

Fat Reduction Using Phosphatidylcholine/Sodium Deoxycholate Injections: Standard of Practice

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Abstract The practice of injecting phosphatidylcholine/sodium deoxycholate compounds into subcutaneous fat is growing rapidly. As with any new procedure, a standard of practice should be developed so that practitioners maintain patient safety as the primary goal. Efficacy and predictability of outcome are another priority. As injection lipolysis, also known as “lipodissolve,” becomes more accepted, many standards are being set, such as indications, contraindications, acceptable postinjection sequelae, best regions to treat, regions to avoid, and expected outcomes. This article establishes a basis of practice for the practitioner interested in adding this procedure to his or her repertoire.

Keywords Deoxycholate · Injection · Lipodissolve · Lipolysis · Phosphatidylcholine · Standard of practice

The practice of injection lipolysis for spot reduction of small localized fat deposits is growing rapidly. Efficacy and safety have been established over a period of 12 years. A compilation of data from 75 worldwide practitioners [1] and a corroborating study from the United Kingdom [2] reflect similar outcomes and a parallel safety profile (Fig. 1).

The efficacy of mesotherapy—multiple superficial injections using a “cocktail” of varying ingredients—used for medical or aesthetic indications has not been established [3]. Because the practice of mesotherapy has not been standardized with respect to indications, formulations,

location, and technique of administration, the practice cannot be accurately evaluated.

Although mesotherapy is the basis for the origin of injection lipolysis, the two processes are distinctly different (Table 1) [4, 5]. Mesotherapy is considered to be a technique for delivering minute amounts of pharmaceuticals intradermally, or for delivering small amounts of combined medications into the superficial tissues to treat ailments such as hair loss, gastrointestinal disturbances, or sports injuries. Injection lipolysis uses a single formula aimed directly at the target: subcutaneous fat.

For any new and evolving procedure, standards of practice must be established to maintain safety and efficacy. Those practicing within the standard of care will be able to achieve reproducible results. Expected sequelae can be minimized, and complications should be rare. Medical malpractice carriers are more likely to insure educated injectors practicing within approved guidelines than those without good training, consistent selection criteria, and precise treatment methods.

For the past 5 years, many physicians worldwide have decried the use of injection lipolysis, claiming a lack of both scientific data and longevity of treatment experience [5–9]. Those claims can no longer be supported because a plethora of data on the subject have been published. As interest in the process grows, refinements, precision, and finesse in treatments have been developed to such a degree that reasonable predictability of results is a reality [10–22] (Fig. 2).

The standard of practice for injection lipolysis involves multiple factors. The most important of these are the injector’s credentials, training, and adherence to protocol. A licensed and experienced physician interested in practicing injection lipolysis should carefully choose sources of training and should attend one or more training courses

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Fig. 1 Female patient with bulges below her bra line before injections, (*above*) and 3 weeks after injections with PC/DC into and below the area of maximal protrusion. In small, well-localized areas of lipodystrophy, a significant reduction of fat and overlying skin retraction can be seen

Table 1 Difference between mesotherapy and injection lipolysis

| Mesotherapy | Injection lipolysis |
|---|--|
| Nappage, point-to-point, single injection | Grid type pattern 1.5 cm apart, perpendicular injections |
| Results are temporary | Fat necrosis is permanent |
| Formulas are anecdotal | Formula is pharmaceutically driven |
| Depth is superficial (4–6 mm) | Deeper pattern (6–13 mm) |
| Multiple treatment goals | One focused goal: fat reduction |

taught by experienced physicians who practice the technique routinely and have published research in recognized journals. An extensive review of the literature by the student before taking any teaching is recommended. The physician's education process should have "hands-on" training because many facets of injection lipolysis cannot be taught by lecture alone. Patient selection, the feel of responsive versus nonresponsive fat, the amount of skin excess that can be corrected, and the surface area that can be safely treated in a single session all are factors better conveyed in person than in a written treatise.

A source of controversy worldwide is the lack of safety and efficacy recognition by the Food and Drug Administration (FDA), Medicines and Healthcare products Regulatory Agency (MHRA), or any other health regulatory agency [23–24]. Currently, in the United States, the practice of injection lipolysis is state regulated [25]. Compounding pharmacies, which generally supply the various lipolytic injectables, are under the supervision of each individual state, and guidelines vary. Recently, the Kansas Board of Healing Arts deemed that injection

lipolysis was not to be performed in that state except by a licensed physician either participating in research or following certain guidelines [26].

A ban on the use of Lipostabil in Brazil caused major controversy [27] and is partly to blame for the cloudy reputation of injection lipolysis. The main factor causing Agencia Nacional de Vigilancia Sanitaria (ANVISA's) ban on Lipostabil for subcutaneous fat injections in Brazil was reluctance on the part of Aventis to stand behind this use of their product for the purpose of fat reduce [28]. A secondary problem in Brazil and in many other countries is clandestine or "charlatan use" of the injections by unlicensed, nonmedical practitioners [29].

Injection lipolysis is a medical procedure and should be performed by a trained physician. A nurse, physician assistant, nurse practitioner, or aesthetician not licensed to practice independent medicine cannot evaluate, diagnose, and treat patients safely, effectively, or legally. The history, physical examination, consultation, evaluation, diagnosis, and treatment should be performed by a physician who has completed a certified training course. Licensed nurses should be able to assist with injections only after evaluation, consent, and marking has been done by the physician, with the physician directly supervising. The practice of having an unsupervised nurse, aesthetician, or other paramedical personnel performing these injections is not medically safe, nor is it legal in most states. The basis for this recommendation stems from the general surgical "golden rule": do not perform procedures if you cannot fix the complications.

Although complications from injection lipolysis are very rare, most nurses, aestheticians, and paramedical personnel cannot write a prescription for antibiotics, Benadryl, compounds for hyperpigmentation, or pain medication. They certainly do not have the training or expertise to treat local skin loss, which may require debridement, hyperbaric oxygen, and later excision and closure (Fig. 3).

The growing Medspa industry, focused on noninvasive procedures, is an attractive source of noninvasive body contouring. The serious nature of injection lipolysis should not be minimized. Although safety data currently are excellent, a poorly chosen patient or location for injection, or a quick and minimal treatment by untrained or unlicensed individuals could easily result in a poor result, an atypical mycobacterial infection, or an uneven contour [30]. Also, if the injector is not highly knowledgeable regarding the underlying anatomy of the injection region, these injections could cause skin loss, hematoma, muscle injury, or nerve damage. There have been several reports of skin necrosis or multiple areas of skin ulceration and blistering occurring when individuals ordering Lipostabil off the Internet have self-injected after communicating with others to learn injection techniques in Internet chat rooms [31].

