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The Art of Submental Contouring: Novel Treatment Approaches for Total Facial Rejuvenation

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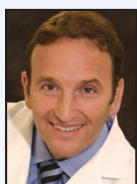
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The Art of Submental Contouring: Novel Treatment Approaches for Total Facial Rejuvenation

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CONTENT SOURCE

This continuing medical education (CME) activity captures content from a roundtable discussion held in March 2017.

ACTIVITY DESCRIPTION

Balanced facial proportions reflected in ancient and classical art have not changed significantly over millennia, and they guide aesthetic physicians today. While fillers and neurotoxins can be used to remodel the mid-face non-invasively, the effects of chin dimensions and submental fullness have been difficult to modify without invasive surgical measures. Furthermore, in keeping with trends that focus on holistic approaches to aesthetic treatment,

cosmetic surgeons are interested in treating submental fat within a regimen that also includes injectables and device-based interventions for pan-facial rejuvenation.

TARGET AUDIENCE

This certified CME activity is designed for dermatologists and cosmetic surgeons.

LEARNING OBJECTIVES

Upon completion of this activity, the participant should be able to:

- Discuss ideal proportions of facial anatomy and the affects of submental fullness on the individual's appearance.
- Articulate the method of action of deoxycholic acid and identify its role in the management of submental fat.
- Identify ideal treatment parameters for deoxycholic acid injection that optimize patient comfort and long-term outcomes.
- Determine optimal strategies for use of deoxycholic acid along with other interventions that target submental fullness.
- Describe effective strategies that incorporate targeted treatment of the submentum into a pan-facial rejuvenation strategy.

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The Art of Submental Contouring: Novel Treatment Approaches for Total Facial Rejuvenation

BASED ON A ROUNDTABLE DISCUSSION BY STEVEN H. DAYAN, MD, MATHEW M. AVRAM, MD, DEBORAH SHERMAN, MD, AND SACHIN M. SHRIDHARANI, MD

Body contouring has been growing rapidly—and improving the appearance of submental fat is playing a part in this growth. A 2015 survey by the American Society for Dermatologic Surgery (ASDS) found that about 67 percent of respondents were concerned with excess fat under the chin/neck, making it the third most common cosmetic concern among consumers.¹ More recently, results of survey commissioned by Allergan plc to better understand the personal impact of submental fullness as well as how others perceive individuals with submental fullness were revealed at the March 2017 American Academy of Dermatology (AAD) Meeting. The survey of 1,996 men and women in the US between the ages of 18 and 65 found 47 percent of respondents reported being bothered by the appearance of the area underneath their chin, and 49 percent said the area under their chins negatively impacts their appearance.² The survey respondents also reported altering their behavior to address their double chin. For example, 35 percent shy away from photos, 35 percent avoid video chats and conference calls, and 29 percent of men reported having grown a beard to hide the area under their chin (younger men were more likely to do this than their older peers).²

Submental fat is difficult to target and treat through diet and exercise and can be a consequence of aging and genetics as well as weight gain.^{3,4} While surgical liposuction was the primary available treatment for several decades, there have recently been significant advances in the availability and effectiveness of minimally invasive and non-invasive treatment options, including recently approved cryolipolysis (CoolSculpting) and deoxycholic acid injection (Kybella).

DEFINING THE IDEAL SUBMENTAL PROFILE

While the ideal submental profile will vary from patient to patient, a youthful submental profile is based on having reasonable proportions, less overall amount of subcutaneous fat, an acute cervicomental angle (CMA), and well-defined jawline.^{5,6} An ideal CMA for a youthful profile and jawline has been shown to be between 105° and 120°. Accumulation of submental fat within

the pre-platysma or sub-platysmal fat compartment results in an obtuse or blunted cervicomental angle and loss of mandibular and cervical contours, creating a less youthful appearance.^{7,8} The position of that fat and the pattern of its deposition determines the best treatment approach—patients with a pre-platysmal fat compartment are candidates for non-surgical treatment. Other anatomic concerns, such as the position of the hyoid, the angle, shape, and length of the mandible, position and size of the digastric muscle, and skin laxity also affect the appearance of submental fullness and must be assessed prior to treatment. Determining the best treatment option to eliminate the submental fat and improve the CMA requires knowledge of the anatomy of the submental region and a clear understanding of each individual patient's treatment goal.⁵⁻⁸

For example, minimal to non-invasive treatment options to eliminate fat will be poorly effective on patients with large digastric muscles. Also, while non-surgical submental fat reducing treatments may result in a modicum of retraction and skin tightening, if a patient has significant loss of neck skin elasticity, he or she may not be a good candidate. Patients with obvious platysmal bands, and a large platysma diastasis, may not be satisfied with the amount of tightening achieved and would likely be better treated with a surgical neck treatment.

