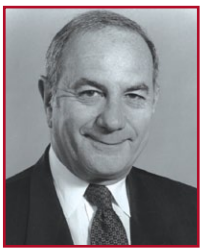

Injectable Poly-L-Lactic Acid (Sculptra™)

Melvin L. Elson, MD

Sculptra, known as *New-Fill*™ outside of the United States, is one of the newer fillers to be approved by the US Food and Drug Administration. It contains microparticles of poly-L-lactic acid, a polymer of the α-hydroxy acid family, which has been used in suture materials for decades.[1] Because Sculptra is made up of lactic acid units and there is no species specificity for this molecule, there is no need for skin testing. This filler has other advantages as well. Although Sculptra initially degrades to its primary base, lactic acid monomers, and then ultimately to CO_2 and glucose, there is evidence that during the process, the polymer stimulates collagen production (neocollagenesis) to replace the implant with new collagen, which leads to long-lasting correction.[2]

Indication

Sculptra was approved by the US Food and Drug Administration in August 2004 to restore and/or correct signs of facial lipoatrophy in patients with human immunodeficiency virus (HIV).[3] The approval was placed on a "fast track" because there was no other filler specifically for this indication at that time. Although there have been some claims that the implant produces permanent correction, clinical data do not support this. The results appear to be long lasting but certainly not permanent. As a condition for its approval, Dermik Laboratories will conduct an open-label registry study of 100 patients with HIV-associated facial lipoatrophy. The patients are to be followed for 5 years to evaluate the long-term safety of the product, and the study is to contain at least 30 women and 30 patients with darker skin types.[2]

Efficacy

Marcus Conant, MD, has been treating patients with acquired immunodeficiency syndrome since 1981 and is a consultant to Dermik on Sculptra.[3] He has more than 100 patients awaiting treatment with this product and has enrolled 22 patients in a trial that to date has followed the patients for up to 6 months. Dr. Conant already has determined that patients who have lost essentially all of their facial fat would need about 6 treatments spaced at least 2 weeks apart or preferably 1 month apart. If the lipoatrophy is less severe, patients may need only 1 or 2 treatments at 2-week or 1-month intervals. Although the study is not complete, Dr. Conant has found that both he and the patients generally are pleased with the cosmetic results.[3]

The first article in this column, "Soft Tissue Augmentation—Overview," published in 2004, discussed the nature of the perfect material for soft tissue augmentation.[4] Sculptra meets the following criteria: it is nonallergenic, nonpyrogenic, noncarcinogenic, requires no skin test, can be shipped and stored at room temperature, and requires little downtime. However, it does not meet some of the other criteria; for example, it is painful during implantation, must be mixed, is not forgiving, and cannot be used to access all areas of the face, such as fine lines. Furthermore, it remains to be determined if the product is malleable. It also needs to be determined if it feels and looks natural when used in the common areas, such as nasolabial folds and oral commissures, for soft tissue augmentation (S. Levy, oral communication, November 2004).

Sculptra must be reconstituted prior to injection, and the manufacturer is adamant that sterile water be used as the diluent.[5] However, a number of presentations at meetings for the American Academy of Dermatology, as well as the American Society for Dermatologic Surgery, have reported using normal saline or lidocaine. I am not certain how this may affect the results obtained with this filler. The physician must add 3 to 5 mL of sterile water to the vial containing the powder, and the mixture should stand for at least 2 hours to ensure that the powder dissolves. The physician must then shake the vial to ensure that the suspension is homogeneous.[5]

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Although I have not attempted to mix or inject the material since it was approved for use in the United States, I have attempted to inject the material at scientific meetings in Europe and Latin America over the last 3 years and have found it to be virtually impossible to inject after 2 hours. I discussed this problem with the manufacturer and was told that the physician could reconstitute Sculptra the day before the patient is scheduled to be treated (S. Levy, oral communication, November 2004); however, I think this is an unsatisfactory solution to the problem.

Injection Technique

Once the material is prepared satisfactorily, it is implanted into the subcutaneous space with a 26-gauge needle using a fanning technique, similar to ArteFill™, with avoidance of overcorrection.[5] Patients should be reevaluated in 2 to 4 weeks for possible further correction. Patients experience considerable discomfort with the injection; thus, a topical anesthetic or nerve block should be used. Side effects from the injection of soft tissue materials are not unusual and include bleeding, bruising, or swelling, all of which subside within 36 hours.[5]

Off-Label Use

One issue with using Sculptra is that it is approved in the United States to treat lipoatrophy secondary to HIV/acquired immunodeficiency virus only, but it is being used off label by many physicians. There are other fillers available that produce more consistent results in the most commonly treated areas of soft tissue augmentation at a significantly lower cost to the physician and therefore to the patient; thus, it is best to reserve this material for use in volume deficit correction, for which it is indicated, until more information is obtained regarding how it behaves clinically.

Comment

Although there is still more clinical data to be obtained on the use of Sculptra, it may be the first true volume filler to be approved for use in the United States, and it fits nicely into the armamentarium of substances already available for soft tissue augmentation. Whether or not the manufacturer can devise a method that will allow more effective mixing and use of Sculptra will determine if it will be used worldwide.

References

1. Guttman C. Sculptra "fills void" for deeper defects. *Dermatol Times*. August 1, 2004;Special Report:39, 49.
2. FDA Oks Sculptra for HIV patients. *Cosmet Surg Times*. September 1, 2004:1, 10.
3. Mechcatie E. Filler approved to treat HIV facial atrophy. *Skin & Allergy News*. 2004;35(9):7.
4. Elson ML. Soft tissue augmentation—overview. *Cosmet Dermatol*. 2004;17:747-748.
5. Sculptra [package insert]. Berwyn, NJ: Dermik Laboratories; 2004. ■