collagen formation; FDA-approved for filling moderate to severe wrinkles around the nose and mouth; all other uses considered off-label; no risk of animal-based disease transmission
Calcium hydroxylapatite (Radiesse)	Microspheres of calcium hydroxylapatite inducing production of collagen	Volume enhancer (nasolabial and cheeks)	Biocompatible and ultimately biodegradable; long-lasting (12 months and maybe beyond); moldable	Clumping, lumping, and nodules can appear when injected into the lips	Do NOT use Radiesse in the lips; FDA-approved for facial lipoatrophy and moderate-to-severe wrinkles around the mouth
Poly-L-lactic acid (Sculptra and New Fill)	Synthetic material is injected into the face, causing body to produce its own collagen	Volume enhancer (nasolabial, cheeks, and temples)	Long-lasting (18–24 mos)	Results not immediate, may require multiple treatments; skin nodules and granulomatous reactions possible	In a clinical study of Sculptra, the treatment results lasted for up to 2 years after the first treatment session; FDA-approved for facial lipoatrophy
Fat transfer	Fat cells are harvested from one part of the body and injected into the face to replenish volume	Volume augmentation (cheeks, periorbital, and temple); not used for finer contouring	Most natural filler; fat can be stored for touch-ups	For volume replacement, less effective at finer contouring; duration is unpredictable: 6 months–10 yrs	"Predictably unpredictable"
Silicone (Silikon 1000 and Adaptosil 5000)	Highly refined silicone oil is injected using microdroplet technique	Volume replacement and contouring	Permanent	Cannot be removed after being injected	Beware of black market non-medical silicone; off-label cosmetic use
Polymethylmethacrylate (PMMA; Artecoll and Artefill)	PMMA microspheres surrounded by collagen	FDA-approved for nasolabial folds, deep wrinkles	Permanent	Numerous injections needed for volume; allergic reactions possible; requires 3 months for full effects; sometimes visible under skin	Because of the bovine collagen component, allergy skin testing is required; PMMA does not break down

FDA, U.S. Food and Drug Administration.
Adaptosil 5000 is manufactured by Bausch Lomb (Rochester, NY). Artecoll is manufactured by Artes (San Diego, CA). Captique, Cosmoderm, Cosmoplast, Hylaform, and Juvederm are manufactured by Allegan, Inc (Irvine, CA). New Fill is manufactured by Ashford Aesthetics (Brussels, Belgium). Perlane is manufactured by QMed (Eatontown, NJ). Radiesse is manufactured by Bioform Medical (San Mateo, CA). Restylane is manufactured by Medicis (Scottsdale, AZ). Sculptra is manufactured by Sanofi-Aventis (Bridgewater, NJ). Silikon 1000 is manufactured by Alcon (Fort Worth, TX). Zyplast is manufactured by Inamed Aesthetics (Santa Barbara, CA).

Calcium Hydroxylapatite

Radiesse (Bioform Medical, San Mateo, CA) was approved by the FDA in December 2006 for the correction of facial wrinkles and folds, such as nasolabial folds, and for the correction of facial lipoatrophy associated with HIV. Radiesse is composed of calcium hydroxylapatite (CaHA) microspheres (25–45 μm) surrounded by a 70% methylcellulose carrier that dissipates quickly in vivo, leaving the CaHA microsphere as a scaffolding to promote collagen in-growth.[11] Radiesse has a good safety record and stimulates only minimal foreign body reaction secondary to the spherical shape of the product, which incites less inflammation then an irregularly shaped product.[12,13] Granulomatous reactions and migration of the product are unlikely.[14] The calcium and phosphate minerals comprising Radiesse microspheres are the same as found in bone. While there was an initial discussion about potential osteoneogenesis after injection, these concerns have been demonstrated as unfounded[15] because osteoneogenesis has never been reported in more than 6 years of clinical use. The product is faintly visible on radiographs but has not been reported to obscure radiographic interpretation. After implantation, this product is slightly more malleable than HA. Additionally, the same volume goes further, because a lower volume of CaHA is needed to fill the same defect as compared with HA. Importantly, CaHA is not recommended for lip augmentation, because an unacceptable number of labial nodules have been reported from the product clumping together.[16]

Collagen-Based Products

Cosmoderm and Cosmoplast (Allergan) are human-derived, bioengineered collagen implants from a single cell line of fibroblasts screened for viral and bacterial pathogens. Approved by the FDA in March 2003, these products have a limited and waning role in the filler market. Because these products are of human origin, allergy skin testing is not required. Both of these injectable products are packaged with lidocaine (to provide anesthesia), making regional nerve blocks generally unnecessary. Although rare, complications with collagen injections have been reported, including vascular necrosis following glabellar collagen injections.[17,18] However, the most significant issues with collagen products have been their lack of longevity and their potential for a bumpy, irregular outcome. A new porcine-based collagen product called Evolence (ColbarLife Sciences, Herzliya, Israel) may help to restore collagen's reputation in the filler market. With results lasting up to 18 months in 66% of treated patients,[19] Evolence is anticipated to receive approval by the FDA in the near future.

