# ASPS, AAD lead 'state of science' conference on soft-tissue fillers

BY JIM LEONARDO

The desire to provide the FDA with information for its deliberations on facial soft-tissue fillers and the need to assemble primary stakeholders for intensive discussion relating to the medical device provided the impetus for the Facial Soft Tissue Fillers State-of-the-Science Conference held Dec. 6-7 in Washington, D.C.

Plastic surgeons, dermatologists, ophthalmologists, researchers, device manufacturers and others attended the joint conference called by ASPS and the American Academy of Dermatology (AAD) and co-chaired by ASPS past President Rod Rohrich, MD, and AAD past President C. William Hanke.

In addition to ASPS and AAD, the conference was held in cooperation with the American Academy of Facial Plastic and Reconstructive Surgery; American Academy of Ophthalmology; American Academy of Otolaryngology-Head and Neck Surgery; American Society for Aesthetic Plastic Surgery and American Society of Dermatologic Surgery. Other physicians also were in attendance, although they did not officially represent the organizations to which they belong.

Among the stated objectives tackled by the approximately 60 attendees were patient safety, efficacy and effectiveness in relation to approved and off-label use of soft-tissue facial fillers, and the training and experience level of those administering them. The conference also addressed future research needs – including appropriate study designs and clinical study endpoints that would capture long-term outcomes, as well as effective strategies for collecting and communicating information on adverse effects and other safety concerns to physicians, other clinicians and, most importantly, patients.

Relevant research information was provided by several physicians, including ASPS Member Surgeon Andrea Pusic, MD, creator of the BREAST-Q® and FACE-Q® patient-reported outcomes measurement tools, who helped attendees gain a greater understanding of methods through which they can add to the growing amount of soft-tissue fillers data.

The conference also helped prepare stakeholders for a future, yet-unscheduled meeting with the FDA, which served as catalyst for the gathering when the agency in November 2008 questioned the growing off-label use of facial fillers. At that time, the FDA's General and Plastic Surgery Devices Panel set forth recommendations on fillers that included updated labeling on adverse events and the continued collection of post-market performance data.

### Harmony in numbers

ASPS President Michael McGuire, MD, says the conference was remarkable for several reasons, chief among them the free-flowing and candid information exchange as well as the spirit of cooperation among the participants.

"I found the conference composed of professionals who are very experienced, knowledgeable, forthright and collegial," Dr. McGuire says. "Not only did agreement result from this conference, so did harmony among the core specialties as well as the subspecialties. From the perspective of meeting official and unofficial goals, it was a great success. And after two days of sitting beside and consulting with AAD President David Pariser, MD, we departed not only as colleagues, but as friends."

Dr. Rohrich says the elements that came together in the unprecedented conference elevated the discourse and resulted in tangible gains. "It was truly the first time all the disciplines of cosmetic medicine – plastic surgery, dermatology, facial plastic surgery, ophthalmology and industry – met in a unique setting that focused specifically upon questions posed by the FDA," he says. "We talked about what hasn't worked, what's worked and what's needed to make it work better. The focus rightfully was on safety – and outcomes for our patients, and how we can improve those."

The core organizations initially wanted the FDA involved in this conference, but due to agency regulation, it instead became a preliminary conference in anticipation of a subsequent one that would adhere tightly to regulations that would allow the FDA to participate.

"The agency is limited by its governmental process in how it can participate in meetings, and the format of this meeting was not in line with their guidelines – so their representatives were unable to participate in this particular meeting," Dr. McGuire says. "Nevertheless, we agree that a greater dialogue with the FDA is desirable from both sides."

The ASPS president adds that the unprecedented composition of the conference was among the elements that pointed to a bright future for the discussion of, and action relating to, facial soft-tissue fillers.

"Never before had all these groups gathered in one room to discuss a common area of interest and concern, and to share education with each other," Dr. McGuire adds. "In the long run, that might be the most important outcome of this meeting."

### Six sessions over two days

The conference was broken down into six sessions that addressed:

- Approved and off-label short- and long-term efficacy and effectiveness of fillers
- Approved and off-label short- and long-term safety
- Tools for predicting and assessing fillers' efficacy, effectiveness and/or safety
- Adverse-event labeling, and related communication with providers and patients
- Current and future research needs
- The synthesis of state-of-the-art findings and implications

Through her Dec. 7 presentation, "Deriving Meaningful Data from Subjective Study Endpoints and Quality of Life Data," Dr. Pusic provided a systematic review of existing data collection methods, as well as ways to design additional studies to collect data on product effectiveness based on subjective study endpoints – including the FACE-Q. "The overall message was that understanding patients' perceptions of outcomes is clearly important with regard to facial fillers, but we didn't fully know how to capture that information in a way that was reliable and valid," she says.

