

Advancing Mesotherapy Through Clinical Trials

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Botulin Toxin injection is currently the most frequently performed cosmetic operation in the United States. Its popularity as a method of fighting signs of aging such as frown lines began to rise in the 1990's, before it ever gained FDA approval for such cosmetic uses. The FDA approved botulin toxin in 1989 to treat eye muscle disorders such as uncontrollable blinking. Practitioners quickly realized the positive cosmetic effects on wrinkles while using the drug for its approved purposes. This discovery of the new cosmetic use led to clinical testing, which led to the 2002 FDA approval of this specific application, which has led to botulin toxin's current status as the most commonly used cosmetic procedure in the US.

Mesotherapy does not have a long history of use in this country. However, in this short history, it has gained popularity as evidenced by the increased media coverage of this innovative medical technique, both in print and on the television. With this notoriety has come increased scrutiny of the practice by those skeptical of its effectiveness and safety. Two major critics of mesotherapy have been the American Society for Dermatologic Surgery (ASDS) and the American Society of Plastic Surgeons (ASPS). Both of these groups have issued statements that they do not endorse the safety of mesotherapy and cannot do so until more clinical studies are performed. Indeed, proponents of mesotherapy have had to rely on their own experiences and other anecdotal evidence to promote the safety and effectiveness of the practice. But anecdotal evidence will not suffice to gain regulatory approval, no matter how convincing or how much success any particular practitioner might experience with the procedure.

Critics also argue that mesotherapy lacks standardized protocols or standard instrumentation, which heightens the critics' safety scrutiny. They argue that techniques vary from

practitioner to practitioner and even from one area of the body to another, leading to diminished ability to develop safer and more effective therapies. The variation in techniques arises from the several possible combinations of ingredients, whether pharmaceutical, herbal, or otherwise, that practitioners can choose to inject into patients. Although mesotherapy often involves the off-label use of FDA approved drugs (as discussed in a prior article), and physicians are free to use their professional judgment in making such off-label uses, no drug has undergone FDA review specifically for use in mesotherapy. Nor has any of the combinations of these ingredients been reviewed by the FDA.

While this wide variety in technique from practitioner to practitioner illustrates the versatility in application of mesotherapy, it also contributes to the call for additional scientifically reliable evidence of the safety and effectiveness of mesotherapy. This in turn has led many practitioners who do not presently incorporate mesotherapy into their practice to adopt a "wait-and-see" attitude. They are looking for additional scientific evidence of mesotherapy's safety and effectiveness. Consequently, these critics argue for more clinical studies in mesotherapy, in a traditional double-blind placebo controlled format, and published in peer reviewed journals. Such studies will arguably lead to wider acceptance, stronger endorsement, and FDA regulatory approval of mesotherapy techniques.

The good news is that clinical studies have already begun to take place in mesotherapy. The American Society for Aesthetic Plastic Surgery (ASAPS) announced on April 21, 2006 the launching of a double-blind placebo study in mesotherapy. The results of that study will be published in the peer reviewed Aesthetic Surgery Journal. Also, the Center for Laser Surgery has posted on its website two clinical trials it is currently con-

ducting or organizing, one involving mesotherapy to treat lipomas, and the other involving mesotherapy to treat lower eyelid fat pads. These studies are a step in the right direction, but more need to follow to address the safety concerns raised by the critics such as the ASDS and ASPS.

To quiet the critics and to move toward more general approval of mesotherapy techniques, these clinical studies should consider the questions of possible side effects of the treatment as well as other health and safety issues. Also, they should investigate whether the effects of mesotherapy are permanent or to what extent they have a lasting effect. They should explain how the various ingredients used in mesotherapy work in the body to achieve their intended result, or their mechanism of action. Specific health effects to address include whether mesotherapy causes anaphylactic reactions or any other adverse reactions, the threat of mycobacterial and other forms of infection, the likelihood of side effects such as scarring or hyperpigmentation, and the effect of mesotherapy on the liver and other organs.

The data gathered from these clinical studies may be used to obtain FDA approval for drug applications specific to mesotherapy and, possibly, for the more common formulations of drugs and/or other ingredients used in this practice. Like botulin toxin before it, mesotherapy could benefit immensely from this, especially in light of the already increasing popularity of the practice prior to obtaining such approval. These studies can also lead to more standardized procedures in mesotherapy, which could improve results, increase acceptance within the medical community, and grow the practice of mesotherapy as a whole.

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