Questions and Answers: ASCDAS 3rd Annual Meeting

New Options in the Recognition and Treatment of Lipoatrophy With Volume Restoration

At the 3rd Annual Meeting & Exhibition of the American Society of Cosmetic Dermatology & Aesthetic Surgery (ASCDAS), Wm. Philip Werschler, MD, and Douglas R. Mest, MD, presented an educational program focusing on the use of poly-L-lactic acid (Sculptra®) for nonsurgical total facial restoration. This issue features selections from the question and answer portion of the program.

Q: Can poly-L-lactic acid be injected no matter what the CD4 count?

Werschler: I believe that the CD4 count is irrelevant with regard to treatment for facial lipoatrophy. You would certainly want to make sure that there's no active disease or infection in the areas to be injected, as you would with any type of facial cosmetic procedure.

Q: What is the duration of results? Also, which is better for correcting nasolabial folds: poly-L-lactic acid or Restylane® (nonanimal stabilized hyaluronic acid)?

Werschler: The answer is both. Let me start with the second half of the question. Conceptually, when you use poly-L-lactic acid for the nasolabial folds, what you're doing is restoring both volume and the natural convexity of the cheek. This puts "air in the balloon," which lifts the cheek, which lifts the fold. So, there is a 3-dimensional volumetric or volumizing effect.

When you use nonanimal stabilized hyaluronic acid or any other dermal filler, you're actually looking at the fold itself and elevating it or the downside of it (making the cliff into a slope), and you're trying to reapproximate an evening of the dermis. So, the question then is not so much, which is better but rather, can you use both? The answer is: you certainly can.

Poly-L-lactic acid ideally lends itself to the concept of nonsurgical total facial restoration for use with fillers as appropriate to where you would use them. In fact, one of the things that I have just recently started doing in my practice is to use some Hylaform® (this is in the aesthetic patient principally) because patients do undergo this paradoxical depression as the water is reabsorbed. So, the patients wake up and the effect is practically gone. At the time that I inject poly-L-lactic acid, I slip in some Hylaform, which has a little shorter life in the body than nonanimal stabilized hyaluronic acid. I think of the onset of the poly-L-lactic acid as a 12- to 14-week period and, in fact, the onset of the catalyst-driven results typically begins to have good effect by the third month. So, to the patient, it really becomes transparent because the Hylaform is wearing off about the time that the neocollagenesis effect of the poly-L-lactic acid is taking place, and the patient just continues to look good.

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Dr. Werschler is a consultant, clinical investigator, and lecturer for Dermik Laboratories, and a clinical investigator for Inamed Corporation. Dr. Mest is a consultant and has received a research grant from Dermik Laboratories.

Regarding duration of results for poly-L-lactic acid, I have been doing the procedure for 14 months, so I can tell you that I've seen a duration of 14 months with poly-L-lactic acid. I think Dr. Mest has been doing it for much longer.

Mest: We've seen results up to 2 years and beyond. The product insert says up to 2 years, which is because the study ended at 2 years. However, there have certainly been reports out of Europe. Vleggaar and Bauer have reported results lasting even beyond 2 years. I think it depends on what the underlying condition is. People continue to age, and patients with HIV-induced lipoatrophy may continue to experience underlying fat loss. So, at some point you do need to re-treat. When you need to re-treat depends on each individual patient, but I think the best thing to tell your patients is that it's long lasting, which means that it can last up to 2 years.

Q: For a deeper area, would you inject more poly-L-lactic acid or the same amount?

Mest: It is important to avoid overcorrecting. You want to treat an area, but you don't want to pummel a whole lot of material into one deep depression because you will get an abundant collagen reaction and it will not give you the nice, pliable, normal-looking appearance that you want. So you want to do an even distribution over the area and then, as you re-treat, that area will get smaller and smaller.

Q: Please address the amount of poly-L-lactic acid used per session (1 or 2 vials) and give a general guideline as to how much to use per session.

Werschler: Think of it this way: When using fillers for correction of a depression or augmentation, you would ideally correct to optimal correction. I don't say to someone who wants big lips, "Oh, let's put 1 cc in today, come back in a couple of weeks, we'll look at it, put another cc in, and, eventually, we'll get there." I give them the mirror and say, "Do you want 1 tube, 2 tubes, 3 tubes?" With poly-L-lactic acid, it's different because it is not a filler. It's a catalyst that causes the body to produce collagen. So, how much you use per treatment session is a function of the 2-dimensional surface area. Someone in the workshop yesterday used a good analogy. Ask yourself, "How many square feet are in the room?" So, it's a question of how many areas are you treating and how big are the areas being treated? Are you treating a large man or a petite woman? Are you treating multiple facial areas? Is there bitemporal wasting? Are you treating the hollow eye rings? Are you treating a mid-face concavity? What you are treating will determine how much to use per treatment session. The rule of thumb is half a vile per side in the aesthetic patient. I would encourage using half a vile per side as you get started with it and learn to use the product. In a patient with severe lipoatrophy, you may be using an entire vile per side, and I think that would probably be more typical in the HIV patient.

Mest: Yes, the recommendation for the HIV patient is always 1 vile per side, but it is more difficult to determine with other patients, which is a question that comes up all the time when I do training. I'll refer you to the article by Woerle and colleagues, which discusses cosmetic use extensively and also gives some numbers. In general, it's OK to start lower. You will probably be a little disappointed if you start too low. Just because this is an expensive product, don't cheat the patient and only use 1 cc over the entire face: you won't get a result that way. The article gives an idea of the number of sessions and the amount used per session at a 5-cc dilution.