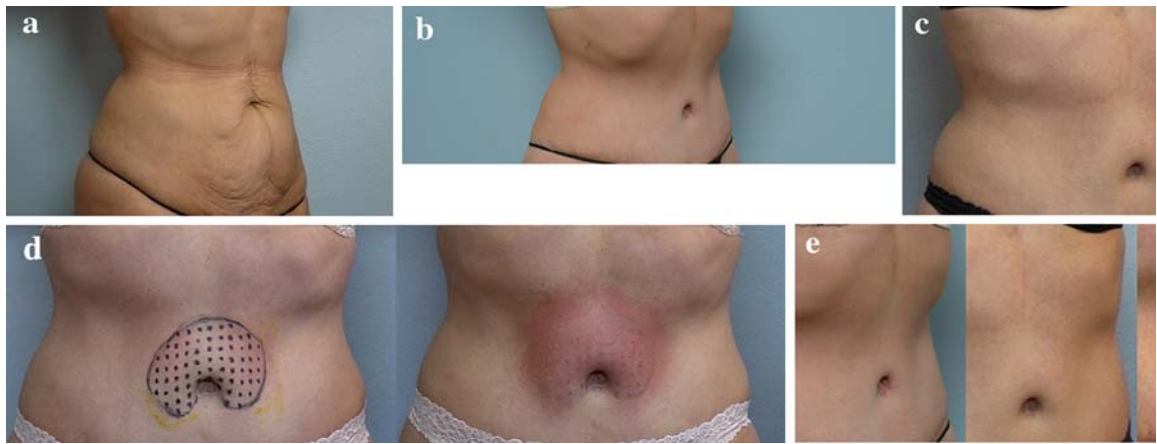


Fig. 2 (a) A 38-year-old mother with severe post-childbearing skin excess, striae, and diastasis recti. (b) She underwent an abdominoplasty and had an excellent result at 2 months. (c) However, 8 months after the procedure, she reported a periumbilical fat deposit with slight weight gain (10 lb). The weight gain showed in her clothing and was a source of distress. Physical examination confirmed that she did not have a periumbilical recurrence of her preoperative diastasis recti. (d) Markings and grid pattern for correction of this localized deformity. To reduce the protrusion, 15 ml of PC/DC solution was

superficially injected using a 1-cm grid pattern. The photo on the right shows swelling and erythema expected 15 min after injection. (e) Early 2-month postoperative abdominoplasty result followed by mild periumbilical deformity with supraumbilical protrusion (*center*). The far right figure is the result 2 months after injection lipolysis to treat this postoperative deformity. The correction, without any weight loss on the part of the patient, shows a significant improvement. The supraumbilical concavity is not as pronounced, but the patient had no protrusion, and was very satisfied with the outcome



Fig. 3 (a) A 48-year-old patient who underwent 18 injections of 0.4 ml per injection site located 1.5 cm apart for correction of a postliposuction deformity on her right inner thigh. This procedure was performed by a nurse with no experience, but following verbal instruction. The patient's history is significant in that she underwent the liposuction, which she characterized as "aggressive," 11 years previously. (b) Same patient 2 weeks later. The area is red and indurated, and has clinical skin loss plus a large area of underlying fat

necrosis. (c) Same patient 3 weeks after the previous photo. She has had hyperbaric oxygen therapy plus osmotic dressings, with a dramatic reduction in the surface area of skin loss. If faced with an area of impending skin loss, immediate treatment with hyperbaric oxygen, if available, is recommended to minimize the degree of ultimate deformity. (d) Same patient, with thigh skin surface well healed. Note the discoloration is prominent, but there is a relative lack of surface irregularity. Courtesy Dr. V. A. Ward

Complications and Their Treatment

Seven instances of skin loss in small areas have been reported by both new and experienced physician injectors. Close attention to the location of the needle tip when injecting is essential. Large amounts of formula injected intradermally or a concentrated solution can be catastrophic. If the injector is using a multi-injector or Mesorelle type needle cluster, the depths of the needle tips may vary significantly, and the risk of not injecting the target tissue is high, especially if the procedure is performed by nurses or by inexperienced physicians.

Poor judgment in choosing an injection site has caused several instances of draining fat necrosis in multiple areas and overlying skin loss. A common factor in these cases has been ischemia, induced surgically either by aggressive liposuction or by physicians treating extremities or thick abdominal fat pads in regions with a compromised blood supply.

An additional cause of regional blistering and localized skin loss appears to be excessive compression. Although external compression has been used successfully for many years in conjunction with liposuction, it currently is not recommended for injection lipolysis patients. The difference between the two patient populations is that the excess fat is physically removed during the liposuction/Vaser liposelection treatments, but the fat remains behind in the injected patients. Thus, when postoperative swelling occurs, there is not a large volume of residual swollen fatty tissue next to the small veins and arteries supplying the superficial tissue in liposuction patients. However, with injection lipolysis, experience has shown that profound swelling, sometimes up to three times the original volume of the area, can be seen in the first few days after treatment. If there is internal compression of the blood supply by swollen adjacent tissue, compounded by external compression, the intravenous and possibly the intraarterial pressure can be exceeded by external pressure, totally cutting off the regional blood supply. Although this effect can be reduced by lowering the total dose administered, or by diluting the injection formula, the best decision is to avoid injecting these areas. If there is doubt about the degree of risk a potential treatment site poses, a “test” injection—a single 0.4-ml dose of the formula to be used—can be injected subcutaneously to determine the advisability of treating the area. For any risky patient or area, treatment should be declined by the injecting physician. Only for a patient with a relative contraindication (DD1) should a test dose be used.

Another potential complication recently reported by several injecting physicians is the development of clusters of small superficial blood vessels in the treatment region. While the angiogenesis stimulated by injection lipolysis

can improve the appearance of aging, lax skin, in relatively ischemic areas, this reaction can be observed as persistent and unsightly telangiectasias or prominent veins. It is difficult to predict the development of this reaction. Two predisposing factors appear to be treatment of a relatively ischemic region, such as the distal thigh, or aggressive treatment of an area with an extreme degree of subsequent fat necrosis and a strong development of collateral circulation.

