Introduction to the Facial Soft-Tissue Fillers Conference Supplement

Rod J. Rohrich, M.D.
Dallas, Texas

Plastic and Reconstructive Surgery has published numerous conference proceedings and supplements on dermal injectables and soft-tissue dermal fillers, including botulinum toxin,[1,2] semipermanent and permanent dermal and subdermal fillers,[3,4] temporary dermal and soft-tissue fillers,[5] and multimodality combination injectables for facial rejuvenation.[6] Although these supplements were authored by multidisciplinary groups of plastic surgeons, dermatologists, and cosmetic medicine providers, they did not represent a wide range of specialties. Furthermore, those conference proceedings resulted in the collective statements of gathered groups of experts. Those groups of experts provided the best evidence available at the time on the topics at hand.

In sharp contrast, the Facial Soft-Tissue Fillers Conference, which took place in Washington, D.C., December 6 through 7, 2009, represented a milestone multispecialty meeting. As Dr. Hanke's Introduction indicates, the full strength of seven professional organizations representing dermatology, plastic and reconstructive surgery, ophthalmology, and otolaryngology joined together for the first time in a collaborative effort to identify and examine areas where evidence was lacking or absent on various dermal soft-tissue fillers. While the number and type of dermal soft-tissue fillers that provide volume restoration are increasing rapidly, especially in Europe, the safety and efficacy data are not keeping pace. In a word, the medical community needed to identify gaps in our collective knowledge: we need to know what we don't know, and then set about ways to overcome these gaps. This supplement captures the proceedings of the conference and provides a comprehensive literature review. In doing so, it points the way to where clinical and basic science research is needed.

This supplement is groundbreaking for a second reason: it is jointly published in both the *Journal of the American Academy of Dermatology* and *Plastic and Reconstructive Surgery*. The American Academy of Dermatology and the American Society of Plastic Surgeons together believe that the material is of such importance to dermatologists and plastic surgeons that a joint publication would help ensure the widest possible dissemination of the material. Working in concert, both of our journals have jointly worked on the contents of the supplement, cooperating in the peer-review process, the revision and re-review process, and ultimately in the acceptance of the articles. The American Academy of Dermatology and the American Society of Plastic Surgeons, in conjunction with the publishers Elsevier and Wolters Kluwer Health/Lippincott Williams & Wilkins, developed a publishing agreement that will allow the supple-

From the Department of Plastic Surgery, University of Texas Southwestern Medical Center.
Received for publication December 17, 2010; accepted December 17, 2010.

DOI: 10.1097/PRS.0b013e31820c2421

Disclosure: *Rod J. Rohrich, M.D., declares he is the recipient of research grant funds received by the University of Texas Southwestern Medical Center from Medicis, Contura, Mentor (dermal fillers or botulinum toxin type A studies), and Baxter (fibrin sealant study).*

This supplement in its entirety is jointly published by the *Journal of the American Academy of Dermatology* and *Plastic and Reconstructive Surgery*.
Citation of the articles in *PRS* follows this format:
Rohrich RJ, Hanke CW. Facial Soft-Tissue Fillers: Assessing the State-of-the-Science Conference—Proceedings Report. *Plast Reconstr Surg.* 2011;127(Suppl 2):9S–21S.
Citation of the articles in *JAAD* follows this format:
Hanke CW, Rohrich RJ, Busso M, Carruthers A, Carruthers J, Fagien S, et al. Facial Soft-Tissue Fillers: Assessing the State-of-the-Science Conference—Proceedings Report. *J Am Acad Dermatol* 2011;64(Suppl):S53–S65.

ment to be concurrently published in both journals. The supplement will publish in both journals with the April 2011 issue. The text will be the same in both journals, but the formatting and "look and feel" of the articles will reflect the style and format of their own publication. The articles can be referenced correctly as either *Journal of the American Academy of Dermatology* or *Plastic and Reconstructive Surgery* articles. The tables of contents, and each article itself, clearly indicate that it is jointly published concurrently in the other journal as well.

The medical world is rapidly embracing evidence-based medicine. Evidence-based medicine is defined as the conscientious, explicit, and judicious use of current best evidence, combined with individual clinical experience and patient preferences and values, in making decisions about the care of individual patients. Evidence-based medicine has five primary components[7]:

1. Converting the need for information (e.g., about prevention, diagnosis, prognosis, therapy, and causation) into an answerable question.
2. Tracking down the best evidence with which to answer that question.
3. Critically appraising that evidence for its validity (closeness to the truth), impact (size of effect), and applicability (usefulness in our clinical practice).
4. Integrating the critical appraisal with our clinical expertise and with our patient's unique biology, values, and circumstances.
5. Evaluating our effectiveness and efficiency in executing steps 1 through 4 and seeking ways to improve for next time.