Historically, liposuction has been the gold standard for treatment of submental fullness. However, some patients have contraindications to surgery and many today prefer non-surgical noninvasive options with less downtime. While non-surgical treatments and new technologies often don't offer the same therapeutic outcome that surgery does, patients are still satisfied with the results, the authors have found.

Patients seeking to improve the appearance of their submental region will likely have done research about available treatments and may have an opinion about what they think is best, but physician assessment of each patient's anatomy and treatment goals is necessary to guide patients to the most effective treatment option.

CHOOSING THE RIGHT TREATMENT

Laser-assisted lipolysis and radiofrequency-assisted lipolysis offer minimally invasive options for treating submental fullness. There are several minimally invasive devices popular for treating the submental area—NeckTite (Invasix), PrecisionTx (Cynosure), and ThermiTight (ThermiAesthetics).⁶ These devices selectively heat and coagulate adipocytes to permanently destroy fat and also tighten the surrounding skin. Temperature monitors or infrared cameras may be used with these devices to decrease the risk of potentially burning the skin.

The NeckTight hand piece is applied to BodyTite's RFAL (radiofrequency assisted lipolysis) technology for a complete contouring solution. RF energy travels from an internal electrode, which can be simultaneously aspirating coagulated tissue, to an external electrode, resulting in coagulation of adipose, vascular and fibrous tissue, and heating of the entire soft-tissue matrix resulting in gentle fat removal in addition to tightening and contouring.⁹

PrecisionTx is an Nd:YAG 1440nm wavelength laser. The 1440nm wavelength is highly absorbed by water and creates a photomechanical effect which causes micro bubbles at the fiber tip (cavitation effect). This results in bidirectional energy distribution and more focused targeting of tissue. Heat stimulated collagen production leads to skin thickening and tissue retraction.¹⁰

ThermiTight is an application of the ThermiRF device, which is FDA cleared and indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis. The ThermiRF device heats tissue to achieve electrocoagulation and hemostasis by utilizing radiofrequency electrical energy. A small electrode is inserted under the skin to heat tissue to a clinician-selected therapeutic temperature in order to contract collagen molecules and stimulate collagen production, which may result in the appearance of lifting or tightening.¹¹

TruSculpt (Cutera) is a non-invasive RF device that delivers deep heating to adipose tissue for body sculpting, fat reduction and skin tightening.¹² The device is placed over the epidermis and emits RF energy that targets fat.

Both Kybella¹³⁻¹⁵ and CoolSculpting¹⁶ also offer patients effective

noninvasive treatment options to improve the appearance of the submental area.

Cryolipolysis (CoolSculpting) applies noninvasive cooling temperatures to the skin's surface to instigate selective programmed death of underlying adipocytes. Cryolipolysis was first FDA-approved to treat flank adiposity in 2010 with more recent expanded indications to treat the abdomen, thighs, and submental area with the introduction of the CoolMini applicator.¹⁶ Cryolipolysis is delivered via a vacuum applicator and applies temperatures of -10°C (14°F) to the skin for approximately 60 minutes per treatment. Patients typically require one to two treatments for the submental region with results fully realized within three to four months after the last treatment.¹⁶ Treatment has a large safety index and can significantly decrease submental fullness. Patients have little downtime and can usually return to normal activities within a day of treatment.¹⁶

With CoolSculpting, a larger area can typically be treated at once, and there is minimal to no significant downtime after the procedure. However, one disadvantage with the CoolSculpting procedure with the CoolMini applicator is that the applicator is a fixed size. The applicator fits perfectly for certain patients and is an excellent option to contour their submental fat. But, for other patients, their fat configuration may not match the shape of the applicator.

Deoxycholic acid (Kybella) was FDA approved in 2015 to treat moderate to severe submental fullness. Deoxycholic acid is a naturally occurring molecule in the body that has been shown to cause dose-dependent adipocyte lysis, necrosis, disruption and dissolution of fat architecture, and inflammatory targeting of adipocytes by immune cells.^{14,15} When injected into the fat beneath the chin, deoxycholic destroys fat cells, resulting in a noticeable reduction in fullness under the chin.^{14,15}

Kybella is injected into subcutaneous fat tissue in the submental area using an area-adjusted dose of $2\text{mg}/\text{cm}^2$; a single treatment can consist of up to a maximum of 50 injections, 0.2mL each (up to a total of 10 mL), spaced 1cm apart with up to six single treatments administered at intervals of no less than one

EXPERT VOICES

ARE THERE BENEFITS TO USING AN ANESTHETIC IN TREATMENT?