Risky patients are frequently identified based on a combination of physician experience, known risk factors, a thorough history, physical examination, and a review of the patient’s goals. Only a physician has the knowledge and skills to identify, through careful examination, patients who may have areas unsuitable for treatment, as indicated by signs of possible local ischemia, previous surgery, or unsuitable local and subcutaneous tissue anatomy. If guidelines for patient selection are not followed closely, bleeding, extensive bruising, infection, and local skin loss could possibly occur. An experienced and careful physician can choose good candidates for injection lipolysis based on a thorough history of current and previous medical conditions; medications and allergies; previous surgery, liver, renal, and cardiac status; pregnancy/breast feeding; bleeding dyscrasias; and psychological issues such as expectations and long-term commitment to maintenance of a healthy lifestyle. The liability incurred with the performance of any aesthetic procedure is not inconsiderable. Independent injectors who are not supervised medically will have no defense against unhappy patients if a complication or less than expected outcome occurs.

The physician should see, evaluate, and treat every patient receiving an injection lipolysis treatment. It is highly recommended that although a nurse may oversee the logistics of the practice and assist the physician, he or she should not be the primary provider of the injection lipolysis program in a given medical practice.

Training

The physician and any assistants should be trained well by a course offering certification and taught by reputable physicians, not by paramedical personnel. Mesotherapy training covers a broad area but is not considered adequate for injection lipolysis. The training program should be given by one or more physicians well published and experienced in the field. Both didactic and hands-on training is desirable.

The apparent ease of “just an injection” belies the complexity of the decision-making process with its questions: where to treat, how much to inject at each point, how far to space the injections. Is this a good area to treat? Will

this particular area or patient even respond to treatment? Although the mechanics may seem simple, the decision-making process is much more involved. This is crucial with facial treatments because a small overcorrection could result in a permanent contour abnormality/deformity and an adverse aesthetic result.

Certified training should offer a discussion of the history and origins of injection lipolysis, both basic and applied science, and guidelines on the different types of formulas available as well as the maximum safe dosage. The pharmacologic basis of action and formula additives as well as their potential risks and benefits should be discussed.

Patient evaluation and selection, indications and contraindications to treatment, and management of patient expectations should be thoroughly taught. The course should include a session on evaluating a site for responsiveness to injection. Some areas tend to respond poorly to injection, whereas in other areas, a dramatic improvement in contour can be seen. Expected sequelae should be reviewed and differentiated from real complications. The injector should learn how to treat the complications and how to manage the patient who perceives a less than expected aesthetic result.

After the basic didactic information, a thorough review of necessary and optional equipment should be offered. Various techniques of pretreatment evaluation, measurements, and photographic standards are a necessity. Documentation of the patient's preinjection status is an important part of the patient's medical record. The instructor should be able to teach the physician to judge the best area or areas to treat, and should help trainees learn how to evaluate the safe maximum surface area that can be treated in a single session. Contour variations should be taken into account when injections are performed. The injection technique should not be uniform when hills and valleys are present.

The various injection techniques including use of a syringe, use of a multi-injector device such as the Mesorrelle, and use of a mesogun should be covered in the course. Depth of injection, distance between injection sites, volume, and dilution of solutions are essential criteria for a successful outcome.

After a verbal review of this information, an interactive training session with actual patients receiving injections should follow. This is a valuable source for reinforcement of the didactic training, and it significantly reduces the chance that many complications will occur the week after training [31].

Malpractice insurance and FDA issues should be discussed. The laws vary from state to state in the United States and from country to country in the world, and the national regulatory agency may not govern the compounding pharmacy, which is the most common source of injectable lipolysis formulas. In the United States, it is most

common for the individual states to regulate compounding pharmacies, and thus injection lipolysis. The patient–physician–pharmacy triad must be maintained [25] for the process to remain legal. A doctor's office may not keep multiple vials of lipolytic agents on hand. Each must be prescribed by the physician for a specific patient. The pharmacy can compound only 100 vials or fewer of a formula submitted by the physician each day. Any complications should be reported so that both the pharmacy and physician are careful to address problems before a widespread reaction occurs.

A resource for answering further questions should be an ongoing benefit of the physician's training. The training agency should provide assistance to its trainees in answering questions and troubleshooting problems so that the new injectors have a resource if it is needed.

Choosing a Patient

Careful patient selection is essential for success. The procedure works only on subcutaneous fat. Soft fat responds better than firm or fibrous fat. Also, areas of mild skin laxity without underlying fat will not respond to these injections.

Younger women (<30 years) and men often tend to have this firm, more fibrous fat. Also, in any given patient, the fat often tends to be firmer on the buttocks, outer thighs, flanks (love handles), and around the knees. It often is softer on the abdomen, middle back, inner thighs, and sometimes under the chin. These areas can sometimes be dramatically responsive. The best way to assess likely responsiveness is through feel and palpation of the subcutaneous tissue. However, this requires some experience and is very subjective. It may be possible to use ultrasound to assess tissue density if suitable equipment can be found.

Patient Selection and Indications

At least one of seven criteria [32] should be met when a patient is seriously considered for injection lipolysis of the limbs, torso, or both (Table 2). The universal indication is a

Table 2 Indications for injection lipolysis

1. Small soft areas of localized fat
2. Lipomas, especially small, soft, multiple lipomas
3. Postliposuction deformities
4. Skin contour irregularities due to traumatic fat necrosis
5. Cellulite
6. Post-fat grafting deformities
7. Depressed scars with adjoining areas of protruding fat

patient with a small, well-localized deposit of subcutaneous fat. Large fat deposits, fibrous fat, or thinner fat deposits spread over a broad surface area do not respond well to treatment by injection. Generally, a volume of 100 to 500 ml is considered ideal, especially if the lipodystrophic region has soft, spongy fat.

The second indication [33] is a lipoma or multiple lipomas. Injection lipolysis is ideal for patients with numerous lipomas because there are no incisions. More than one treatment may be necessary to obtain the best result.

A third indication for injection lipolysis is cellulite. There is a specific technique for treating irregular contour deformities. The hills and valleys of the cellulite landscape respond better to minimally invasive treatments such as injection lipolysis than they do to surgery.

A fourth potential use for these injections is postliposuction deformities and traumatic injuries to the subcutaneous layer that cause localized fat necrosis. Treatment is similar to that for cellulite in that the hills and valleys are treated separately, resulting in a smoother, more even contour.

Plastic surgeons and dermatologists who perform fat grafting may find that occasionally an area may have too much “take” of the injected fat, or the fat injected may “take” unevenly. Injection lipolysis offers an excellent nonsurgical alternative to surgical removal of excess fat. Because minute amounts can be used with each injection, a precise result can be more easily obtained with less risk and “down time” than a surgical revision may create. These treatments provide a more predictable outcome than injection with steroids.

