

Cosmetic Surgery Times®

Where the Exchange on Aesthetic Perspective Begins

July 2003

SPECIAL REPORT | Surgical Restoration of the Face

Collagen alternative for facial soft tissue augmentation offers good results

By **Liz Meszaros**
CONTRIBUTING EDITOR

Nashville, Tenn. — A new injectable product, Radiance FN (BioForm Inc., Franksville, Wis.), can be used with good results for facial soft tissue augmentation, Thomas L. Tzikas, M.D., said. Results of this new product for soft-tissue augmentation and restoration seem long lasting, so far, and patient satisfaction has been high.



Dr. Tzikas

Calcium hydroxylapatite suspended in a carboxymethylcellulose gel comprise this injectable implant. Injections of calcium hydroxylapatite, a normal constituent of bone, do not cause chronic inflammatory or immune responses. In addition, the gel carrier does not require allergy testing, as does collagen, before injection.

“Radiance FN has been studied in many different surgical applications in the past, and no antibody reactions have been reported. It does not form chronic inflammation, does not migrate, and requires no skin testing,” according to Dr. Tzikas, a facial plastic surgeon in private practice in Delray Beach, Fla.

Currently, the injectable is approved for augmentation of the vocal cords in patients with vocal-cord paralysis and for the radiographic marking of soft tissue. This new implantable product has an FDA application pending approval for chin augmentation, but its use in soft-tissue augmentation is still con-



Patient pre-treatment (left) and post-treatment (right) with Radiance FN. This patient had 1 cc total for lip augmentation — 0.2 cc in each of four quadrants and +0.1 cc for corner marionette lines.



Patient pre-treatment (right) and six months post-treatment (left) with Radiance FN. This patient had 2 cc injected in total for lip augmentation.

sidered off-label, said Dr. Tzikas, who is a member of the American Academy of Facial Plastic & Reconstructive Surgery and board-certified by the American Board of Facial Plastic & Reconstructive Surgery and the American Board of Otolaryngology – Head & Neck Surgery.

Dr. Tzikas performed a patient survey after his first seven months using Radiance FN to determine efficacy and patient satisfaction.

In all, there were 207 patient treatment sessions, and 274 syringes (1 cc) used in patients ranging from an age of 25 to 85 years. The areas injected included the face, the nasolabial folds, the marionette lines, the glabellar rhytides, some acne scars, and even minor surgical soft-tissue defects of the face.

Patient satisfaction

Dr. Tzikas collected patient satisfaction sur-

veys from 88 patients followed for six months. Below are the variables assessed by the survey and how patients responded.

Pain. Most patients had minimal to moderate pain upon injection, Dr. Tzikas said. In total, 33 percent of the 88 patients reported minimal pain; 50 percent reported moderate pain; and 7 percent severe pain.

“Injection of this material does hurt, like the dull ache of a toothache. But it hurts for one to three minutes, and after that, the discomfort resolves,” he said.

Bruising. Most patients experience some bruising upon injection with Radiance FN, but bruising in all patients resolved within two weeks. A total of 33 percent of patients reported no bruising; 49 percent reported minimal bruising; 17 percent reported moderate bruising; and 1 percent reported severe bruising.

Skin erythema. In all, 8 percent of patients reported no erythema the day of injection; 41 percent reported minimal erythema; 46 percent reported moderate erythema; and 5 percent reported severe erythema. Only two patients had mild erythema that persisted for up to four weeks, but this resolved with the application of a topical steroid cream, Dr. Tzikas said.

Presence of nodules. “The main potential problem that occurs with injection is the poten-

tial for nodule formation,” Dr. Tzikas said. “These are submucosal nodules in the lip, and the lip is the only area in which it can happen,” he said.

A total of 56 percent of patients had no nodules; 36 percent had minimal nodules (which all resolved within four to six weeks of treatment); 8 percent had moderate nodules, and none had severe nodules.

In all, seven patients had visible nodules, Dr. Tzikas said. Four of these required intervention consisting of a steroid or going back to break up the material with a needle. Only one patient need some of the material removed with a needle.

Dr. Tzikas postulates that the main reason these nodules occur in the lips is their high mobility.

“There is a significant lip sphincter function in the area. As material is injected into the lips, it can extravasate and go to the path of least resistance, which is towards the mucosal surface. It will aggregate there and form tiny nodules,” he said.

Lip injections of Radiance FN must be made in the middle plane of the lip, superficially to the muscle of the lip. This must be done conservatively, with only a fine strand of material, he said.

Softness. The material remained soft at six weeks in all patients, except the seven

with lip nodules, Dr. Tzikas said. In all, 45 percent reported excellent softness; 33 percent reported good softness; 17 percent reported fair softness; and 5 percent reported poor softness six months after injection.

The cellulose gel is absorbed by six to eight weeks, Dr. Tzikas said. “The initial injection causes an inflammatory reaction, and the gel undergoes breakdown. It is absorbed over six to eight weeks and it reacts with tissue, which results in collagen ingrowth. Collagen replaces the gel, and this is why the material cannot be felt after six to eight weeks,” he added.

Appearance. The results reported by Dr. Tzikas’ patients were good, with 40 percent reporting an excellent appearance; 36 percent reporting a good appearance; 21 percent reporting a fair appearance; and 3 percent reporting a poor appearance.

Satisfaction. Patient satisfaction was excellent as well, Dr. Tzikas said, with 51 percent reporting excellent satisfaction; 40 percent reporting good satisfaction; 7 percent reporting fair satisfaction; and 2 percent reporting poor satisfaction.

Dr. Tzikas said, “Patients were very happy with the results overall. After nine months of follow-up, I have not seen anyone who has lost the material.”

Dr. Tzikas has no financial interest in or affiliation with Radiance FN. **CST**