Critical to evidence-based medicine is determining the level of evidence being used for evaluation. Although there are numerous scales that rate levels of evidence, most scales rank the evidence more or less similarly. Table 1 shows the American Society of Plastic Surgeons' Level of Evidence Scale for Therapeutic Studies.[7]

Based on this level of evidence scale, the earlier consensus statements published in *Plastic and Reconstructive Surgery* were level of evidence V, documents based on expert opinion. They were useful in that they represented the best available evidence at the time, but in retrospect, their utility was clearly limited because of the low level of evidence of their data. The conference proceedings chapter in this supplement similarly offers level V data. With that said, the materials contained in the supplement are not considered to be practice guidelines or best medicine protocols, but are merely the authors' collective experience and expertise in the proscribed area. These articles represent the state-of-the-art expert opinion by the meeting participants and have been rigorously peer-reviewed and revised before acceptance. What is unique about this supplement (and its real value for the researcher), however, lies in the literature review article and its appendices, which provide extensive level-of-evidence–based evidence tables. Appendix A provides the following key information points for readers:

Table 1. American Society of Plastic Surgeons Rating Levels of Evidence and Grading Recommendations: Evidence Rating Scale for Therapeutic Studies

Level of Evidence	Qualifying Studies
I	High-quality, multicenter or single-center, randomized controlled trial with adequate power, or systematic review of these studies
II	Lesser-quality, randomized controlled trial, prospective cohort study, or systematic review of these studies
III	Retrospective comparative study, case-control study, or systematic review of these studies
IV	Case series
V	Expert opinion, case report or clinical example, or evidence based on physiology, bench research, or "first principles"

- Type of study (randomized controlled trial, systematic review, case series, expert opinion, and so on)
- Full reference of the study for easy identification
- Study design (multicenter, blinded, randomized, prospective or retrospective, and so on)
- Nationality of the study subjects
- Sample size
- Duration of follow-up
- Treatment protocol
- Injection description
- Conclusions
- Grade of the study for evidence-based medicine purposes

Appendix B is the American Society of Plastic Surgeons/American Academy of Dermatology evidence table on adverse events. It provides the following:

- Type of study
- Full reference of the study
- Sample size
- Follow-up duration
- Treatment
- Injection description
- Outcome measures, if indicated
- Results
- Adverse events

These appendices give clinical and basic science researchers a wealth of data at a glance, collecting and summarizing key articles on the subject in a highly condensed format. In the future, we hope that best practice protocols will eventually come from what was begun at the Washington meeting and this supplement.

Evidence-based medicine represents an invaluable methodology and discipline to help us evaluate our practices and determine their true effectiveness. They will ultimately enable us to provide the best possible care and safety for our patients. Because of this, the American Society of Plastic Surgeons and *Plastic and Reconstructive Surgery*, along with other sister societies, plan to adopt evidence-based medicine as a major strategic initiative over the next many years. I encourage you to read more details in the January 2011 editorial in *Plastic and Reconstructive Surgery*.[8]

Along with Dr. Hanke, I am grateful for the support, encouragement, and logistical expertise provided by the American Society of Plastic Surgeons and the American Academy of Dermatology. In particular, special thanks go to Keith Hume, American Society of Plastic Surgeons vice president of research, for his tireless efforts in coordinating not only the conference but also the communication between the two societies. Additional thanks go to Michael McGuire (past-president), Phil Haeck (current president), Bill Seward (vice president, health policy and advocacy), and Michael Costelloe (executive vice president) of the American Society of Plastic Surgeons, as well as to the American Academy of Dermatology Executive Committee. This project would not have been possible without the expertise and troubleshooting of Jim Mulligan, publisher of *Plastic and Reconstructive Surgery*, nor without the daily "boots on the ground" work of Dan Sullivan, managing editor of *Plastic and Reconstructive Surgery*, who has been involved at nearly every level of this work. I thank the conference participants, who made this project possible, and the industry supports who provided financial assistance in the form of unrestricted educational grants. I thank the Lewin Group for their logistical, writing, and meeting support. I hope that this supplement proves a great resource to you in your ongoing search to provide the best care and outcomes possible to your patients.

Rod J. Rohrich, M.D.
Editor-in-Chief
Plastic and Reconstructive Surgery
5959 Harry Hines Boulevard
P.O. Box 1, Suite 300
Dallas, Texas 75390-8820
rjreditor_prs@plasticsurgery.org

REFERENCES

1. Cosmetic Use of Botulinum Toxin (entire issue). *Plast Reconstr Surg.* 2003;112(5 Suppl):1S–192S.
2. Carruthers JD, Fagien D, Matarasso SL, Botox Consensus Group. Consensus recommendations on the use of botulinum toxin type A in facial aesthetics. *Plast Reconstr Surg.* 2004;114 (6 Suppl):1S–22S.
3. Matarasso SL, Carruthers JD, Jewell ML, Restylane Consensus Group. Consensus recommendations for soft-tissue augmentation with nonanimal stabilized hyaluronic acid (Restylane). *Plast Reconstr Surg.* 2006;117(3 Suppl):3S–34S.
4. Semipermanent and Permanent Dermal/Subdermal Fillers (entire issue). *Plast Reconstr Surg.* 2006;118(3 Suppl):1S–132S.
5. Temporary Dermal and Soft-Tissue Fillers (entire issue). *Plast Reconstr Surg.* 2007;120(6 Suppl):1s–105s.
6. Carruthers JDA, Glogau RG, Blitzer A, Facial Aesthetics Consensus Group Faculty. Advances in facial rejuvenation: Botulinum toxin type A, hyaluronic acid dermal fillers, and combination therapies—Consensus recommendations. *Plast Reconstr Surg.* 2008;121(5 Suppl):5S–36S.
7. Swanson J, Schmitz D, Chung KC. How to practice evidence-based medicine. *Plast Reconstr Surg.* 2010;126:286–294.
8. Rohrich RJ, Eaves FF III. So you want to be an evidence-based plastic surgeon? A lifelong journey. *Plast Reconstr Surg.* 2011; 127:467–472.