Depressed scars [34] surrounded by areas of protruding fat also are well treated with a combination of injection lipolysis and collagenase injections. A good example of a candidate for this treatment is a patient who after one or more cesarean sections has a depressed lower abdominal scar accompanied by overhanging skin and a small amount of soft abdominal fat.

Patient History

The physician should personally evaluate each candidate for injection lipolysis. A history of previous treatment—of any type—to the desired region should be elicited. Current medical conditions, allergies, routine medications and supplements, previous surgical history, and family history should be obtained. A social history is helpful in determining how the temporary deformity will be tolerated. The areas the patient wants to have treated should be discussed, followed by a thorough physical examination.

The patient’s goals and expectations should be reviewed. This is one of the most important points of the initial patient interview. If the patient really wants a surgical result, then liposuction or dermolipectomy is recommended. If the patient has only a small localized region of diet- and exercise-resistant fat deposits, both authors would consider him or her a candidate for injection lipolysis if subtle improvement is acceptable to the patient.

Recovery issues also may be a determining factor for the patient. Although no “down time” is required for any area treated with injection lipolysis, the temporary deformity can be significant. Patients receiving injections in the neck and jowl area may need to avoid social engagements for about a week because they may be fairly swollen and mildly bruised. Although treated body areas are easier to camouflage, temporary swelling may restrict clothing choices and activities.

If the patient with an area of fatty excess more than 500 ml wants a single treatment, desires a dramatic change in contour, and can afford to take time away from work, school, or daily obligations, a surgical option may be best. If the patient has a 100- to 500-ml excess of localized fat, cannot take time off for recovery, and does not mind two or three injection sessions, then injection lipolysis might be a good choice. Although not absolute, these rules are reasonably accurate guidelines [35].

Patient Selection: Facial Injections

Care must be taken in selecting patients for chin and jowl treatments. Again, only soft subcutaneous fat responds well. Sometimes the patient may think he or she has a problem with fat under the chin when in fact there is just loose skin, connective and muscle tissue that would benefit only from surgery. If treatment is attempted when the subcutaneous fat layer is very thin, it becomes thinner. This can worsen the gaunt appearance of the neck by increasing the prominence of the platysmal bands and the appearance of a witch’s chin.

Other patients may think they have a double chin due to prominence of subcutaneous fat when in fact there is none. They may have an angled appearance of the chin/neck due to their individual anatomy such as a small/short mandible, low hyoid bone, and/or an anteriorly positioned thyroid cartilage. Careful palpation will show the absence of subcutaneous fat. Such patients should not be treated, even though they may appear to have an obvious “double chin,” because they will not respond at all. Although jowls respond extremely well as a rule, with a dramatic improvement in the degree of hanging skin, the skin and fat quality definitely directs the final outcome. The puffy area just behind marionette lines should be treated with extreme care, if at all. It is possible to overinject this area, causing a

Fig. 4 Correction of prominent jowls. Photo courtesy Dr. Palmer



“hollow” that then needs to be injected with fat to restore an aesthetic appearance (Fig. 4).

Evaluating Skin Quality

With all patients, skin elasticity must be considered in the decision about the kind of aesthetic improvement they might receive and whether to treat (or continue treating) or not. Although in many cases, skin retraction has been documented with treatment [36], it is never guaranteed. Patients who already have skin laxity, striae, platysmal banding, or pendulous skin are advised that surgery may be much more beneficial than injection lipolysis (Fig. 5).

Contraindications

Clearly, not every patient seeking treatment should receive injection lipolysis. The injector needs to take adequate time for thorough discussion of the medical risks and benefits as well as the social issues and expectations. There are absolute contraindications (situations in which no treatment could be justified) and relative indications. Considering both, the patient needs to be thoroughly interviewed and evaluated before any treatment should be considered [35].

Absolute Contraindications

- Age younger than 18 years
- Pregnancy
- Breastfeeding
- Fully anticoagulated patient receiving Coumadin, Plavix, or heparin
- Current (or recent) serious or significant illness or active infection
- Known allergy to soy products or any ingredients of the injection compound (unlikely)
- Injections for breast reduction (if breast cancer develops subsequently, the physician will be liable)

- Insulin-dependent diabetics with unstable diabetic control or impaired circulation
- Severe generalized obesity (body mass index [BMI] >30)
- Previous significant adverse reaction to this treatment
- Severe needle phobia
- Immunocompromised patients such as transplant recipients and those undergoing chemotherapy



Fig. 5 Skin quality. *Above:* The irreparably damaged skin does not lend itself to correction with either liposuction or injection lipolysis. *Below:* This patient's skin is ideal for treatment using either method. The small amount of fat present in the lower patient's abdomen makes her an ideal candidate for injection lipolysis

- An expectation that the treatment will absolve the recipient of all health and weight maintenance issues

Relative Contraindications

- Unrealistic expectations with regard to outcome
- Microangiopathy or vascular insufficiency of distal extremities. The injection site is not the extremity area.
- Autoimmune conditions such as scleroderma, Sjogren's syndrome, lupus, and the like. Patients with rheumatoid arthritis and Hashimoto's thyroiditis usually can be safely treated.
- Diabetes type 2
- Unstable hypertensive or cardiac patients
- Patients recently treated with chemotherapy and those with other immunocompromised states
- Patients with human immunodeficiency virus (HIV), although the HIV "buffalo hump" responds well to injection lipolysis
- Patients receiving aspirin or nonsteroidal antiinflammatory agents
- Patients receiving high doses of steroids
- Patients with liver or renal failure
- An open sore or localized skin conditions in or near the treatment area
- Active eczema or psoriasis in or near the treatment area
- Inability or refusal to follow a diet and exercise maintenance program

Steps in Preinjection Evaluation and Documentation

1. Thorough consultation and explanation of the treatment process
2. Full medical history and examination as appropriate
3. Accurate standardized photography of the treatment region with minimal, nondistorting clothing
4. Weight measured, not asked
5. Tape measurements of the treated area if possible (standardized as far as possible by measurement up or down from a fixed anatomic landmark). Retractable tape measure available in fitness stores should be used because this reduces the variability of tension in pulling the measuring tape tight.
6. Skin fold caliper measurements of the most prominent portion of the treatment area, measured from a fixed landmark for reproducibility. Frequently, three measurements are taken, and the average is recorded.
7. Outline drawn around the treatment area by the patient to document his or her desired region of treatment. This eliminates any errors in communication between the patient and the physician about the exact site of treatment.

