EXPERT REVIEWS

Mesotherapy: myth and reality

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Fatima Al Faresi[†1] and Hassan I Galadari[2]

[1]*Department of Dermatology, Tawam Hospital in affiliation with Johns Hopkins, Al Ain, United Arab Emirates*
[2]*Faculty of Medicine and Health Sciences, United Arab Emirates University, Al Ain, United Arab Emirates*
[†]*Author for correspondence: alfaresifatima@gmail.com*

Mesotherapy simply describes a method of drug delivery. It consists of intra- or sub-cutaneous injections of variable mixtures, including multivitamins, lidocaine, calcitonin, tretinion, hyaluronic acid, hyaluronidase, collagenase, minoxidil, phosphatidylcholine and many others. Mesotherapy can be used for many indications, but its main indication of fat dissolution has been primarily used. Other popular uses include facial skin rejuvenation and alopecia. Given the ease of treatment and its quick effect, with little to no downtime, mesotherapy has become extremely popular. As with any new technology, it is crucially important to assess the benefits and safety. Most of the published data regarding mesotherapy consisted of single case reports and small series. None were large, randomized controlled trials. Given that no large population, randomized controlled trials have ever been performed, it is advised that the use of mesotherapy be limited, and practiced with extreme caution.

KEYWORDS: alopecia • injection lipolysis • mesotherapy • phosphatidylcholine • skin rejuvenation

Mesotherapy emerged more than 50 years ago in France, and was made popular in South America, mainly in Brazil. The treatment utilizes a minimally invasive technique that consists of the intra- or sub-cutaneous injection of variable mixtures in microscopic quantities through dermal multipunctures. Mesotherapy simply describes a method of drug delivery and does not imply treatment of any medical condition. Ingredients that are used in treatment depend on the condition being treated and may vary between natural plant extracts, homeopathic agents, pharmaceuticals, vitamins, botanicals and other bioactive substances. The composition of common mesotherapy formulations is selected and mixed in a 'cocktail' before injection depending on the indication (TABLE 1).

In 1952, Dr Michel Pistor (1924–2003) founded the field of mesotherapy when he utilized the technique as a novel analgesic therapeutic method for a variety of rheumatologic disorders. With his first publication of the technique in a local medical journal in 1958, he coined the term 'mesotherapy', which can be strictly defined as treatment of the mesoderm [1]. With time, the treatment has garnered a following, and numerous indications were reported to be treated using mesotherapy. In 1987, the French National Academy of Medicine acknowledged mesotherapy as an official specialty of medicine, and fellowship training has also become available [1]. Given the ease of application, it received wide acceptance in Europe and South America, and has recently begun to gain popularity in the USA.

With the escalating demand for noninvasive cosmetic procedures across the world and an easy learning curve, mesotherapy has become part of the therapeutic armamentarium of many aesthetic practices. However, despite its attraction, its safety and efficacy remain unknown, making its use questionable until further standardized studies are performed.

Introduction to mesotherapy

Although initially used for pain relief, modern use of mesotherapy has included its use for the treatment of local medical and cosmetic conditions. Based on the condition that needs to be treated, the constitution of the solution varies. What components are combined and in what proportions tend to be based on anecdotal reports or the physician's experience, rather than empirical data. With the exception of local anesthetics, calcitonin, hyaluronidase and collagenase (all of these are used off-label), the US FDA has not approved or granted orphan drug designation to any other mesotherapy ingredients by subcutaneous delivery [1]. Furthermore, manufacturers fail to disclose the ingredients and their concentration. Although this has made the modality of

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Table 1. Topical ingredients used in traditional mesotherapy cocktails, categorized by their intended role.

Intended role	Ingredients
Analgesic: muscular	Orphenadrine, baclofen, diazepam
Analgesic: soft tissue	Procaine, prilocaine, lidicaine
Anti-inflammatory	Piroxicam, ketorolac
Calcium deposition removal	Calcitonin, ethylenediamine tetracetic acid (EDTA)
Circulatory stimulation	Pentoxifylline, buflomedil, coumarin, artichoke, *Ginkgo biloba*, melilotus, yohimbine, arnica
Collagen rejuvenation	Tretinoin
Collagen remodeling, medication dispersion	Hyaluronidase, collagenase
Hair growth	Finesteride, minoxidil
Immune stimulation	Vaccines, interferon, metronidazole
Lipolysis	Phosphatidylcholine, deoxycholate, organic silicium, aminophylline, theophylline, caffeine, isoproterenol, ephedrine, calcium pyruvate, L-Carnitine, ma huang, T3/T4, triiodothyroacetic acid
Metabolic and antioxidant support	Vitamins (biotin, pantothenic acid, C, E, A), minerals (Se, Zn, Cu, Mg, Cr), melatonin
Nausea reduction	Prochlorperazine
Skin hydration, tightening, exfoliation	Hyaluronic acid, dimethylaminoethanol (DMAE), silica, glycolic acid

Data taken from [1].

treatment questionable, its popularity has skyrocketed. This has been attributed to the ease of injection and the popularity of minimally invasive procedures. The procedure has also been marketed, and thus become sought for, by those who shy away from other traditional treatments such as liposuction. To lobby for its legitimacy and use, practitioners of mesotherapy, who range from having medical and nonmedical backgrounds, have begun forming societies, organizing meetings and setting up fellowship training programs on the field.