Dr. Shridharani: I like using an anesthetic prior to Kybella treatment for a few different reasons. Other than to reduce bruising, I've used it to trick the body, so to speak. I use the lidocaine, if I'm going to be treating aggressively, as a litmus test for if I'm too close to the marginal mandibular nerve. There have been times that I've adjusted my markings or my depth of injection, because I've injected them with lidocaine. I come back 7 to 10 minutes later, I'll look and ask the patient to show me their lower teeth, and when they do I've seen a little bit of asymmetry. So I know that either I was too close, or that I was too deep. In which case, I've adjusted my Kybella injection and it's spared me from getting a temporary marginal mandibular nerve paresis.



EXPERT VOICES

DISCUSSING PRICING WITH PATIENTS

Dr. Avram: Submental fat is part of someone's appearance. They see it in a mirror, they know that their parent had it and it got worse over time, and they want to avoid that, or they want to look a certain way. I think the key to these treatments, which makes them popular and less price sensitive than some of the other treatments we do, is that the results, at least to the extent we know at this time, look to be long-lasting, if not permanent.

It's a different conversation with a toxin or filler, where you're talking about results for three to six months, six to 12 months, 12 to 18 months. When the patient understands that this is going to be a long-term or even permanent reduction in fat, there is a greater willingness to spend more money on it.

Dr. Sherman: Kybella is a new aesthetic tool, a first-in-class treatment that works like no other. It's not like Botox, it's not like fillers, except that it resides in a syringe. If we think about it as a scalpel in a syringe, you can certainly see the value and potential of a customizable, nonsurgical facial contouring agent. It is good to know that we now have five-year data that supports the fact that it is a lifetime result.

When it comes to pricing, I've moved towards a package of treatment pricing. I think that we have to explain what it takes for optimal outcomes, and offer a package treatment based on best predicted results, rather than selling it on a per-vial or a per-treatment basis. Most people need more than one treatment, for sure. We don't guarantee results with one treatment, as one treatment does not correlate with the findings from the clinical studies, and often multiple treatments are needed for best results.

Dr. Dayan: I think that's critical—pricing is a big issue with this and how we price is key to this product being successful in the marketplace. Like you, Dr. Sherman, we're doing package pricing. We go small, medium, and large, and we charge them one price upfront.

Dr. Shridharani: I agree. I present this to patients and the clinicians as, what I like to call, surgery in a syringesm. If someone is a little concerned about the price, and say, "Ooh, my Botox is \$X," or "My filler cost \$X," I'll hold up a syringe, a cc of Botox and a cc of Kybella and say, "Both of these look like water, smell like water, inject like water; however, one, you come in for three to four times a year to temporarily get rid of fine lines and wrinkles, and you know how much you're paying for that and you know how many times you're going to be doing this over your lifetime. This one (Kybella) permanently destroys fat cells and is going to also help tighten the skin, and you're basically avoiding surgery."

Since the mentality of our practice has gone in that direction, patients present to the office often expecting to spend more, because they think it's a premium to avoid surgery. We've really seen an interesting paradigm shift.

When you look at the original clinical trial data and the dropout rate of the placebo arm, which was less than 2 percent, that tells you how motivated people are, to echo what Dr. Avram said, to get rid of this fat. They came in month after month at 30-day intervals for normal saline injections in hopes that one time treatment would actually work. When someone is concerned, or interested in getting this treated, they come up with the finances just like they do if they want a rhinoplasty, if they want a facelift, if they want a breast augmentation, because we tell them that this is permanent rejuvenation, not a temporary procedure. It's surgery in a syringe.sm

We treat aggressively with the first treatment and package treatment so the first is most expensive. My practice manager tells the patient, "You're going to need two to three treatments based on the doctor's experience, and the first treatment will

be your most expensive.” We try to then create enough of a margin that for the second treatment, we don’t typically need to use as much product. So, for patient satisfaction, we’ve been able to decrease a little of the price on the subsequent treatments. Each time they come in, they have less swelling, they have less downtime, they have more of an improvement, and their price is a little bit cheaper. When they realize the third treatment may cost the same as the second or less, they’re really encouraged to come in. It’s amazing how knocking a hundred dollars off of something goes such a long way.

month apart.¹⁴ Kybella allows physicians to be selective and precise in targeting the exact area of a patient’s submental fat. However, patients do typically have side effects from treatment, including swelling, redness, bruising, tenderness, or numbness.^{14,15} Although these are temporary and are typically worse after the first treatment than after follow-up treatments, these may cause downtime for some patients.^{10,11} For optimal results, patients must undergo a series of treatments with Kybella and while in the pivotal trials patients received up to six treatments, in clinical practice three to four treatments is often enough to achieve optimal results.