Silicone

While silicone is not currently approved for cosmetic use by the FDA, it is used by some practitioners nevertheless. Silicone has a history shrouded in controversy.[20] Currently, the 2 brands most commonly used off-label are Silikon 1000 (Alcon, Fort Worth, TX) and Adaptosil 5000 (Bausch Lomb, Rochester, NY). Both of these products are approved by the FDA for ophthalmic use, but have been injected for soft tissue cosmetic augmentation. The centisokes (Cs) designation of the silicone preparations refers to the compound's viscosity. A Cs of 1000 is highly viscous and can be difficult to depress through a 30-gauge needle (by comparison, water has a viscosity of 100 Cs). Reports of serious and troubling complications after cosmetic silicone injections include granulomas, surface deformities, lymph vessel blockage, rosacea-like reaction, delayed hypersensitivity, migration, embolism, and blindness.[21–25] However, severe complications may be mostly avoided if pure silicone, as opposed to adulterated versions, is used with proper technique and indications.[26] Some practitioners have reported long-term effective and safe experiences with silicone.[27–29] Silicone injections are very technique-sensitive and require deep product placement. Overly superficial injections may result in excessive fibrosis, nodules, ridging, beading, and hypertrophic scar–like elevations.[30] A serial droplet injection technique may provide the best aesthetic results for correcting fine lines, wrinkles, and acne scarring with silicone. Undercorrection with multiple treatments spaced 2 to 3 months apart is recommended, because the injected silicone droplets continue to be coated with the patient's own collagen for up to 3 months.[26] The technique of microdroplets allows a monocellular fibrotic capsule to encompass each silicone particle, creating a microparticle. The collagen coating of the microparticles prevents migration and allows for a stable implant with permanent results.[31] However, uncertain long-term risks remain a concern with silicone injections.

Polymethylmethacrylate

A novel filler agent approved by the FDA for cosmetic use in January 2007 was originally marketed as Artecoll (Artes, San Diego, CA) in Europe and Canada and is now approved in the United States as Artefill. Artefill is comprised of smooth round polymethymethacrylate (PMMA) microspheres (30 to 42 μm diameter) surrounded by bovine collagen. Because of the bovine collagen component, allergy skin testing is required before correction.[32] The PMMA spheres provide permanent correction, because the bovine collagen is replaced within 3 months by host connective tissue. After 7 months, it has been demonstrated that there are very few differences between the collagen fibers around the implant and those of the surrounding connective tissue.[33] Patient satisfaction outcomes have been favorable, with one study reporting high levels of patient satisfaction (89%).[34] The complication rate was 7%, with nodule formation in the lip the most commonly reported issue.[35] It is crucial to bear in mind that Artecoll/Artefill results are permanent and are therefore exquisitely technique-sensitive. Multiple treatments are prudent, with extra care being taken in placement of the product in or around the lips, where nodule forma-

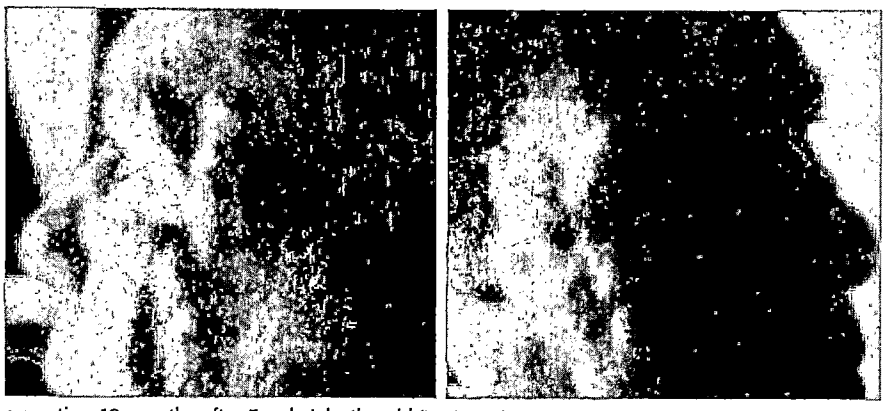

Figure 2. Granulomatous reaction 12 months after 3 poly-L-lactic acid treatments.

tion is more likely. Appropriate patient selection and injection techniques are of paramount importance when injecting any permanent filler products.

Poly-L-lactic acid

The poly-L-lactic acid Sculptra (PLLA; Sanofi-Aventis, Bridgewater NJ) provides a semipermanent correction and was approved by the FDA in 2004 for use in HIV facial lipoatrophy. Sculptra works by providing a volumizing effect with results lasting up to 2 years after the first treatment, but with multiple treatments often needed to achieve complete correction. As a major component of Vicryl suture (Ethicon Inc, Sommerville NJ), PLLA was formulated into an injectible filler and marketed under the name "New Fill" in Europe in 1999. The 40 to 63 μm PLLA particles are suspended in a sodium oxymethycellulose carrier. Histologically, Sculptra causes formation of microscopic nodules of multinucleated giant cells in the subcutaneous tissues.[11] Unlike HA fillers, the effects of PLLA are gradually achieved as Sculptra induces an expansion of dermal thickness. The substance is degraded by conversion to lactic acid monomers that are subsequently metabolized to glucose and CO_2.[36,37] Before approval by the FDA, studies in the HIV population revealed good results, documenting increased skin thickness with visible improvement in the signs of facial lipoatrophy.[36,38,39] Adverse events include palpable but nonvisible nodules that can be effectively dissipated with daily massage.[40] Concerns over delayed-type hypersensitivity reactions occurring months following injections[41] may be hindering its widespread acceptance as a cosmetic agent (Figure 2). Overall, the delayed results, pain on injection, and high price contribute to a product that is not as "user-friendly" as some of the other materials used for HIV lipoatrophy and aesthetic correction.

Fat Transfer

As a usually abundant substance with no risk for immunologic rejection, fat is traditionally noted for its unreliable persistency. However, recent advancements in preparation, harvesting, and injection techniques provide for longer lasting and more predictable results.[42–45] A patient's own fat is an ideal volume source because there are no allergic reactions, it is readily available, relatively inexpensive, and can be used to effectively augment facial volume. Fat transfer as a volume correction technique is becoming an increasingly popular method among many cosmetic physicians for achieving a natural appearing facial rejuvenation, especially when performed simultaneously with a surgical procedure. However, fat transfer can also be performed in the office.

Substantial skill and experience are necessary to achieve good and consistent results with fat transfer. If used well, fat is an excellent filler material; however, the results of fat transfer remain predictably unpredictable, lasting from 6 months to 10 years. Repeat injections of stored, initially harvested fat may be necessary to maintain the desired fullness of the treated areas.