Indications

Mesotherapy has been marketed for use as a treatment for many disease processes and aesthetic indications, but its main indication is that of fat dissolution. Other popular uses include facial skin rejuvenation and alopecia (mainly androgenetic).

Lipodissolve or injection lipolysis

Perhaps the most popular form of mesotherapy is the one used for the treatment of fat aggregates, cellulite and body sculpting. It has also been called injection lipolysis, lipotherapy and lipodissolve. This occurs by the theoretical promotion of dissolution of fat deposits. The basic ingredients that are frequently used in the solution mixture for this purpose are phosphatidylcholine and/or deoxycholate. The FDA has yet to approve the use of these two substances for treatment and for safety [2].

Phosphatidylcholine, extracted from soybean lecithin, is the predominant phospholipid component of cell membranes and a precursor to acetylcholine [1]. The substance is abundant in nerve tissue, the liver and semen. Phosphatidylcholine has been shown to reduce the systemic levels of cholesterol and triglycerides [1,3]. It has been used in the intravenous treatment of lipid atheromas, hypercholesterolemia, fat embolism, fatty deposits or plaque adhering to arterial walls [3]. The cosmetic use of phosphatidylcholine for body contouring began in the mid 1990s as an off-label use in Brazil [3]. The substance known as Lipostabil was injected in several pockets of fat in different body parts. Phosphatidylcholine was mixed with many other substances, including corticosteroids. The mixtures varied from practice to practice, with each physician catering the cocktail according to their own practice. Due to this nonstandardized approach, it made scientific studies on the material difficult. After many reported cases of scarring, dyspigmentation and body contour irregularities, the Brazilian National Agency of Health Inspection (ANVISA), which regulates the use of medication in Brazil, published a resolution in January 2003 prohibiting the use of the agent in this form [3]. This was later echoed by the American Society of Plastic Surgeons in a statement warning against the use of these chemical compounds as an alternative to liposuction. However, lipodissolve still remains widely used in Brazil and the world, and has been primarily marketed to target fat deposits in the subcutaneous tissue, such as buffalo-hump, lipomas, eye bulging, xanthelasmas and localized fat on the thighs, hips, abdomen, flanks, neck and lower third of the face.

The pharmacology of injectable phosphatidylcholine in the subcutaneous tissue has not yet been explained, and the mechanism of localized fat reduction is unknown. Some authors have theorized that the lipolytic effect of these subcutaneous injections relies on its lipid-modulating effects in the blood and liver. However, this has never been demonstrated experimentally [1]. In a study by Rittes *et al.*, the investigators compared the local action of a phosphatidylcholine formulation with that of a physiologic saline solution by looking at the fat tissue of rabbits [4]. Necrosis of the fat cells in all the phosphatidylcholine injected animals was observed. Areas injected with saline showed minimal signs of local inflammation, and no necrosis was observed. They recommended that further studies should be performed to clarify and determine the mechanism of action. In March 2010, Khan *et al.* reported that phosphatidylcholine induces lipolysis via the activation of cyclic-monophosphate [5].

There are no standardized trials or research studies reporting clinical, histopathological and laboratory data that prove the effectiveness of phosphatidylcholine in the treatment of localized fat areas [3]. Phosphatidylcholine injections alone have been used to treat localized fat accumulations in HIV lipodystrophy and lipomas [5]. Hexsel *et al.* have reported phosphatidylcholine as a safe and efficacious method to achieve the reduction of small localized fat deposits on the face and body, which may serve as a substitute for liposuction in some specific indications [3]. The investigators also emphasized that the recommended dose and safe application technique should be standardized through wide investigation protocols for new indications and long-term studies. Another study by Brown reported that there was no standardization of dosage and no protocol or treatment algorithm to enable prediction of how much tissue or fat will be dissolved with a specific solution in a defined quantity, and injected at a specified subcutaneous tissue depth [6]. Another trial, which was both subjective and not placebo-controlled, using phosphatidylcholine (250 mg/5 ml) to dissolve lower orbital fat pads, revealed cosmetic improvement in patients who received the injections [7]. By comparing pre- and post-treatment photos, the researchers concluded that the mesotherapy can delay or even substitute for a lower eyelid blepharoplasty. Albon and Rotunda also studied infraorbital fat herniation using phosphatidylcholine injections and concluded that 80% of the patients showed physical grade improvement [8]. Nabavi *et al.* went further to report that the cause for periorbital fat pad reduction was an acute inflammatory reaction [9]. This was supported by histology after mesotherapy to the inferior orbital fat compartments.