As a first-in-class treatment fairly new to the market, best practices for treatment and patient management are still being developed. In order to get a better understanding of how Kybella is being used clinically we aggregated a group of leading physicians with robust Kybella experiences. This roundtable offered the authors an ability to reveal their candid insights into how they are using Kybella in clinical practice, as well as what they have learned and what they are no longer doing. Some of their practices may surprise you.

TREATMENT TIPS: DOSING, PROTOCOLS, AND PATIENT SELECTION

The authors concur that the FDA-indicated 0.2ccs of product per injection is ideal for treatment. Kybella is distributed with an injection guide, which can be placed over the patient’s submental area to direct injection sites for the treating provider. (*For more injecting techniques, see Understanding the Anatomy: Injecting for Optimal Treatment Results on page 8.*)

The clinical trials showed that increasing the injection dose to 0.3ccs did not increase efficacy, but did increase the occurrence of adverse events.^{14,15} Experience in practice, has prompted the authors to extend the time between treatments from the one-month intervals used in the trials. Improvements are noted to progressively improve up to 12 weeks after a treatment. By extending the intervals between sessions, fewer treatments may be necessary. Consensus between our authors suggest eight weeks between treatments allows patients and physicians to evaluate the efficacy of each treatment and determine if a follow-up treatment is needed. A caveat noted by the authors is that a longer interval may result in a patient losing interest or initiate discouragement that the series of treatments could potentially take close to a year to complete.

While the clinical trials allowed for up to six treatments, very few patients in clinical practice will need that many treatments. In general, patients who need five to six treatments are those

in the severe to extreme category, and likely associated with a significantly elevated BMI. One option proving clinically relevant and practical is first debulking with one or two CoolSculpting treatments followed by a Kybella “cleaning up” to reduce residual fat not reached by the CoolMini applicator.

Most patients undergoing Kybella only, will need between three and four treatments and two to three vials per session. During consultation it is best to inform patients they will likely need more than two treatments and that they may not see significant results until after that second treatment.

And although Kybella is FDA approved for moderate to severe submental fullness, patients with mild to modest amount of fat may also be candidates for treatments. In fact, patients with a minor amount of laxity and a small amount of fat accumulation are some of the happiest patients treated, according to the authors’ experiences.

BEST PRACTICES IN PATIENT MANAGEMENT STRATEGIES

The patient consultation is absolutely paramount to successful outcomes and satisfaction rates with Kybella. Patients must understand that they will need to undergo a series of treatments in order to experience optimal results. Pricing treatments strategies to improve patient follow up include package pricing and upfront payments in full. (*For more expert opinions on pricing, see the Discussing Pricing with Patients on page 6.*)

Patients must also be counseled about any and all potential side effects, including swelling, redness, bruising, injection site tenderness, and the potential for a temporary “bullfrog” look following treatment. Patients should be educated that the inflammation they experience post injections means the treatment is working. It may be helpful to reiterate this is a definitive treatment and side effects are necessary for a permanent outcome.

It’s also important to explain that the side effects of swelling, tenderness, and temporary numbness tend to be the worst after the first treatment and decline significantly after subsequent treatments.¹⁴ Most patients find the side effects manageable and feel comfortable going back to work or other social engagements soon after the treatment. In general, the authors have found that most patients seeking the treatment are willing to experience the minor inconvenience requisite for a permanent non-surgical solution.

Rare more serious side effects that maybe secondary to technique such as skin necrosis and marginal mandibular nerve paresis have been reported. Fortunately they have all resolved. Temporary alopecia in the hair-bearing beard skin of men has also been reported.¹⁷ Proper training and adhering to approved treatment protocols should greatly reduce or eliminate severe adverse events.



EXPERT VOICES

UNDERSTANDING THE ANATOMY: INJECTING FOR OPTIMAL TREATMENT RESULTS

A firm understanding of the anatomy of the submental area and knowing where —and where not —to inject when treating patients with Kybella is critical. Allergan plc offers injection training with an injection diagram that can be placed on the patient to guide physicians on where to inject to avoid nerve damage and improve outcomes.

Dr. Shridharani: I use the diagram as a guide. We really want to create a lot of definition along the body of the mandible, up to the angle of the mandible. For me, my main landmark to stay safe is to go from the ear lobe along the angle

of the mandible and have it join right into the submental crease and then I make a little hash half-way between the central menton and the angle of the mandible and I drop two and one half centimeters below and make a small curved line there, and that's my no-fly zone.