PATIENT EVALUATION AND SELECTION

The choice of which filler to use and when to use it is primarily dependent on the patient rather than the product. Astute patient selection exponentially enhances aesthetic results and patient satisfaction. The following are some important questions to consider when determining which filler to use.

What has or has not made the patient happy in the past? If a patient has been pleased with their current filler regimen, there is no reason to change the filler unless there is significant cosmetic or safety advantage to using a different product. It is not recommended to readminister a product with which the patient has been previously dissatisfied. In this situation, it is best to attempt an alternate treatment or product or simply not to retreat at all. Realistic patient expectations are paramount to all successful injection procedures.

Does the patient demand either permanent or reversible products? Certain patients insist on treatment with a permanent filler although a temporary filler may be the more judicious recommendation. If the patient is an appropriate candidate with significant temporary filler experience, a permanent filler may be an option. In contrast, patients new to filler therapy are best treated with reversible, nonpermanent agents. As such, the patient and physician have flexibility in terms of treatment volume, repetition, reversibility, and ability to modify and customize the outcome as needed.

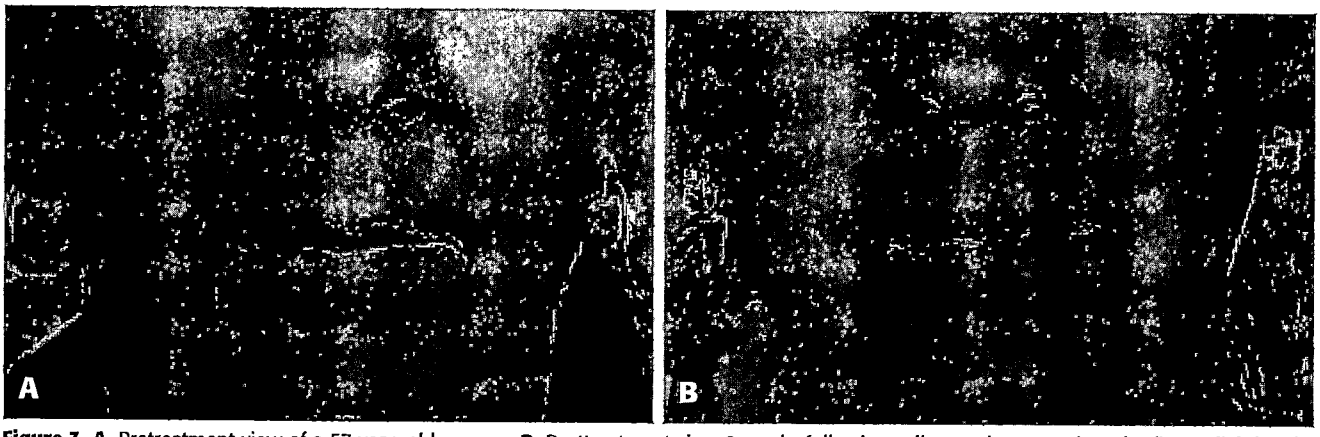

Figure 3. A, Pretreatment view of a 57-year–old woman. **B,** Posttreatment view 8 weeks following collagen placement into the fine radial rhytids of the upper lip, providing a limited but successful correction of the fine lines.

Can the patient tolerate downtime? Patients who cannot tolerate excess posttreatment downtime are not ideal candidates for larger semipermanent volumizer and fat transfer procedures. These treatments are placed deeper in the dermis with larger-gauge needles and can result in more significant bruising and swelling. For patients who require rapid recovery, the thinner HA products or even collagen based products may be better choices.

Is the patient undergoing simultaneous surgery? For the patient who is undergoing surgery simultaneously, fat transfer is often an excellent option. It is abundant and easy to harvest while the patient is under anesthesia. A sterile controlled environment is assured. Additionally, fat transfer usually involves more downtime than the off-the-shelf injectable products and most patients undergoing surgery are expecting at least a week of recovery time.

Is the patient older? Older people tend to have a minimized immune response to a foreign body injection. Therefore, a permanent product, which may cause an intense inflammatory response in a younger patient, is more appropriately offered to an older person. Additionally, in the event of a complication requiring skin excision of the permanent product, it is easier to camouflage a scar in the expected creases of an older patient's face than in the mildly blemished to unblemished thicker skin of a younger patient.

Is the patient's skin thick or thin? Thick skin tends to better accept the deep semipermanent volumizers, resulting in a better outcome and greater longevity. Thin skin can appear lumpy when injected with thicker HA products. Often, a customized treatment using 2 or 3 different products on the same patient in different areas can achieve optimal correction.

FILLER SELECTION AND PLACEMENT BASED ON ANATOMIC REGION OR DEFECT

The goal is to find the best match for the patients' problem with the optimal choice of filler therapy. Astute diagnostic skills, combined with an in-depth understanding of filler materials and their properties, will yield successful treatment outcomes.

Fine Etched Lines: Cosmoderm and Silicone

To erase fine, superficially etched facial lines, a product that can be placed superficially and not show through the skin is best. The consistency of collagen-based products makes them an excellent treatment for this circumstance (Figure 3). Unfortunately, their longevity (8 to 12 weeks), is not ideal. In experienced hands, silicone injections can achieve excellent aesthetic results (Figure 4). However, these permanent results are balanced against the risk of delayed hypersensitivity reactions and increased complications.[46] As such, silicone treatments are best limited to older patients with previous experience with injectables. Importantly, as mentioned earlier, use of liquid silicone for cosmetic purposes is currently off-label.

Superficial Facial Lines and Creases: Restylane and Juvederm Ultra

For medium-depth fine lines and creases, HA products can achieve excellent results. The product is placed just beneath the dermis to provide lasting and predictable results. When treating superficially, make sure the product is placed in the deep dermis. Superficial placement may be visible through the skin, worsening the patient's appearance.

Deeper Facial Lines, Folds, and Creases: Perlane, Juvederm Ultra Plus, Radiesse, and Fat

For deeper lines and creases, the more robust volumizers, such as the larger particle HAs and CaHA, can effectively fill deeper facial lines and crevices. These products are injected deep in the dermis or subdermis to fill the defect completely (Figure 5).