Phosphatidylcholine versus phosphatidylcholine with organic silicium for reducing submental fat was studied by Co *et al.* [10]. Theoretically, organic silicium is thought to regulate cellular metabolism and cell division, in addition to preventing the formation of free radicals by reinforcing the cell wall. The investigators concluded that both were equally clinically effective. However, there were no accompanying ultrasound and histological changes documented. Hasegawa *et al.* reported the use of the phosphatidylcholine compound with lidocaine, aminophillin, L-carnitine and phosphatidylcholine with deoxycholic acid in injecting a 42-year-old male patient who presented with benign symmetric lipomatosis, also known as Madelung disease [11]. The case report revealed improvement and achieved good cosmetic results. A MRI was performed before and after, and showed that the volume of subcutaneous fat tissue around the neck was reduced.

A study by Rose and Morgan looked at skin biopsies obtained 1 and 2 weeks after mesotherapy with phosphatidylcholine and deoxycholate [12]. The study revealed a mixed septal and lobular panniculitis. They concluded that phosphatidylcholine and deoxycholate affects the subcutaneous fat, and that the reduction of subcutaneous fat likely follows inflammatory-mediated necrosis and resorption.

An increasing number of reports demonstrate localized fat loss in multiple anatomic sites after the subcutaneous injection of a formula containing phosphatidylcholine combined with its emulsifier, deoxycholate [1]. Rotunda *et al.* have identified sodium deoxycholate, a detergent that produces nonspecific destruction of cell membranes, as a major active ingredient in this therapy [13]. Injection of deoxycholate into lipomas causes focal necrosis, acute inflammation and hemorrhage histologically [14]. This has led some to believe that deoxycholate is the main cause of fat dissolution, and not phophatidylcholine as previously noted.

Caruso *et al.* have evaluated other mesotherapy solutions that are used for inducing lipolysis and treating cellulite [15]. These include isoproterenol, aminophylline, yohimbine and melilotus to stimulate lipolysis. Park *et al.* studied the efficacy of mesotherapy for body contouring by injecting the medial aspect of one thigh with a mixed solution (aminophylline, buflomedil and lidocaine) weekly over a 12-week period [16]. The change in the fat level was evaluated by measuring the girth of the thighs and by computed tomograpy (CT) scanning. The loss of thigh girth on the treated side was not significantly different from the untreated side. The CT scans also did not reveal any statistically significant difference in the cross-sectional area or thickness of the fat layer between each group. They concluded that mesotherapy is not an effective alternative treatment modality for body contouring.

Facial rejuvenation

For mesotherapy to achieve rejuvenation it should be able to increase dermal hydration and create a favorable environment to facilitate fibroblast activation. Most cocktail solutions used for facial rejuvenation contain hyaluronic acid (HA). Ultrasound of the skin has been used to visualize and quantify age-related dermal changes. This is possible by evaluating the so-called subepidermal low echogenic band (SLEB), located immediately below the epidermal entrance echo [17]. This is considered to be a marker of photoaging and is strictly related to dermal elastosis, basophilic degradation of collagen, and accumulation of glycosaminoglycans and water in the papillary dermis, as confirmed by numerous studies [17]. Micali *et al.* have demonstrated improvement of SLEB, consisting of increased echogenicity, likely related to increased density of dermal collagen fibers by ultrasound after mesotherapy of photoaged skin on the back of the hand [18]. At baseline, ultrasound evaluation revealed the presence of SLEB in all patients. The patients studied had three sessions of mesotherapy with 20 mg/ml nonreticulated HA at 2-week intervals. A repeat ultrasound evaluation was performed 1 week after the last mesotherapy session, which revealed an improvement in skin texture. This can be explained by the hydrating effects of HA in the tissue due to its ability to absorb many times its normal weight in water. In addition, repeated injections into the dermis can also trigger the healing process, activating fibroblasts and thus producing more collagen. The study, however, lacked follow-up evaluation. The persistence of skin changes after discontinuation of therapy has not been evaluated. This is important, since HA in its nonreticulated form is not stable and dissolves within a matter of days to weeks. Another study by Amin *et al.* evaluated two patients at different time intervals before and after injection [19]. The authors report no significant clinical and histologic changes after multivitamin and HA solution mesotherapy for skin rejuvenation.