Informed Consent

In the United Kingdom, informed consent is a lengthy consensus of risks and benefits agreed upon by the members of the British Association of Cosmetic Doctors (BACD) who are part of the British "self-insurance" consortium. In Britain, the previous commercial malpractice insurers withdrew coverage due to the MHRA controversy. The MHRA now agrees that each individual medical practitioner has the right to practice medicine independently. If the physician who evaluates the patient thinks, in his or her best medical judgment, that the patient has a condition best treated by injection lipolysis, then that practitioner may write a prescription for the injection formula to be used with that individual patient and may treat that person. However, the physician cannot make claims of success that it may not be possible to deliver. Inappropriate claims are prosecuted in both Britain and the United States.

In the United States, the patient should receive full disclosure—that this process is neither approved nor regulated through the FDA, although the FDA approval process is underway. The importance of maintaining the pharmacy–patient–physician triad model should be reviewed, and the process before, during, and after the injections should be explained. The patient should receive a thorough explanation of the risks and benefits of treatment, as well as its considerable limitations. This part of the process should not be hurried or glossed over.

The entire process should be explained to the patient, from pretreatment through documentation, marking, preparation, injections, immediate sequelae, and a day-by-day range of progress from day 1 to 1 week. The sequelae are expected and not considered complications. Considerable swelling, itching, redness, and bruising, as well as some discomfort are expected, much as one might see with liposuction.

Landmarks of treatment progression should be explained, such as the probability that no contour improvement will be seen until week 4 to 6 after injection. The possibility of hyperpigmentation, skin loss, prolonged pain, swelling or tenderness, late onset of hives or itching, and skin contour irregularities should be reviewed. Emphasis should be placed on the fact that more than 12% of patients experience disappointment in the final outcome, as the degree of aesthetic improvement may not meet expectations.

To be effective, informed consent should be explained to the patient, and a signature by the patient should be obtained before *each* treatment. It is not sufficient to have the patient initial the old consent, or for the injecting physician to assume that the patient remembers the possible complications from review of the last injection. The consent should include a list of both the expected sequelae

and the possible complications, with a distinction as to which is which.

Choosing a Site to Inject

Generally, the patient strongly directs the choice of treatment areas. However, if a desired treatment site is inappropriate, the injecting physician should discuss why injection lipolysis would not work well in this region.

Usually, the abdomen and back roll regions in nonobese patients are excellent sites to treat. Flanks are responsive if the fat is soft and slightly pendulous rather than firm, flat, and fibrous. The submental neck and submandibular jawline are very responsive when the correct technique is used.

Upper arms, thighs, and knees get mixed reviews. The quality and quantity of fat determines the degree of responsiveness. If the upper arms are slightly flabby with soft fat, an injection from the bicipital groove anteriorly to the triceps groove posteriorly can really improve skin quality and reduce the arm diameter by as much as 1 cm with each treatment. However, if the skin excess is prominent, the area has been surgically treated previously, the area is too large to see a good result, the fat is fibrous, or the injector perceives that the degree of probable improvement will not meet the patient's expectations, then treatment should be declined.

Safety is Paramount

The injector should never inject any area circumferentially—around a limb or around a torso—especially with a high dose of concentrated solution. The swelling can be much more severe than that seen with liposuction due to the intensity of inflammation that the solution initiates. The possibility of skin loss in this situation is high. The degree of patient discomfort would be extreme, and the small possibility of a compartment syndrome should not be discounted.

Skin distensibility is an emerging factor for predicting potential skin loss. If a patient has thick taut skin in a treatment region, the treatment should be avoided, or a test pattern should be performed using a minimal 0.1-ml dose per injection site. Areas previously treated with liposuction are at risk due to the nondistensibility of the subcutaneous “compartment” that can occur when tethering scarring is present. Patients with large volumes of highly concentrated lipolytic solution can swell tremendously. If they wear a tight compressive garment after injection, the swelling combined with external pressure can create areas of blistering or skin loss, especially at locations where the girdle or tight jeans dig into the underlying tissue.

The distal extremities also are a “forbidden” zone. Even if the patient has no apparent circulatory insufficiency, the risk of treating these areas is not worth the mild improvement that could be obtained. Treating knees is unwise as both young and older patients have reported small areas of skin loss or delayed healing. A small test dose would be strongly recommended for patients considering injection lipolysis in the knee region.

Areas to Avoid

Injectors should avoid treating any area distal to the patella, forearms, or breasts. It also is recommended that practitioners stay away from any area in the face above the jawline. Lower eyelid fat pad injections are not particularly effective and fraught with risk. Only if the injector is very experienced (i.e., has managed more than 100 cases), should he or she inject the lower eyelid fat pads with a very small dose of phosphatidylcholine/sodium deoxycholate (PC/DC). However, if the injector is not a plastic surgeon and cannot repair a potential complication stemming from a lower eyelid injection, then the patient should be referred to an appropriate caregiver. It is recommended that injectors avoid any area where the fat pad is particularly thin, such as the epigastrium, because underlying muscle may be inadvertently injected. Physician injectors should stay away from regions that have a large amount of skin laxity but little fat, especially in the central neck. Any area with a large fat deposit should be treated surgically.

No fat deposit exceeding 500 ml can be corrected reliably with injection lipolysis. Although the patient may claim that “anything would be an improvement,” there have been multiple reports of patient dissatisfaction and requests for refunds, even if a disclaimer had been given and is well documented. If the patient expresses an expectation that cannot be met and the area is risky, treatment should be declined.

Formula/Additives

In standard practice currently, Lipostabil is used in Europe, and PC 50/DC 42 type compounds are used in the United States. Approximately 70% of all lipolysis practitioners use these formulas or a variation [37]. Additives such as vasodilators (procaine, lidocaine, pentoxifylline), local anesthetics (bupivacaine), and vitamins such as alpha-tocopherol or vitamin B complexes are traditional but have not been scientifically proven to improve the final result. In fact, one dispersion study [26] described pentoxifylline added only to the right side of the abdominal injection

formula. To both formulas, equal volumes of methylene blue were added.

After injection of the formulas, several areas of liposelection were performed in other nonadjacent body regions. The half of the abdomen injected with the vasodilator additive had very little residual blue discoloration remaining in the subcutaneous tissue, whereas in the other half, the plain formula appeared still to be strongly present in the abdominal fat on the left. Although vasodilators may deliver the substance to the tissue more quickly (the theory behind vasodilator use), it also appears to hasten its disappearance from the target tissue.