Lip Augmentation: Restylane and Juvederm

Successful lip augmentation requires significant skill and aesthetic expertise. One author uses thinner HAs to define the vermilion border and lift the oral commissure (Figure 6). Larger volumizing HAs can be used for creating a full pouty lip.

Periorbital Treatments: Juvederm and Restylane

Thinner and conservative deposition of HA in the periorbital region can achieve a satisfactory result in appropri-

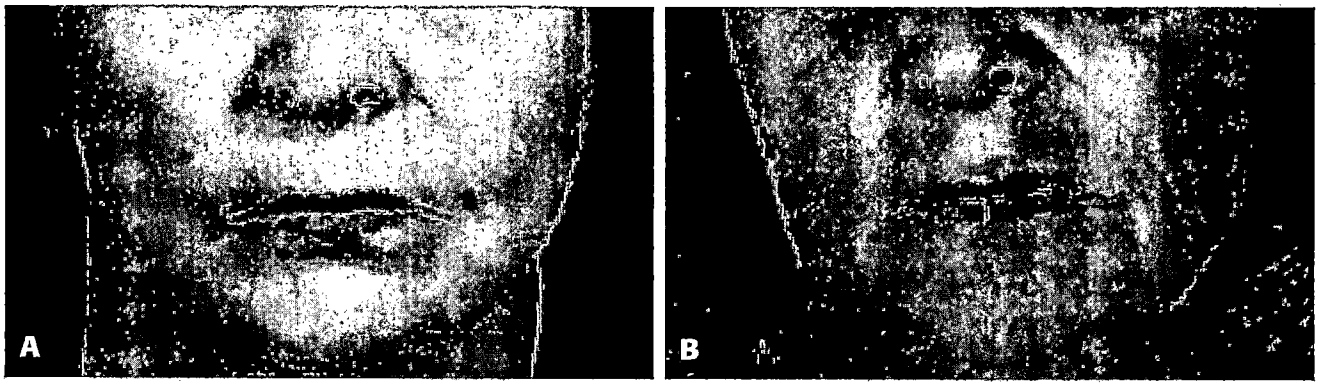

Figure 4. A, Pretreatment view of a 67-year–old woman. **B,** Posttreatment view following 2 silicone treatments (separated by 8 weeks) to the upper lip rhytids.

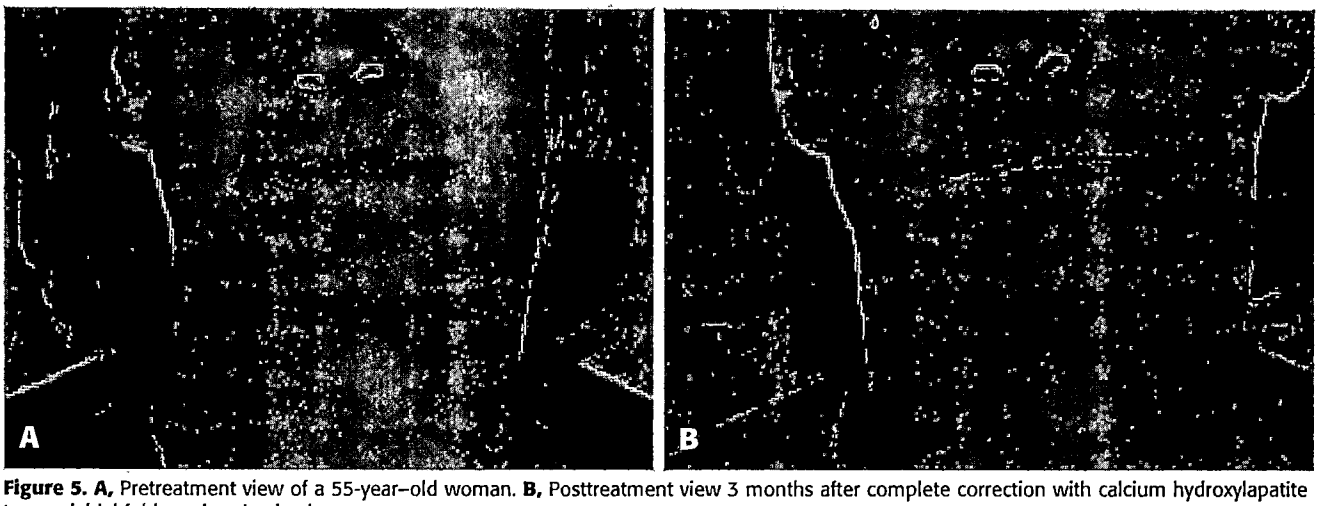

Figure 5. A, Pretreatment view of a 55-year–old woman. **B,** Posttreatment view 3 months after complete correction with calcium hydroxylapatite to nasolabial folds and prejowl sulcus.

ate patients (Figure 7).[47] Unfortunately, this treatment is often administered to a poorly selected patient and in excessive or inadequate volumes. Undertreatment and deep placement are important to achieving a good result in the periorbital region. Patients with thick skin, significant cheek pad ptosis, hollowing out of the infraorbital rim/nasojugal groove, and minimal pseudoherniation of orbital fat are the best candidates. Effective periorbital treatment is achieved by placing no more than 0.25 mL filler per side, injecting deep along the orbital rim in a serial depot manner. Fortunately, if the results are not acceptable, the volume augmenting effects of HA can be reversed by injecting 15 to 20 units of hyaluronidase (Amphadase; Amphastar Pharmaceuticals, Rancho Cucamonga, CA) or Vitrase (Ista Pharmaceuticals, Irvine, CA) into the overcorrected area.[48]

Midface and Lower Face Volume Enhancement: Radiesse, Perlane, Juvederm Ultra Plus, and Fat

These products nicely replace volume in the midface, cheeks, and prejowl sulcus (Figure 8). Newer intraoral injection techniques greatly decrease pain, posttreatment ecchymoses, and edema (Figure 9). The product is placed deeply in the subcutaneous tissues and along the supraperiosteal plane. After injection, the product is manually molded to achieve the desired contour. Large volumes of product are necessary in order to appreciate the enhancement.