That two and a half centimeters below has kept me safe because when we consider where the nerve resides, posterior on the angle of the mandible, irrespective of how much laxity or how heavy or how mature or aged that neck is, it's very firmly here with the facial artery and vein in the antegonial notch as we migrate anteriorly. Then of course we get some ptosis of the nerve, if they're a little bit older or have some variation where it could sag a little bit. Again, it makes its quick turn up toward the lower lip depressors halfway point along the mandible.

I don't go more posterior to the anterior board of the sternocleidomastoid and that has also kept me safe. With that, we have had less than 1 percent of marginal mandibular nerve paresis in our cycles of treatment.

Dr. Avram: I tend to do the treatments mostly in the submental area and sometimes I still draw it out as a matter of just doing it in a disciplined fashion. I map out about a centimeter below right at the submental cleft—just draw that line out. I'm basically staying medial and inferior but mostly medial to the area of where the marginal mandibular nerve is. So, it hasn't been an issue but the treatments that I'm doing are more conservative so they're more submental treatments and I'm not going as lateral as Dr. Shridharani. When I have patients who have more fullness going laterally, I'm more likely to use cryolipolysis in those patients.

Avoiding nerve damage hasn't been an issue for me, but I'm using Kybella more traditionally and more to the on-label FDA indication. Knowledge of anatomy and seeing where you are, knowing that there's a variation and that the marginal mandibular nerve can drop down further, as long as I stay medial to it, I stay safe. I haven't had an issue with the any of the alaryngeal nerves as well.

Dr. Sherman: For about the first year of performing this treatment, I stayed more anterior, but now I am using it more as a contouring agent and extending the treatment based on assessment, it really can be strategic contouring as long as we are very attentive to where we know the nerve is. Dingman and Grabb, in 1962, did a beautiful study of the anatomic path of that marginal mandibular nerve by dissecting 100 skulls in the sagittal plane. As Dr. Shridharani said, if your no fly zone is 1.5-2cm below that mandibular border up to 1cm in front of the anterior border of the masseter, that's really where the variability is as 81percent of the time the marginal mandibular nerve resides above the mandibular border, and 19 percent of the time it runs about 1cm below the mandibular border. Once you get past the masseter, the marginal mandibular nerve is headed toward the depressor labii so at that point, it's above the border of the mandible 100 percent of the time in the front portion of the mandible.



My initial treatment zones were anterior but then as I considered that creating a youthful jawline includes increased contouring laterally, I have extended my treatment zone. I pinch the skin together to assess the thickness and the level of the submental fat in the anterior and lateral submental area. We know from anatomic dissections that there's a tremendous amount of variability, but it tends to be thicker in the middle and then it wings out and has a variable thin layer as it goes toward the angle of the jaw.

After assessing the pattern and deposition of submental fat and subcutaneous fat in the lateral area anterior to the sternocleidomastoid, I will feather the

Kybella. Sometimes I'll even use 0.1ccs in that area to try to create that contour, staying careful to leave more fat than to take more fat because to take too much fat would be the bigger problem. But, I am enjoying contouring the lateral area anterior to the border of the sternocleidomastoid.

Dr. Avram: To the extent you're going out further and more laterally, especially if someone has more adipose tissue there, do you run a risk if you are feathering in those areas, that you're leaving a little bit more behind? You're not getting as much of a nice contour in those areas because you're moving around the area where you're close to the marginal mandibular nerve or are you not finding that?

Dr. Dayan: I don't think that's an issue. It kind of blends as you move your way out. I haven't seen any significant asymmetries from doing that because I feather as well, laterally.

Dr. Sherman: I haven't seen that. But I do think that in the more slender patient, as we go up laterally, it's very important to pinch the skin up in front, so that you're hitting the pre-platysmal fat and making sure you don't go into the platysma because we also know that there are very fine arborized branches of the marginal mandibular that are in the platysma.

I have a theory that some slender patients that have marginal mandibular nerve temporary palsies may be because it's actually hitting a platysmal branch, rather than actually hitting the main branch of the nerve.

If a patient is highly averse to potential downtime, treatment approach can be tailored to reduce the initial swelling and better assure their retention. Conversely, a more aggressive treatment initially may lead to more significant results quickly. For these patients, embrace, and even glorify, the swelling—be sure patients know to expect it and that it means the treatment is working. It may be beneficial to tell patients to send a selfie the day after treatment so that their swelling can be assessed in order to confirm that treatment was on target. Determining what motivates a patient and then designing a treatment approach that meets those needs is warranted.