Injectable vitamins also are a traditional ingredient in many mesotherapy and injection lipolysis formulas. Although the vitamins are considered antioxidants, they also cause a lathyrogenic effect on skin. Few patients would welcome thinning of the overlying skin, so vitamin E is not currently recommended as an additive.

Vitamin B complex also is a popular additive, especially in Europe. Although rare, the potential for an anaphylactic reaction to injected vitamin B is possible. Unless a strong lipolytic boost can be attributed directly to any vitamin complex, it is recommended that oral supplements be used rather than an injectable additive.

Effect of Dilution

Currently, the standard maximum dose of phosphatidylcholine per injection session is recognized as 2,500 mg. Although some practitioners have treated patients with slightly higher doses, there is a clear dose-related increase in nausea, vomiting, and lightheadedness with larger injection volumes. In an effort to increase the surface area that can be treated in a single session, many physicians dilute the solution to increase the available volume.

As might be suspected, both histology and dispersion studies show a decreased lipolytic response with solution dilution. Although a 25% reduction in PC/DC per milliliter still appears to diffuse smoothly, creating a definite clinical change, reduction of the solution's strength by one-half strongly reduces both efficacy and diffusion properties (Fig. 6).

Technique of Injection: Spacing, Depth, Volume per Injection, and Maximum Dosage

Although a modest amount of fat reduction can be seen when injections are somewhat random, precision in injecting the solution can maximize the subcutaneous fat loss per injection session. The need for injecting only to a certain volume using a small range of formula volumes per injection and actually measuring the distance between

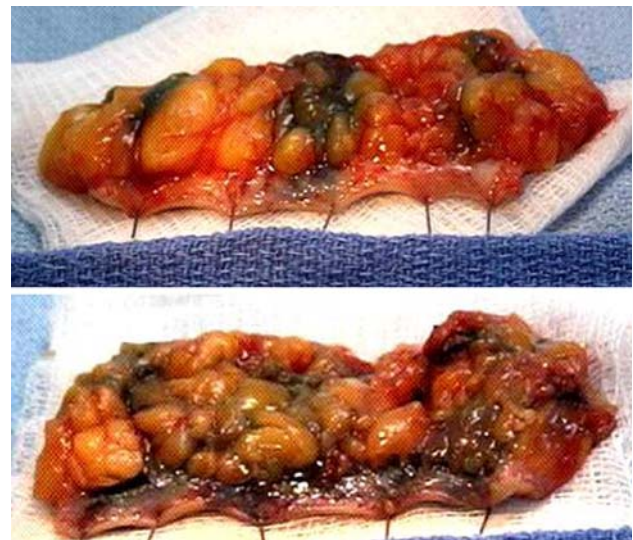


Fig. 6 The effect of dilution on dispersion. *Above:* PC25/DC21. *Below:* PC50/DC42. By diluting the standard formula by half, the spread of the solution within the subcutaneous compartment is dramatically altered. Note the “skip” areas between injection sites above and the more homogenous distribution pattern below. There is much more uptake into the dermis with the more concentrated formula, predicting more skin response with a stronger formula. Distribution is depicted by a combination of both solution concentrations with 0.1 ml methylene blue per 10 ml of formula. These injection studies were performed *in vivo* on abdominoplasty volunteers. PC 25/DC21 is diluted by 50%, dispersion pattern at 1 h. The dispersion pattern of full-strength PC50/DC42 at 1 h is shown

injection sites was first discussed in 2005 by Duncan and Hasenschwandtner [5]. Parameters were calculated based on dispersion studies that had been repeated on five more occasions to make sure that the clinical guidelines were correct.

Depth of injection cannot be emphasized too much. If 0.4 ml of lipolytic formula is injected 1½ inches deep into an abdomen of a patient with a BMI of 30, there will be no visible result, although some lipolysis will occur. However, if the same formula is injected into the lower abdomen of a 120-lb mom at 8 mm, she will get both visible lipolysis and some accompanying skin retraction. The depth of the skin thickness must be exceeded, but only slightly, when the primary goal is correction of cellulite, postliposuction deformities, sagging skin with accompanying fat, and areas in thinner patients, such as a swimsuit model's inner thighs. If fat reduction is the primary goal, a 9- to 11-mm range usually will deposit the solution near Scarpa's fascia. Only if the fat pad is small and very thick would we recommend injecting to a depth of 13 mm.

Generally, deeper injections appear to have less clinical effect than more superficial injections when the same formula and same volume are used. If the fat pad is more than 3 cm thick, the patient may be a candidate for a surgical correction of the contour deformity.

The injection volume and the volume per poke also are very important. Volume affects the diffusion characteristics—the spread of the fluid throughout the tissues. If insufficient volume is injected, the injected aliquots will not coalesce, causing “skip” areas and the risk of visible waviness in the skin contour. If the volume is too great, skin loss and/or draining subcutaneous fat necrosis can occur. The pH of deoxycholate, the lipolytic initiator, is 8.08. If too much is injected at one site, it can cause firm painful nodules that persist, a rubbery feel to the subcutaneous fat, and a “cement-like” consistency to the overlying skin. The desired end point in these treatments is a smooth and even diminution in the thickness of the subcutaneous layer, with retention of the normal look and feel of the skin and underlying fat. If the skin is tethered to the fat by scar tissue and does not slide back and forth when massaged, a very unnatural appearance will result.

When a multi-injector such as the Mesorelle is used, 2 ml per shot is injected with the 5-needle linear multi-injectors. This is 0.4 ml per injection site. It is possible to use a little less volume for volumetrically small areas or for “finishing off” larger areas. Tapering—using a little less volume around the periphery of the fat pad as it begins to thin out—is a good practice for reducing the possibility of any demarcation irregularities. When tapering is used with the Mesorelle, an injection of 1.5 ml per shot would give a dose of 0.3 ml per needle (Fig. 7).

When a handheld syringe or a mesogun is used for injection, the best volume per injection site in the torso and limb region, as demonstrated by dispersion studies (Fig. 8), is 0.4 to 0.5 ml when the injection depth is 6 to 13 mm and the spacing is 1.5 cm. This is a standard for body-contouring injections.