ANESTHESIA FOR FILLER TREATMENTS

Anesthesia is essential for most patients undergoing filler treatments; only rarely does a patient not require it. The type of anesthesia, whether a local nerve block or a topical anesthetic, is chosen according to the area to be treated and the pain threshold level of the patient. Pain perception is also location-dependent; for example, the lip area is very sensitive, and a local nerve block is almost always required while treatment under the eyes is barely felt with a sharp, thin needle and a topical anesthetic.

Topical Anesthetics

Topical anesthetics are commonly comprised of betacaine, lidocaine, and tetracaine in various combinations. Many pharmacies will compound the products to a higher concentration than what is available over the counter. ELA Max (Ferndale Laboratories, Ferndale, MI) is available over the counter.

Icing

Icing is a low cost, easy, and safe method for blunting the pain response. Some pain will still be felt during the

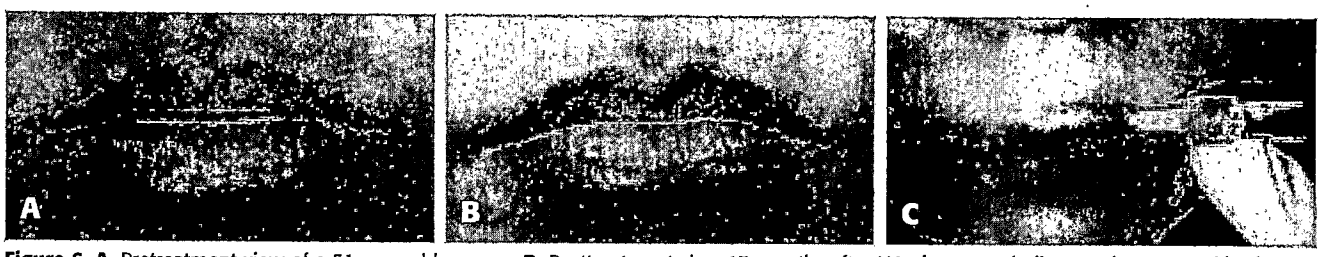

Figure 6. A, Pretreatment view of a 51-year–old woman. **B,** Posttreatment view 13 months after HA placement in lips. **C,** Placement of hyaluronic acid into vermilion border.

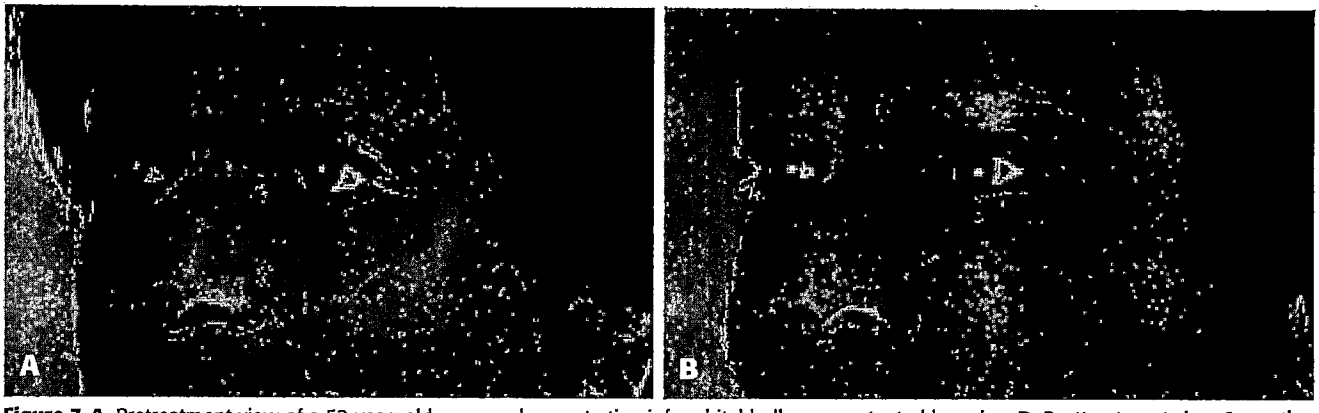

Figure 7. A, Pretreatment view of a 52-year–old woman demonstrating infraorbital hollow accentuated by aging. **B,** Posttreatment view 6 months after placement of hyaluronic acid into infraorbital hollows.