In the authors' experiences, patients with a larger accumulation of fat tend to have the biggest reactions and should be counseled appropriately. The induced inflammatory panniculitis and discomfort can be alleviat-

ed with up to 600mg of ibuprofen just prior to injections.¹⁸ Ice is another effective option for helping to control pain.¹⁸ In fact, Dr. Sherman conducted a small in-office experiment when first starting to inject Kybella. Using physicians as patients, one side of the neck was injected with a field block prior to treatment and the other side with numbed with ice—one part alcohol, two parts water—prior to treatment. The side that was blocked tended to have slightly more swelling and bruising. The treated physicians found the ice was a better anesthetic.

While the authors agree that lidocaine prior to treatment for discomfort has not been a necessity, a local anesthetic with epinephrine may be beneficial in controlling the ecchymosis. (See sidebar "Are there Benefits to Using Anesthetic in Treatment?" on page 5 for more.)

None of the authors recommend using steroids to try to con-



GOING OFF LABEL: PHYSICIAN EXPERIENCE INJECTING IN AREAS BEYOND THE SUBMENTAL REGION

Dr. Dayan: Do you offer any off-label treatments with Kybella in your practice? I have treated some jowls and buccal pads, and tried it on the stomach and the triceps.

Dr. Shridharani: What was your experience with buccal fat? I've been curious but I haven't treated that area yet. Did you go intra-oral injection? Do a gingivobuccal sulcus?

Dr. Dayan: I injected subcutaneous. I've done it on two people. One is thrilled with the results—when she came back for her second treatment, she reported significant swelling, but she came back for second treatment. For the second patient, only one treatment has been completed so far.

Dr. Sherman: What has been your experience in treating the jowls?

Dr. Dayan: I've done two of those also. I did okay with them—I pinched them to make sure I injected into the fat. Of course, you have to be aware of the nerve, but I have not had a problem with it.

Dr. Shridharani: I've been really enjoying treating them, and often will do it simultaneously with the submental region, or in isolation as well. I've gotten really nice, early results with it, so I'm pretty excited about treating it. It doesn't require much product, which is a beauty. I'm only injecting about two or three sites with 0.2 ccs or 0.15 ccs, or something like that. So, I'm getting a lot of mileage out of just one vial, bilaterally. It's still kind of early. I have had some with transient neuropraxia or transient asymmetry from buccal branch, those terminal fibers. For the most part, we're seeing some really nice outcomes and changes.

I've ventured into several other parts of the body and seen some really nice results. I've done anterior peri axillary fat, arms, posterior peri axillary fat, an abdomen, chest, love-handles, periumbilical, inner and outer thighs, medial knee, suprapatellar, and calf and ankle.

Dr. Dayan: Are there any areas you would not treat with Kybella?



65-year-old patient: 1 Tx, 4 Vials Kybella in submental and jowl, jawline filler with Voluma.
Photos courtesy of Dr. Shridharani.

Dr. Shridharani: I won't treat above the jowl. I am fearful of other fat in the face. I have not injected buccal fat and I will not inject lower eyelid fat pads, which patients have asked me, as have other clinicians. I think the amount of retractions one can get is unpredictable. My biggest concern is causing a cicatricial ectropion, or of course, a retro-septal hematoma or any of the other traumatic injuries that could

occur from injecting this drug. I have a lot of respect for it, although you may not think that from the other areas that I injected.

Dr. Sherman: Have any of you treated “bra fat”?

Dr. Shridharani: I’ve seen some really good early outcomes with it, but I think when you’re injecting around the breast or breast tissue, you have to be very careful in knowing that it is actually subcutaneous fat. With the terminal extension of the axillary tail of Spence, from looking at NCI data we know that about 0.1 to 2 percent of breast cancer is found in that axillary tail of Spence.

The bigger concern or issue for me would be, if you are not screening patients, do you have an up-to-date mammogram, did you palpate the area, documenting that you don’t have any fibrosis or any mass or lesion. Then the patient comes back with a nodule secondary to necrosis, which you’re trying to create. Then, all of a sudden they come back six to eight weeks later, with induration. Is that breast cancer that you’ve unmasked, or is that just from the Kybella? Now you’re doing a fine-needle aspiration (FNA), or of course referring them out for an FNA or breast workup, or all these things. It takes a patient from wanting some fat taken out, to all of a sudden this scary process that wasn’t thought through.