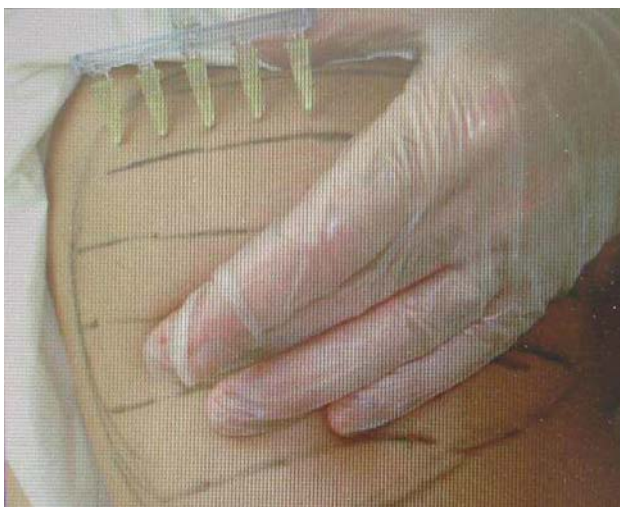


Fig. 7 Use of the Mesorelle injector. The skin is compressed on either side of the target region, and the injector is inserted so that all needles inject to the same depth



Fig. 8 How the dispersion pattern is influenced by spacing. The specimen above was injected with 0.5 ml of PC50/DC42 at a 2.5-cm interval 1 h before this photograph was taken. The specimen below was photographed 1 h after injection. While the formula, volume per injection, and depth of injection remained the same, the distance between injections in the lower photo was 1.5 cm. There are no skip areas in the specimen below

When the facial region is injected, spacing of 1.0 to 1.5 cm can be used. If a tighter grid pattern is used, more skin retraction can be achieved. However, if the 1-cm spacing is used, a smaller dose of 0.2 to 0.3 ml per injection site is recommended. A 6-mm needle depth should be used in the face and neck unless the patient's skin is very thick. The mesogun has a depth adjustment, enabling the same depth of injection to be achieved every time without the need to angle the injection or leave part of the hub showing once the needle has been inserted (Fig. 7).

The depth of injection is varied depending on the estimated thickness of the skin and of the subcutaneous fatty layer. If the skin and fat layer are both thick, it is possible to inject up to 13 mm (i.e., the full length of the 1/2-in. needle) perpendicular to the skin's surface. However, if there is any danger of reaching the muscle layer below the fat, the needle can be angled or, more reliably, a shorter needle or mesogun can be used to regulate the depth of injection.

In the face, to avoid an intramuscular injection, an injector should never inject deeper than 6 mm unless the skin is very thick. With multiple injections, it is difficult to judge exactly one-half the distance of a 13-mm needle. Therefore, the correct needle length should be used, and the needle should be inserted at a perpendicular angle.

The Second Treatment Session

In body contouring, the depth of injection should be alternated so there is no retreatment at the same level

Fig. 9 Treatment of the lower face and neck. This patient was treated with a single injection session. The depth of the injection was 6 mm. Due to the large size and broad surface of this particular fat deposit, a dose of 0.5 ml per injection and a spacing interval of 1.5 cm were used



during the second treatment session. We know from clinical experience that injection lipolysis does not work well where the fat is fibrous and does not work at all if fat is not present. If an injector is treating the abdomen, generally the first injection level is 10 mm, followed by 13 mm if the fat pad is sufficiently thick. If the patient has a strong request for skin retraction, a slightly more superficial injection pattern of 7- to 8-mm depth can be used for the first injection session.

Another technique to enhance outcome makes use of an offset grid. Frequently, 4 to 6 weeks after the first injection session, some palpable nodules still remain. A grid is helpful in outlining the old injection pattern by demarcating several nodules close together. The grid then is “offset” from the original pattern so that none of the nodules are reinjected.

Many patients report that the second injection session is noticeably more painful than the first, as would be expected in the face of some residual fat necrosis and inflammation in the region. To date, no increased risk of complications has been noted at the second session, other than increased discomfort.

Versatility of Treatment

A huge advantage of injection lipolysis is the ability to individualize the treatment for each patient. Instead of treatment that can achieve only 1 to 1.5 cm, as with some machines, the injections can be superficial, deep, or both as long as the rules for volume, spacing, and maximum dosage are followed.

Although the lipolytic formula is not a neurotoxin, we advise injecting as if botulinum toxin is being used. Lack of attention to detail, talking during injection so that an area may get injected twice, and failure to use a grid or to follow these guidelines may result in an area of compromised tissue after injection.

Facial Treatments

Facial treatments differ from body treatments in several ways. A 5- to 6-mm injection depth is used routinely. If the region is very thick, such as when a submental fat pad is large, a 13-mm needle can be used. A 1-cm grid can be used to maximize the outcome for a single injection session. Because the swelling is profound in the neck and jaw area, most patients request the fewest number of treatments possible. The volume per injection site varies from 0.2 ml in the posterior submandibular region to 0.5 ml in a thick submental fat pad (Fig. 9).

Pinch and Pull Technique

The authors recommend the pinch and pull technique for both body and facial injection sites. The skin at the injection site is pinched, with the injector’s fingers about 1½ in. apart, and the tissue is pulled away before the injection to ensure that any deeper structures are avoided (Fig. 10). It is good practice to mark known landmarks such as the facial artery and vein and the branches of the facial nerve close to the region. Any visible subcutaneous blood vessels are demarcated and avoided.

Before injection, every injection site on the face and neck is carefully preplanned by placement of a dot with a washable marker. When the injection sites are planned, it is vital that the face and neck be evaluated with the patient in a completely vertical position and the chin horizontal. Experience is important for good results with facial treatments (Fig. 9).

The maximum safe dosage of phosphatidylcholine is considered to be 2,500 mg per treatment session. When slightly larger doses are injected in a single session, a definite increase in degree of response occurs. However, more side effects such as nausea, diarrhea, orthostatic hypotension, and a transient vasovagal response also occur. It is recommended that all injectors observe the 2,500 mg PPC per day limit.



Fig. 10 The “pinch and pull” technique. It is imperative that during the injection process, the tissue to be injected is firmly pinched and pulled away from the underlying structures. This technique ensures that only the fat will be injected. The pinch also decreases the perception of the needle piercing the skin

Injection Technique

For body contouring, it is recommended that the patient mark the area of deformity so both the patient and doctor agree on the area to be treated. Ideally, the fatty area to be reduced will measure no more than 500 ml per side. Once the patient circles the area to be injected, the markings can be modified if needed.