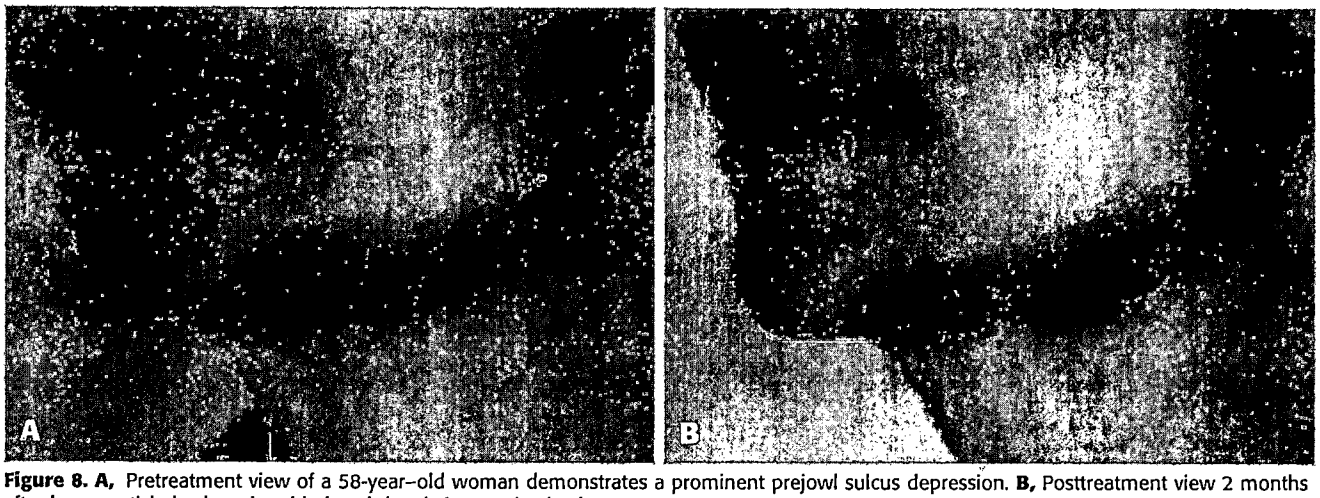

Figure 8. A, Pretreatment view of a 58-year–old woman demonstrates a prominent prejowl sulcus depression. **B,** Posttreatment view 2 months after large-particle hyaluronic acid placed deeply into prejowl sulcus.

filler injection despite the precooling, but patients may prefer this method to a medicated anesthetic. Placing an ice cube or two in a clean surgical glove and then allowing the patient to hold it over the planned area of injection for 1 to 2 minutes is usually adequate. The same ice can be used immediately posttreatment to help reduce bruising and edema. Caution is advised to not overexpose the skin to the cold, because a burn might result.

Topical Refrigerant Spray

Topical dichlortetrafluoroethane and ethyl chloride skin refrigerant spray (Pain Ease; Gebauer Co, Cleveland, OH) can be applied to the treatment area 30 to 60 seconds before needle insertion for topical skin anesthesia (Figure 10). Such spray is perceived by the skin as very cold and desensitizes topical nerves immediately upon application. Superficial skin pain response is significantly thwarted; however, the deeper dermal pain fibers still respond. The spray is not intended for use on oral mucosa and is offered only for use on the cheek and nasolabial folds. Caution should be exercised in use for those at risk for inflammatory or reactive hyperpigmentation.

Local Nerve Blocks

Local nerve blocks[49] are frequently necessary perioral-ly, especially for lip injections. Injectable anesthetic choices include lidocaine, with or without epinephrine, which are both painful upon injection. This can be blunted by placing a topical intraoral anesthetic, such as Denti-Care topical anesthetic gel, with 20%

Figure 9. Intraoral injection technique for midface correction with large-particle hyaluronic acid.

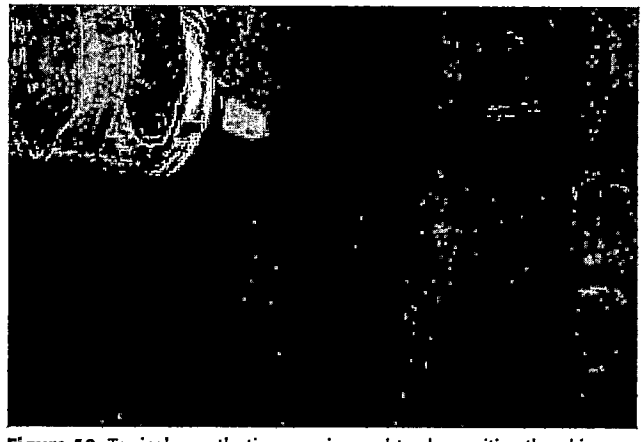

Figure 10. Topical anesthetic spray is used to desensitize the skin.

Benzocaine (Medicom, Lachine, Québec, Canada) to alleviate the discomfort associated with mucosal injections. However, the burning sensation is still noted as the anesthetic product is injected, likely because of the acidic nature of the agent.

Epinephrine in the anesthetic may help to reduce bruising; however, if epinephrine is included, the anesthetic effect may persist for 8 to 10 hours. This can be an uncomfortable experience for many patients because of the lack of oral sensation and can reduce oral competency. Septocaine articaine hydrochloride 4% with epinephrine (Septodont Inc, New Castle, DE) is favored by many dentists and is an excellent alternative to lidocaine. Even with its epinephrine content, its duration of effect is limited to 2 hours. Additionally, the Septocaine has a higher pH, thereby minimizing the burning sensation upon injection. Rarely, persistent paresthesias have been reported with Septocaine injections, specifically with mandibular injections. Caution is recommended to prevent direct injection of the neural foramen.[50]

Local Nerve Block Techniques

A Septocaine ampule is placed into a stainless steel dental injector syringe with a 27-gauge, 1.25-in needle (Kendall Tyco Healthcare Group LP, Mansfield, MA). A cotton-tipped applicator with topical local anesthesia is placed on the buccal or gingival labial sulcus for 3 to 5 minutes (Denti-Care topical anesthetic gel). The needle is placed just above the canine at a 30° angle up to the canine fossa, with the bone of the anterior maxillary wall just lateral to the nasal-alar insertion. The needle is directed down to the bone and approximately 0.3 mL of anesthesia is injected. Distraction devices, such as a vibrating massager placed on the maxillary eminence, can significantly minimize injection discomfort (Figure 11). Injections are made bilaterally to achieve anesthesia to the entire upper lip within about 2 minutes. Alternatively, the injections can be accomplished transcutaneously (Figure 12). This technique is easier and more reliable when first learning nerve blocks, but it is also associated with a greater discomfort to the patient.

For lower lip anesthesia, following retraction of the lower lip, the second premolar is located and the needle is inserted into the gingivolabial sulcus, about 0.5 in beneath and onto the bone of the mandible. Approximately 0.2 mL of anesthetic is injected bilaterally to anesthetize the entire lower lip and chin area (Figure 13). Because mandibular injections are slightly more painful then the maxillary injections, a distraction device placed on the mentum will significantly blunt pain perception (Figure 14).

Some physicians utilize a micro-nerve block technique, in which small aliquots of anesthetic are injected along the mucosal border of the lip near the gingival sulcus. Microblocks have the advantage of not producing as deep a regional anesthetic. However, this technique may take longer to perform and the potential for incomplete anesthesia is greater.