Werschler: Consider the "hole" that you are trying to fill. If you are using the traditional filler, you need to keep pumping it in until the hole is filled. With poly-L-lactic acid, the depth of the hole and the amount of correction that is ultimately desired is more reflective of not using more product per session but rather more treatment sessions and keeping the amount of product you put in per session fixed.

Q: Can Thermage® be used before, during, or after poly-L-lactic acid?

Mest: Ideally, I would recommend using Thermage before poly-L-lactic acid. During the 3- to 6-month period when you are waiting for Thermage to work, treat with poly-L-lactic acid. Then, ideally, you have a great result at the end. The use of poly-L-lactic during and after Thermage has not really been studied whether the radiofrequency energy is going to have an effect on the poly-L-lactic acid. I have done Thermage over some patients (3 or 4) treated with poly-L-lactic acid, and I haven't seen any problem (diminution or change). But that's hardly a study.

Q: Has a double-blind study with plain water versus poly-L-lactic acid in one patient with 2 sides been done?

Mest: No it has not. The closest to any blinding has been the Chelsea and Westminster study where they did the randomized part (Moyle et al). The mechanism of stimulating fibroblasts and making collagen results in a low-level irritation and a very controlled, local, soft-tissue

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reaction occurs. The fibroblasts come in as a reaction to that and that's what stimulates the type I collagen.

Q: Can you treat the nasolabial fold without treating the cheek, and can you inject medial to the fold as you do with nonanimal stabilized hyaluronic acid?

Werschler: The answer is absolutely. When I am treating a patient who has a rounder face with no midface atrophy or concavity and has a rather large shelflike drop-off on the nasolabial fold, what I do is inject deep dermal, subdermal, medial to the fold, and I lift up that contour and I make it smoother from side to side. This is not a vermilion lip filler. So when I say that I inject into the lip, I am referring to the keratinized lip or the white lip versus the red lip, and I will inject medial to the fold. In my experience, these patients usually have perioral atrophy, and they appear to have "smoker's lines" even if they are nonsmokers. I will fill the white of the lip with poly-L-lactic acid, and when the patient returns for follow-up, the result looks very much like that achieved from fat transfer to the upper lip. This method reduces the elevation change on either side of the nasolabial fold and, in essence, the nasolabial fold begins to disappear.

Mest: I will caution that in the white part of the upper lip (we don't use poly-L-lactic acid in the red portion), it has a very strong response. In other words, a small amount of material goes a long way and tends to react quicker. And that's true in any very mobile area. Be aware that you will probably need to start lower, treat, have the patient come back, see how they are doing, and re-treat.

Werschler: And that's a key take away message on the use of poly-L-lactic acid is to treat, wait, assess, and decide on your next treatment. That's very important. We're not looking for optimal correction out of the box. We're looking for it on the backside at 2, 3, or even 6 months later.

Q: Your dilution level is 5 cc per vial. In highly dynamic areas, like around the lip where there is a lot of musculature, what are your thoughts on using 7 cc or 10 cc?

Mest: I think that doing a 6-, 7-, or even 8-cc dilution under the eye area and in highly mobile areas (like around the eye and around the lip) is OK. I wouldn't use those dilutions in larger areas and nonmobile areas. But in highly mobile areas, I think that it's a good idea.

Werschler: I think this is very much like when Botox™ first came out. Everyone used a 1-cc dilution, then it went to 2 cc, and now 4 to 5 cc is more of a standard. Certainly, I would feel comfortable going more dilute. I would caution, however, if you go more concentrated you may run the risk of the patient developing micronodules.

Mest: I wouldn't go more concentrated. However, I wouldn't advise diluting too much because of the cost of the product. At some point you will lose efficacy. Certain areas respond better (highly mobile areas). In these areas it is OK to dilute more. In other areas, 5 cc would be the dilution.

Q: Since poly-L-lactic acid is indicated for HIV lipoatrophy, what ICD-9 and CPT codes would you use to obtain insurance authorization. Also what code for nerve block if used?

Mest: There is no good code currently because the product is so new. We're using 11952 for injection of subcutaneous filler, but that doesn't really do it justice, and we use a generic code for the product (L21138). We leave it up to the patients to fight it out with the insurance companies. In California, there is a state law stipulating that if an illness or deformity is due to drug or disease, it needs to be covered. Poly-L-lactic acid injections for HIV lipoatrophy should be covered under that same law, but the insurance companies are a little slow to react to it. In terms of the rest of the country, the product is so new that I would recommend leaving it up to the patients. Have them submit the claim to their insurance companies. I have all of my patients pay up front for this procedure, and if they get reimbursed from the insurance company, that's great.

Cosmetic Dermatology® will publish questions and answers from other programs presented at the ASCDAS meeting in future issues. For more information on ASCDAS, visit www.ascdas.org.

Suggested Readings

Moyle GJ, Lysakova L, Brown S, et al. A randomized open-label study of immediate versus delayed polylactic acid injections for the cosmetic management of facial lipoatrophy in persons with HIV infection. *HIV Med.* 2004;5:82-87.

Vleggaar D, Bauer U. Facial enhancement and the European experience with poly-L-lactic acid. *J Drugs Dermatol.* 2004;3:542-547.

Woerle E, Hanke CW, Sattler G. Poly-L-lactic acid: a temporary filler for soft tissue augmentation. *J Drugs Dermatol.* 2004;3:385-389. ■