FDA NEWS

FDA advisory committee recommends Radiesse for hand augmentation

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The General and Plastic Surgery Devices Panel of the FDA's Medical Devices Advisory Committee has voted in favor of recommending expanding the indication of Merz's Radiesse Dermal Filler to include hand augmentation for volume correction.

The advisory committee members voted the treatment safe (11 in favor, three against) and effective (12 in favor, two against).

On Dec. 22, 2006, Radiesse received FDA approval for the indications of subdermal implantation for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with HIV, and subdermal implantation for the correction of moderate-to-severe facial wrinkles and folds.

In Merz clinical studies, treatment with Radiesse produced a statistically significant improvement in the appearance of the hand after 3 months, which remained stable over time. Effectiveness after retreatment was similar to that seen after initial treatment. No detrimental effect on hand function was found after treatment, and there were no new safety issues identified during the 12-month study, according to materials submitted by Merz to the FDA.

During the open public hearing, **Paulo Rink, MD,** stated that for 22 years, he has been asked by patients to correct the volume loss in their aging hands. Rink reported injecting Radiesse as an off-label treatment into several hundred patients and only observing mild swelling, which was easily treated with the application of ice.

Lawrence Green, MD, a board-certified dermatologist representing the American Society for Dermatologic Surgery Association (ASDSA), stated that body sculpting represents the largest growing need for patients, based on patient polls by the ASDS.

"The data presented show Radiesse is safe, effective and noninvasive, and we support its approval process," Green said on behalf of the ASDSA.

“Hands have been a real unmet need [in cosmetic surgery],” according to **Heidi A. Waldorf, MD,** a clinical professor of dermatology at Mount Sinai Hospital. Waldorf went on to say that addressing patients’ aging hands goes beyond a “luxury item,” since often the first interaction people have is a handshake, making the hands the first thing people see upon meeting someone new.

One panel member requested adding “volume filler in the dorsa of the hands” to the device indications.

The panel voted that the available data were sufficient to characterize hand function post-injection with Radiesse.

“We need to communicate to the patient that the device is not intended to improve function of the hand,” panel member, **William Y. Oh, MD,** said in clarification of the vote.

Oh suggested more hand-function tests for daily living be added in future studies. In addition, **Kristine Mattivi, MS, PT,** recommended seeking out advice from a hand therapist or occupational therapist for a test of functional dexterity. As a result, the panel voted to require further hand-function testing in the post-marketing phase.

The study photographs presented were met with criticism. Many panel members recommended the photographs be evaluated by unbiased, blinded health care professionals in the future and not on-site during the study.

For future study guidelines, the panels recommended, in addition to including long-term study data on those with severe hand-volume loss, that future studies evaluate patients who receive surface treatments, such as laser resurfacing, and determine whether applicable time lags between treatments should exist.

In the sponsor’s concluding remarks, the speakers stated that the patients are happy with the results, which is why the majority requested retreatment.

When asked whether the benefits for Radiesse for hand augmentation to correct volume deficit in the hands outweighed the risks, the panel voted nine in favor, four against and one abstention. – *By Abigail Sutton*