A grid is used to mark each injection site on the skin. This ensures an even spacing of 1.5 cm. Dispersion studies [5] show that this is the ideal spacing distance for injections to coalesce but not pool, giving an even result with “divots.” As the marks are placed, the injector should count the dots so the dosage can be calculated. That way, if needed, an explanation can be given to the patient before treatment that the area may be too large for safe injection in one session. Depending on the concentration of PC/DC, small areas containing 50 to 75 injection sites per side can be treated with a more concentrated formula, increasing the likelihood of a dramatic response. A larger area—100 injection sites per side—will require injection of a more dilute formula. Results will still be visible, but more than two treatments may be necessary to achieve the degree of change requested by the patient. The maximum dose per treatment is 2,500 mg PPC. Patients sensitive to soy products or patients of small stature may not be able to tolerate this dose; it is best to remain conservative when injecting PC/DC.

Once the marking is completed, the area should be prepped with an antiseptic soap. No topical numbing agents or preinjection medications are necessary if a good injection technique is used. For small areas or for regions with contour irregularities or differing thicknesses of

subcutaneous fat, a 5- or 10-ml syringe is used to inject at depths varying from 6 to 13 mm. The standard volume per injection site is 0.4 to 0.5 ml.

Facial injections require more finesse than body contouring. The four regions of the lower face and neck—the submandibular jawline, the submental fat pad, the jowls, and the chin if necessary—are carefully marked. In facial regions, hand injection using a 3-ml syringe and a 6-mm needle is recommended to avoid intramuscular injections. It is very important to pinch the skin on either side of the injection site and pull the tissue away from the face to ensure a subcutaneous instead of an intramuscular injection. These patients must be told that they may have profound swelling for as long as 1 week, sometimes longer, so that social engagements or work issues can be avoided. The area near the trachea should be conservatively injected to avoid airway compromise.

All injectors should beware of using the Mesorelles in the facial region. The primary rule for any injector is always to know where the tip of the needle is. Frequently, when the injection is along a flat surface with a Mesorelle, the central needle may be at a 6-mm depth (ideal for the face), but the peripheral injections may be intradermal (this can cause blistering or skin loss), and could be much deeper, even intramuscular. Recently, the case of a large facial hematoma due to injection with the Mesorelle device in the face and neck has been reported.

For facial treatments, another acceptable method is to use 2-ml and occasionally 1-ml syringes with single 30-g (1/2-in.) needles. The smaller syringes and single needle ensure a high level of injection volume accuracy and ability to place each injection precisely where required, which is necessary for facial treatments.

Timing Between Treatments and Number of Treatments Necessary

Most experienced injectors usually treat each patient again in 4 to 8 weeks. In performing facial injections, it is best to wait 6 to 8 weeks before injecting again because the region should not be overcorrected.

Total Number of Treatments

The average number of treatments per patient is three per region for a satisfactory result. There clearly is a dose-related response. When broader surface areas and larger volumes are injected, a much more apparent difference can be seen than when only two to six injections are given in each area.

Variation in the total number of injections is determined by patient goals, tolerance of injections, and the dose

Fig. 11 This 51-year-old woman requested a buttock lift. Very fit and thin patients are difficult to accommodate with traditional surgical techniques. This patient demanded no recovery time and no scarring. The photos before treatment (*left*) and 8 weeks after a single injection session (*right*) show a significant lift of the lowermost dependent skin above the buttock crease



injected with each treatment. Physicians used to seeing their patients frequently tend to inject a smaller volume, expecting more subtle results, and plan a maximum of six treatment sessions to reach the desired goal.

Surgeons trained to achieve the maximum result in as few visits as possible tend to inject larger doses per session, thus requiring fewer total treatments. The range of treatment sessions a patient should expect is one to six, depending on the area, fat volume, patient expectations, and type of practitioner injecting (Fig. 11).

The End Point

Unlike surgery, the end point with injection lipolysis is not always clear. At the time of the first interview, the patient should review clear goals and tell the injecting physician what his or her expectations are. The physician should always underpromise results to avoid postinjection dissatisfaction. Generally, the patient determines the end point when he or she sees sufficient improvement to want to avoid another injection session. The physician end point should be a fat thickness reduction of 2 to 3 cm if that much pretreatment and mild skin retraction has occurred and the patient has soft fat, a small well-localized area of fat, and mild skin laxity. Because noninvasive treatments cannot be expected to achieve results similar to those of surgery, the end point for these treatments will be very

different from those experienced with liposuction or dermolipectomy.

Physicians should use professional judgment and discretion in deciding when to stop. Too much reduction in thickness of the subcutaneous fatty layer can result in an adverse aesthetic result, especially in the chin/neck area, where unsightly platysmal bands may become prominent or too much skin laxity may occur [38]. For facial areas, one to three treatments usually are enough, and care must be taken not to overcorrect. Unsightly subcutaneous atrophy may result from facial treatments that are too aggressive or repeated too many times (Fig. 12).

How to Avoid Patient Disappointment

The key to achieving patient satisfaction with outcome is to choose the patient wisely. The difficulty is that the patient's expectations on the day of treatment may not be the same as the expectations once the swelling and bruising disappear. To avoid a confrontation 6 to 8 weeks after the conclusion of treatment, the injector should have the patient write down the expected results in his or her own words.

The patient should be reminded that injection lipolysis will give only a mild to moderate improvement in the region of desired modification. If the patient is willing to accept a lesser outcome in return for little to no "down



Fig. 12 The consequence of overcorrection. This patient underwent two injection sessions for correction of her jowls and marionette region. Initially, she had a good outcome. However, after a 20-lb weight loss, she has an extremely hollow appearance in the perioral

region and now is requesting fat grafting for correction. (a) Preinjection appearance. (b) View 6 weeks after injection of jowls, two treatment sessions. (c) View 4 months later, after a 20-lb weight loss

time,” no incisions, and no time away from work, a subtle difference may be acceptable. Beware of the patient who wants an abdominoplasty result from lipolysis. If the stated goal is one you cannot provide without surgery, the patient should not be treated. Even if the patient requests “only a little” improvement, there will be little photographic difference before and after treatment in areas with more than 500-ml excess on each side.

Although skin retraction is almost universally seen as an adjunct to lipolysis, it should never be guaranteed. The best skin retraction is seen in fair patients with mildly saggy thin skin. When re-treating an area for skin laxity, remember that the treatment will fail if there is no underlying fat.

Summary

The practice of injection lipolysis is rapidly spreading throughout the world. Demand is high for noninvasive body contouring procedures that are safe and effective. For this emerging technique to become a mainstream well-accepted procedure, ongoing research must continue to define the safe and efficacious parameters of the process. This article provides beginning guidelines for safe effective treatments.

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