"While photo analysis and complications data collected by clinicians are still very important, we also can tap into other measurement tools to add to that knowledge base. These won't replace other analyses – they will flesh those out," Dr. Pusic adds. "One of these is the FACE-Q, which will soon be ready to incorporate the collection of patient-reported outcomes data on fillers into studies.

"It's also very positive that we've begun to embrace a common 'language,'" she says. "If we all report with the same outcomes measure, we can directly compare different populations and different studies. And when you think about it, effective action anywhere begins when participants in that action fully understand one another."

### Next steps

The proceedings and related information will be published in the *PRS* journal, an effort that will include a systematic review of facial soft-tissue fillers, Dr. Rohrich says.

"In addition to providing our printed analysis, I'm hopeful that future meetings of these core specialities will lead to a more-streamlined process for the safe approval of fillers – and a more open process in which we can report outcomes, safety and adverse events with more ease than has been historically available," Dr. Rohrich adds.

"This conference laid the groundwork for additional meetings in the same regard," Dr. McGuire says. "The more our organizations get together and recognize how much we have in common, the greater will be the benefit for all of us. The sooner this can happen, the better for our patients. Ultimately, they're the ones we serve. We need to ensure their safety – and be able to prove to them through rigorous data that they are, in fact, in good hands." PSN

# Specialty to launch multifaceted research project regarding breast implant

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ASPS/PSEF and ASAPS/ASERF are convening an advisory council of experts from plastic surgery, epidemiology, pathology, oncology and the FDA to further study anecdotal case reports of an abnormality that has been found in a small number of patients with saline and silicone gel breast implants. The impetus for convening this panel came from recent reports by Garry Brody, MD, professor emeritus at the University of Southern California, who has sought to identify any common factors and gain a greater understanding of these cases. Dr. Brody will be presenting his most current data in March at the meeting of the American Association of Plastic Surgeons in San Antonio, Texas. The abstract for his presentation is available on the AAPS website at *aaps1921.org/abstracts/2010/4.cgi*.

In recent weeks, the leadership of ASPS/PSEF and ASAPS/ASERF became aware of several additional cases and undertook a thorough analysis of the currently available data by meeting with Dr. Brody and his research team, and by consulting with additional epidemiologists, oncologists and pathologists with expertise in this area. What is known is that in more than half the cases reported to date, abnormal lymphocytes have been found in seroma fluid or capsular tissue adjacent to the breast implants. Several of the cases have been confirmed as primary anaplastic large cell lymphoma (ALCL) of the breast; however, the clinical outcome in the cases to date has not been typical of primary ALCL of the breast in women without implants – with most cases appearing to have a benign course.

Many of the known cases were in patients with implants textured using the salt elution manufacturing process. It is important to note that the accurate pathologic diagnosis of the observed abnormality cannot be limited to cytologic or histologic evaluation alone, and requires additional specialized immuno-histochemical testing by a pathologist specializing in this field. Most importantly, it must be emphasized that based on currently available data, the clinical significance and incidence is unknown.

In addition to convening the advisory council of experts, the PSEF through funds from the National Endowment for Plastic Surgery – which was specifically created to fund research on topics of immediate relevance to the practice of plastic surgery – will support continued research by Dr. Brody and his team. Further, ASPS/ASAPS and PSEF/ASERF have received unqualified support from the three major implant manufacturers for additional research to be determined by the advisory council.

Based on what we know today and given that additional information is being evaluated, we are not making specific recommendations to change current clinical practice. As additional information is evaluated, this could be considered if appropriate. We are determined to proceed with this effort in a careful, expeditious and transparent manner to yield the needed and valid scientific data. For additional information and updates, log-in to the "Members Only" section of *plasticsurgery.org* and click the "New Breast Implant Research" link. PSN

# New CME recording process offers greater ease – and speed

In a continuing effort to more efficiently post CME credits and avoid unnecessary delays, ASPS members may now submit the following information online through the "CME Center" on the ASPS website at *plasticsurgery.org*:

- **All Category 2 credits**
- **Category 1 credits from non-ASPS activities, unless special arrangements have been made with other organizations** (including ASAPS, California Society of Plastic Surgeons, Texas Society of Plastic Surgeons and the Florida Society of Plastic Surgeons)

To access the CME submission form – or view your CME report – simply log-in to the ASPS website at *plasticsurgery.org* and click on "CME Center" in the upper right-hand corner of the page.

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