Every area that I’ve gone off-label, I’ve really thought, and had a cognizant discussion with myself about what am I going to do here. What’s the complication? Can I handle that? I’ve discouraged a lot of people from starting to inject here because I don’t want to set the field back. We’re seeing some really nice changes in there and good skin retraction, because that skin’s a little bit thinner, so it tightens up pretty nicely.

The bigger picture and the bigger concern is making sure that it’s not accessory breast tissue that also swells, is painful with menses, or things like that. You have to ask a lot of questions that maybe most clinicians don’t routinely ask because they don’t do a lot of breast surgery.

Dr. Sherman: Have you had any surprises with off-label use, Dr. Shridharani?

Dr. Shridharani: Lower extremity has a lot of edema. We get a lot of dependent edema and that’s to be expected. We see that obviously in liposuction as well. We have to be very mindful of that type of stuff.

More than anything else, I’ve seen a lot of different changes in inner and outer thigh, calf versus ankle, medial or suprapatellar. Patients can go out dancing all night and be told that they were supposed to not do anything. They come back and they look like they have elephantiasis. You have to be really, really careful. That concerns me.

I have been a bit more gun shy about treating along the lower extremity after seeing some of my cases. They’ve all ended up having some very, very nice outcomes, but it requires a significant amount of handholding.

Dr. Sherman: When it comes to jowls, we have to remember that this is a permanent lifetime result. Anytime we’re near an area where there is a nerve there’s going to be a different level of finesse. Since all nerve weaknesses appear to be temporary, hopefully it is just a nerve irritation. With the anatomic variance, we always have to think about that risk-benefit ratio, and inform our patients of all risks and benefits when we’re dealing with uncharted areas.

trol post-treatment swelling, surmising that the brisk inflammatory reaction is part of the process necessary for ideal results.

EDUCATING STAFF FOR BETTER PATIENT COMPLIANCE

Staff play an important role in communicating with patients about the need for multiple treatments and reassuring patients who are concerned about side effects. Whenever possible the authors have found it very helpful to treat staff with Kybella. This allows them to fully understand the process and empathize with patients.

Undertreating is less than ideal. One treatment and one vial really equals essentially a non-treatment—patients will not see an improvement. These patients are going to be unhappy and think Kybella didn’t work and think negatively of the treating physician. The onus is on the clinician to use the requisite amount of product and the requisite number of cycles. Patients counseled appropriately will be more compliant and more satisfied because they understand this is a journey to a lifetime result. (See “Going Off-Label” on page 10 for more on how the authors are using Kybella in areas beyond the submental.)

EXPERT VOICES

A GATEWAY TREATMENT FOR MEN?

Dr. Avram: In my practice, on a percentage basis, we're seeing more men present for Kybella treatment than for toxins or fillers, which has been nice because it brings a new market to our office.

Dr. Dayan: I have seen this in my practice as well.

Dr. Sherman: And these are men who normally wouldn't come in for Botox or fillers. It's not your typical male seeking an aesthetic injectable. It's a new venue and a new gateway for them. Sometimes they're interested in other things, like Botox for crow's feet or laser hair removal.

Dr. Shridharani: I've found that nearly 40 percent of my Kybella patients are men. Of that group, about 70 percent are cosmetic procedure naïve. When I've followed that cohort out for about six months, depending on which group it was, either first or second, 38 to 45 percent have returned to the office within the first six months for a procedure other than Kybella. We've seen a lot of growth and a lot of interest in the male patient population in our practice, because of the way that we've marketed and positioned this.



55-year-old treated with Kybella: 2 Tx: 4 Vials; 3 Vials; Photos courtesy of Dr. Shridharani.



24-year-old treated with Kybella: 2 Tx: 2.5 Vials; 2 Vials; Photos courtesy of Dr. Shridharani.



44-year-old treated with Kybella: 2 Tx: 3.5 Vials; 3 Vials; Photos courtesy of Dr. Shridharani.

SAFETY OF TREATMENT

Kybella was nine years in the making, with 20 studies and approximately 2,600 patients in the studies. Now with 5-year long term data it is easy for a clinician to feel comfortable sharing the safety data with their patients. A follow up contour study with Kybella currently underway with about 500 enrolled participants is sure to soon provide even more definitive conclusions on the long term safety of Kybella.¹³⁻¹⁵

Despite Kybella being the only FDA approved chemoadipocytolytic agent, some physicians continue to use compounded non-branded deoxycholic acid formulations. The quality of these loosely regulated products is concerning. These formulations and their manufacturing processes have not been studied and have even been banned in European Union countries. With compounded formulations, physicians risk putting outcomes, their future, and the reputation of their practices on one compounding pharmacist. Kybella has a good manufacturing process that's been studied, with more than 2,500 patients phase 3 and 4 clinical trials. It's important to be able to trust what is being injected into the face or neck—our patients trust us and it's important to offer FDA approved products that have been studied for efficacy and safety.