INJECTION TECHNIQUES

To achieve successful filler treatments, there are a variety of different techniques used including threading, serial droplet, and fanning methods.

The Threading Method

Probably the most popular technique, threading is best used for treating the vermilion border. Threading is a technique which involves depositing the product as the needle is withdrawn from the tissue. In this technique, the needle is inserted to its hub, taking care that the needle is in the very deepest portion of the dermis or in the subdermal tissues. If the skin dimples down with downward pressure on the needle, then the needle is in the dermis. If the needle can be visualized through the skin, then it is too superficial and will generally not produce an aesthetically pleasing effect. If there is little resistance to the needle and the product upon injection, then the needle is in the subcutaneous tissue.

The Serial Droplet Method

This technique is commonly mentioned with silicone injection. It is described as placing the needle into the deep dermis (or deeper) and depositing a very minimal amount of product, approximately 0.01 to 0.03 mL. Multiple serial droplets are placed along the wrinkle, a

Figure 11. Intraoral injection with Septocaine is used to achieve anesthesia to upper lip. Vibrating distraction device is used to blunt discomfort with injection of anesthetic.

Figure 13. Inferior mental nerve block with injection of Septocaine near the mental foramen.

Figure 12. Transcutaneous injection of anesthetic down to anterior face of maxilla.

Figure 14. Vibrating distraction device on the mentum blunts the discomfort of injection.

technique that can lead to beading and a dull needle, necessitating multiple needle replacements. This method is best utilized for treating the glabellar creases (Figure 15) and for placement along the inferior orbital rim in treating periorbital hollows.

The Fanning Method

The fanning method is the preferred manner for achieving superior, natural appearing, and longer-lasting results. However, the amount of product that is used is dependent on the depth of the crease, the patient's desired outcome, and the patient's financial preferences. The fanning method is appropriate for placement of the product in the immediate subdermis or subcutaneous tissues. It is very difficult (if not impossible) to perform the fanning technique in heavily resistant dermal tissues. Because the subdermal tissues are less resistant, allowing for more diffusion, more product is usually needed for complete correction with fanning as compared with other techniques.

In the fanning method, the needle is placed just below the dermis at a 30° angle with the bevel position irrelevant. The needle is passed back and forth under the fold, extending approximately 2 mm lateral to 2 mm medial to the fold (Figure 16). The product is deposited both as the needle is inserted and withdrawn, filling in an approximately 4-mm wide band of product with the fold in the center. The product should be deposited slowly and steadily. Injecting HA at 0.3 mL/min or slower has been determined to result in less ecchymoses.[51] In most patients, it will take at least 1 mL of filler per fold to achieve a satisfactory result. It is important to achieve complete correction but to stop at the desired cosmetically appealing endpoint and refrain from overcorrection. Results tend to improve over the next couple of weeks as inflammation subsides and as the product "settles" into the fold.

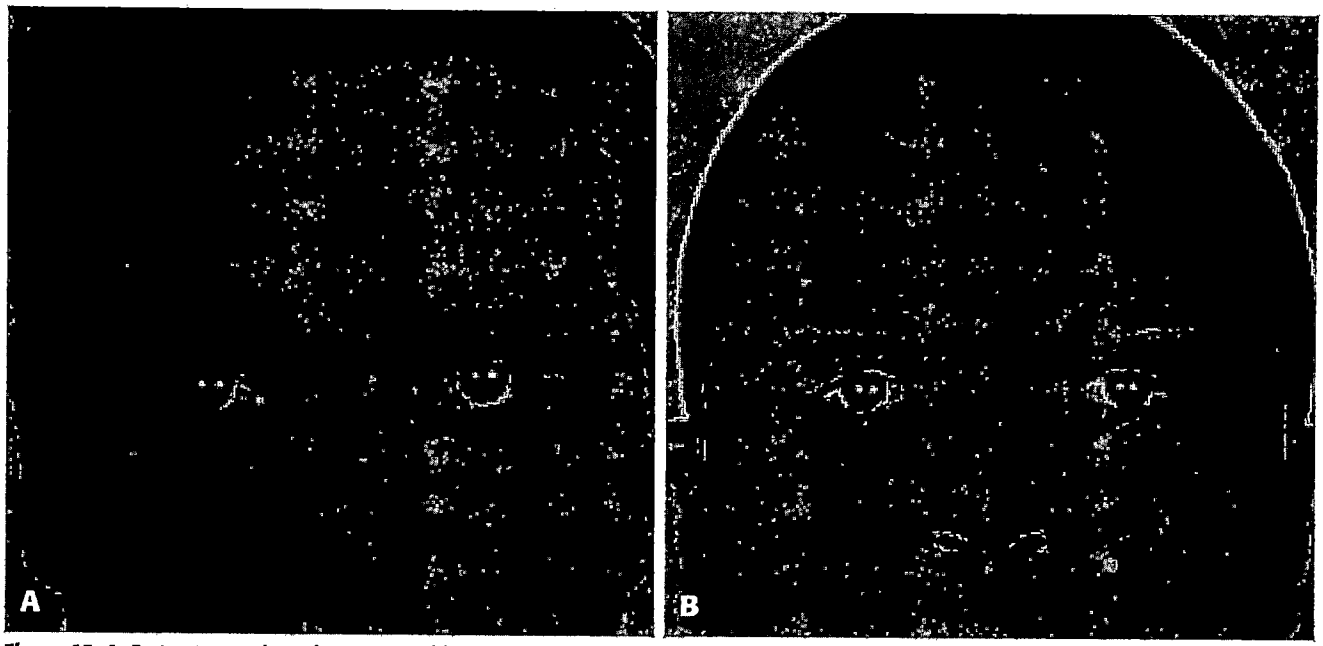

Figure 15. A, Pretreatment view of a 35-year–old man. **B,** Posttreatment view 1 year after placing hyaluronic acid via a serial droplet method into the glabellar creases.