Alopecia & hair loss

Despite the fact that there are no controlled published studies on mesotherapy's efficacy in hair disease, it has been used as a treatment for androgenetic alopecia and hair loss [20]. Finasteride and minoxidil are possible components of the injected solution. These agents are the only FDA-approved agents for the treatment of androgenetic alopecia, when the agents are administered orally and topically, respectively. Data reporting efficacy in the form of mesotherapy has not been published and is not yet approved. In addition, manufacturers fail to disclose other ingredients used for the treatment of androgenetic alopecia and their concentration.

Publication of the use of mesotherapy in alopecia revealed possible complications due to treatment. Three cases of alopecia secondary to mesotherapy were reported [20,21]. The first patient developed alopecia after being injected with a cocktail that contained mesoglycan (Prisma), a heparinoid vasodilator. The 3-month follow-up examination revealed a small residual area of cicatricial alopecia [20]. The second patient developed reversible alopecia after undergoing multiple sessions of mesotherapy containing homeopathic agents of unknown constituents [20]. Another article reports complications of scalp mesotherapy in a woman who developed multifocal scalp abscesses with subcutaneous fat necrosis and scarring alopecia [21].

Other complications

Pain is typically minimal during and after the injections. Although there are reports of systemic side effects, local side effects predominate, including local erythema, induration, allergic reaction, atrophy, lipodystrophy, bleeding, necrosis and infection [2]. Mesotherapy has been associated with atypical mycobacterial infections [22–27], nontuberculous mycobacteria infections [28], urticaria [1,29,30], lichenoid drug eruptions [1,31] and koebnerization of psoriasis [32]. There are also reports of postinflammatory hyperpigmentation, ecchymosis, prolonged swelling and tenderness, ulceration and hematoma formation [33–35]. The long-term side effects, local or systemic, are unknown. Seven cases of a noninfectious granulomatous panniculitis following mesotherapy injections were reported [36,37]. Other reported side effects of mesotherapy include: cutaneous granulomatous reactions [38], delirium with psychotic features [39], disfiguring scarring [23], factitious thyrotoxicosis [40], granuloma annulare [41], localized urticaria pigmentosa [42] and systemic lupus erythematosus after mesotherapy with acetyl-carnitine [43].

Conclusion

Given the ease of treatment and its quick effect, with little to no downtime, mesotherapy has garnered great attention and has become extremely popular [44]. Despite its growing popularity, which has relied primarily on marketing the treatment to lower tier cosmetic outlets, such as spas and beauty salons, it is postulated that 18,000 licensed mesotherapists exist in France alone, some of whom have no medical background or training. As with any new technology or treatment modality, it is important to assess the benefits, safety, experience and standardization of mesotherapy so as to make an informed decision.

Expert commentary

The lack of a precise treatment protocol, the unpredictable outcome, and the risk of localized adverse events has made many health regulatory bodies, including the FDA, not yet embrace the treatment modality. In April 2010, the FDA went further, to shut down outlets marketing mesotherapy under false pretenses and claims. These concerns have also been voiced by many well-recognized international societies, such as the American Society of Plastic Surgeons, which has expressed concern about the procedure and the chemicals used in it as an alternative to liposuction [45,46]. The American Society for Dermatologic Surgery has stated that until further studies are published, the use of mesotherapy is not recommended. Due to the lack of data claiming efficacy and the rising barrage of possible complications, it is advised that the use of mesotherapy for whatever indication using untested ingredients be limited and practiced with extreme caution.

Five-year view

There is an increasing understanding among the plastic surgery and dermatology societies that the use of mesotherapy should be scientific and evidence-based. This is achieved by undertaking controlled trials to assess the safety, benefits and standardization of the treatment modality. With the results of such trials obtained, mesotherapy use will be regulated.

Key issues

- Mesotherapy is a minimally invasive technique that consists of the intra- or sub-cutaneous injection of variable mixture 'cocktails' in microscopic quantities through dermal multipunctures.
- The US FDA has not approved any of the mesotherapy ingredients for subcutaneous delivery except for local anesthetics, calcitonin, hyaluronidase and collagenase.
- Phosphatidylcholine and/or deoxycholate are used for the treatment of fat aggregates, cellulite and body sculpting. Lipodissolve is the most popular form of mesotherapy.
- There are no standardized trials or research studies reporting clinical, histopathological and laboratory data that prove the effectiveness of phosphatidylcholine in the treatment of localized fat areas.
- For mesotherapy to achieve rejuvenation it should be able to increase dermal hydration and create a favorable environment to facilitate fibroblast activation.
- Finasteride and minoxidil have been used as a treatment for androgenetic alopecia and hair loss. This is despite the fact that there are no controlled published studies on mesotherapy's efficacy in hair disease.
- Due to the lack of data claiming efficacy and the rising possibility of complications, it is advised that the use of mesotherapy for all indications using untested ingredients be limited and practiced with extreme caution.

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