(See "A Gateway Treatment for Men" on page 12 to read more about the authors' experiences with Kybella for male patients.)

A BRIGHT FUTURE

The authors agree that there appear to be endless possibilities with this first-in-class treatment of Kybella when you look at all the opportunities for fat reduction in strategic places. With a growing armamen-

tarium of minimally to noninvasive treatment options for submental fullness, the future looks bright for patients and physicians. ■

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THE ART OF SUBMENTAL CONTOURING: NOVEL TREATMENT APPROACHES FOR TOTAL FACIAL REJUVENATION

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1. An ideal cervicomenal angle (CMA) for a youthful profile and jawline has been shown to be:
 - a. less than 105°
 - b. between 105° and 120°
 - c. greater than 125°
 - d. between 120° and 125°
2. Accumulation of submental fat within the pre-platysma or sub-platysmal fat creates:
 - a. a less youthful appearance
 - b. a more youthful appearance
 - c. a more feminine profile
 - d. a more masculine profile
3. Patients with _____ are ideal candidates for minimal to non-invasive treatment options to eliminate submental fat:
 - a. a pre-platysmal fat compartment
 - b. a large platysma diastasis
 - c. large digastric muscles
 - d. obvious platysmal bands
4. Cryolipolysis is delivered via a vacuum applicator and applies temperatures of _____ to the skin for approximately _____ minutes per treatment.
 - a. 10°C/30
 - b. 15°C/60
 - c. -10°C/60
 - d. -10°C/45
5. The authors concur that the FDA-indicated _____ of Kybella per injection is ideal for treatment.
 - a. 0.1ccs
 - b. 0.2ccs
 - c. 0.3ccs
 - d. 0.4ccs
6. Although the FDA-approval of Kybella was based on study of six single treatments administered at intervals of no less than 1 month apart, the authors note that in practice, an ideal treatment protocol is:
 - a. 3 to 4 treatments at 8-week intervals
 - b. 2 treatments at 4-week intervals
 - c. 6 treatments at 6-week intervals
 - d. 8 treatments at 4-week intervals
7. The authors and studies have found that induced inflammatory panniculitis and discomfort of injections can be alleviated with _____.
 - a. steroids
 - b. a cold compress
 - c. up to 600mg of ibuprofen
 - d. Over-the-counter acetaminophen
8. While the authors agree that lidocaine prior to Kybella treatment for discomfort has not been a necessity, a local anesthetic with epinephrine may be beneficial in controlling _____.
 - a. skin necrosis
 - b. temporary "bullfrog" look
 - c. temporary marginal mandibular nerve paresis
 - d. ecchymosis

ACTIVITY EVALUATION

Did the program meet the following educational objectives?

Agree

Neutral

Disagree

Discuss ideal proportions of facial anatomy and the affects of submental fullness on the individual's appearance.

Articulate the method of action of deoxycholic acid and identify its role in the management of submental fat.

Identify ideal treatment parameters for deoxycholic acid injection that optimize patient comfort and long-term outcomes.

Determine optimal strategies for use of deoxycholic acid along with other interventions that target submental fullness.

Describe effective strategies that incorporate targeted treatment of the submentum into a pan-facial rejuvenation strategy.

Your responses to the questions below will help us evaluate this CME activity. They will provide us with evidence that improvements were made in patient care as a result of this activity as required by the Accreditation Council for Continuing Medical Education (ACCME).

Do you feel the program was educationally sound and commercially balanced? ____ Yes ____ No

Comments regarding commercial bias:

Rate your knowledge/skill level prior to participating in this course: 5 = High, 1 = Low _____

Rate your knowledge/skill level after participating in this course: 5 = High, 1 = Low _____

Would you recommend this program to a colleague? ____ Yes ____ No

Do you feel the information presented will improve/change your patient care? ____ Yes ____ No

Please identify how you will improve/change:

____ Change the management and/or treatment of patients. Please specify:

____ Create/revise protocols, policies, and/or procedures. Please specify:

Please identify any barriers to change.

____ Cost

____ Lack of time to assess/counsel patients

____ No barriers

____ Lack of consensus or professional guidelines

____ Lack of opportunity (patients)

____ Other. Please specify: _____

____ Lack of administrative support

____ Reimbursement/insurance issues

____ Lack of experience

____ Lack of resources (equipment)

____ Patient compliance issues

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