Figure 16. Filler is placed in a lane extending 2 mm lateral and 2 mm medial to the nasolabial fold in a fanning method.

DISCUSSION

Using appropriate patient selection, filler choices, and injection techniques, filler outcomes and patient satisfaction can be optimized. Two important ingredients of success are: (1) treating to complete correction and (2) appropriate placement of the filler material in the dermis.

In terms of complete correction, patient satisfaction following a filler treatment may be dependent on whether or not a complete aesthetic correction was achieved. Frequently, previously treated patients who are unsatisfied with their result were shown to have been inadequately treated or undertreated. It is likely that if more product had been initially placed into the area of desired correction, the patient would have been more satisfied. Other than periorbitally (where undercorrection is the rule), when complete correction is attained the patient is more likely to be pleased, subsequently return, and refer other patients (Figure 17). Anecdotally, experienced injectors have recognized that if complete correction is initially accomplished, the correction persists longer. In all cosmetic procedures, the objective is to satisfy the patient. In fact, if the patient appears to be difficult to satisfy, it may be wise to discourage the treatment rather than produce an unhappy patient.

In terms of the appropriate placement of filler material in the dermis, in contrast to initial teachings and package inserts, it is the authors' experience that filler materials should not be placed in the dermis but, rather, deeper, for a more lasting and aesthetically natural result. Placement in the subdermis lifts the crease or fold, whereas product placed into the dermis can result in a "worm-like" blue line under the skin. This "tindle effect" is not only unsightly, but tell-tale evidence of a filler treatment. Fortunately, this misplaced product can be easily removed by nicking the skin with an 18-gauge needle and expressing the product (Figure 18). Filler can be removed in this fashion at any point following injection, from immediately after placement to months post-treatment. Occasionally, for large volume correction (i.e., cheeks and prejowl sulcus), the product is placed deeper into the subcutaneous tissues. At this level, the hydrophilic properties of the HA will diffusely expand in the area of desired correction. However, a significant volume of product may be necessary before the correction is appreciated.

As recently described, it is postulated that the stretch placed on the tissues by HA fillers stimulated dermal

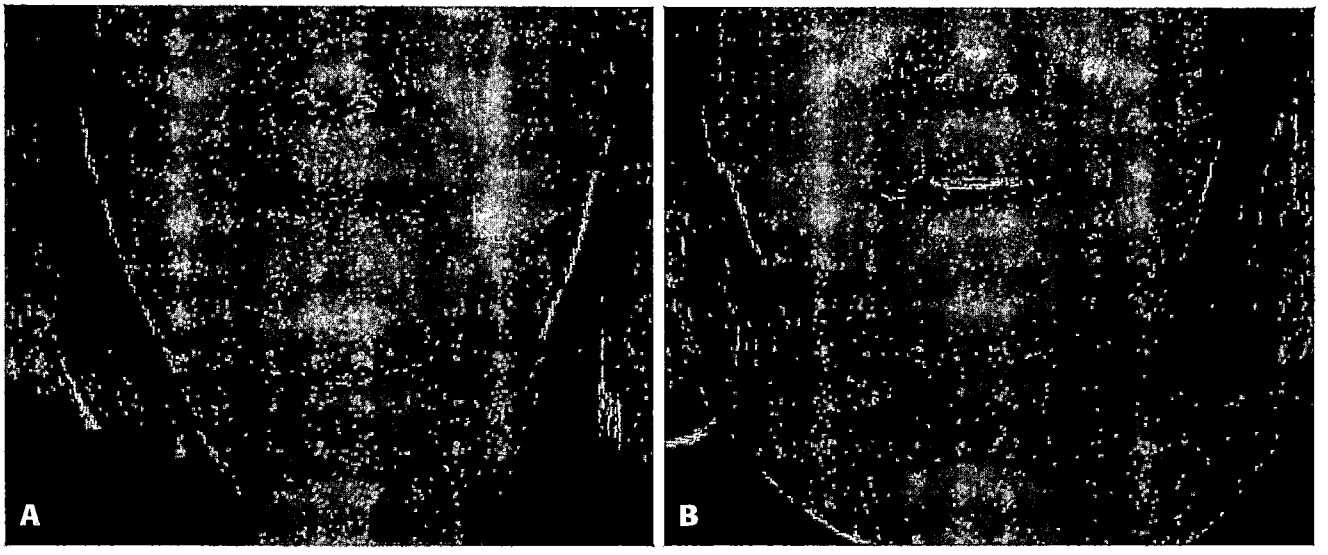

Figure 17. A, Pretreatment view of a 68-year–old woman. **B,** Posttreatment view 12 months after complete correction with large-particle hyaluronic acid into the nasolabial folds.

Figure 18. A, Superficially placed hyaluronic acid leaves a prominent blue discoloration and fullness. **B,** An 18-gauge needle is used to nick the skin overlying the too superficially placed product. **C,** Misplaced hyaluronic acid is extracted 12 months after placement.

fibroblasts to produce collagen. While this study examined Restylane, this phenomenon may be relevant to all facial fillers.[4] Future studies focusing on correction longevity will likely elucidate variables contributing to optimal filler treatments.

CONCLUSION

Current trends in facial rejuvenation have made a shift toward volume replacement complementing, or in lieu of, surgically advancing the skin and supporting ptotic tissues. Contemporary patients overwhelmingly request minimally invasive alternatives for achieving a rejuvenated appearance. Fillers can meet many of their desires, with concomitant high safety profiles and minimized downtime. With the rapidly evolving filler market, it is vital for physicians to make educated and thoughtful choices before broadly applying novel products. With today's commercially available materials, the aesthetic physician's armamentarium of facial fillers can be appropriately and effectively used to achieve significant cosmetic outcomes. Which products are ultimately used in a successful patient–filler scenario is dependent on the patient's aesthetic needs in combination with the physician's knowledge of current facial fillers and injection expertise. ◗

DISCLOSURES

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