

ASAPS/ASPS Position Statement on Stem Cells and Fat Grafting

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You may have heard of the “stem cell face lift,” a “new technique using adult stem cells from the body’s own fat tissue [that] has been found to restore the plumpness, smoothness, and skin tightness of a more youthful face.”¹ Or perhaps you have been interested in the “stem cell breast augmentation,” also known as “natural breast augmentation,” which “employs the latest technologic advances in fat harvesting, adult stem cell transfers and breast splinting technology to provide women the option of enlarging their breasts using their own fat.”² These marketing claims, promoted as the latest cosmetic techniques based solidly on scientific fact, flood the airwaves and Internet. Although there is real hope within the plastic surgery community that stem cells may soon produce beneficial medical therapies to treat a variety of diseases, as of yet, such claims are not founded on the best science.

One of the most untoward byproducts of such claims is that patient safety may be compromised by these “stem cell therapies.” Furthermore, the overall efficacy of these therapies remains unproven. Historically, in an effort to obtain the best scientific data on related subjects, the American Society of Plastic Surgeons and the American Society for Aesthetic Plastic Surgery have commissioned task forces to develop position statements.³⁻⁶ The purpose of these commissions is to pool society resources to determine, evaluate, and report on the best available data. Position statements on the best science and best practices recommendations may change over time in light of updated scientific discovery and long-term patient data.

In similar fashion, the American Society for Aesthetic Plastic Surgery and the American Society of Plastic Surgeons commissioned a task force to re-

search the evidence for the use of stem cells for aesthetic treatments. The joint statement below on stem cells and fat grafting represents the collective position of the American Society for Aesthetic Plastic Surgery and the American Society of Plastic Surgeons on the current state of the science. One overwhelming conclusion of the task force is that there is very limited evidence in terms of assessing the safety or efficacy of stem cell therapies in aesthetic medicine. Widespread use of the term “stem cell therapy” as applied to aesthetic procedures is not adequately supported by the clinical evidence at this time. Much more research needs to be conducted before any definitive statements can be made, and the task force encourages the collection and reporting of data on outcomes and safety by physicians performing stem cell therapies to advance the knowledge and science of stem cells.

The American Society for Aesthetic Plastic Surgery, the American Society of Plastic Surgeons, and *Plastic and Reconstructive Surgery* and other scientific journals encourage plastic surgeons to read the position statement below and carefully join us in the scientific research of stem cell therapies. We urge you to submit your clinical results and experimental research in stem cells to the peer-reviewed plastic surgery journals, not only to help promote good science, but also to foster patient safety and best practices among your peers. In time, good science and long-term results will establish and confirm the truth about stem cell therapies, helping patients and plastic surgeons alike. Good science will then trump clever but unsubstantiated marketing, for the benefit of all.

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To address concerns emerging from claims relating to stem cell therapies in aesthetic plastic

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surgery, a joint task force of the American Society for Aesthetic Plastic Surgery (ASAPS) and the American Society of Plastic Surgeons (ASPS) was created. The task force was charged with examining the use of stem cells in aesthetic surgical procedures and for the enhancement of fat grafting. The task force examined the scope of treatments and available scientific evidence to support the use of stem cells in aesthetic plastic surgery procedures. The taskforce report and recommendations follow.

Stem cells are present within many tissues of the body. Unlike mature cells, they have the potential to develop into different cell types and influence surrounding cells. The scientific rationale for the use of adult stem cells in aesthetic procedures is based upon the ability of these cells to release growth factors that can assist in the process of healing and regenerating tissues, as well as develop into cell types that would be beneficial to the tissues being treated. This is similar to the basis of stem cell therapies that are being investigated to treat diseases such as heart attack and stroke.

There are encouraging data from studies in laboratories to suggest that the use of adult stem cells is a very promising field and may produce beneficial medical therapies to treat a variety of diseases. The clinical potential of stem cells within medicine as a whole - and plastic surgery in particular - has been a source of considerable enthusiasm and scientific curiosity, and it has caught the imagination of the public.

The ASPS and the ASAPS are committed to patient safety, advancing the quality of care, innovative treatments, and practicing medicine based upon the best available scientific evidence. ASPS and ASAPS are eager to learn more about the use of stem cells in plastic surgery and enthusiastically support development of a stronger evidence base in the utilization of stem cells in reconstructive and aesthetic surgery procedures. In the meantime growing concerns have emerged regarding advertising claims and/or clinical practices using stem cells that have not been substantiated by scientific evidence. These concerns include:

- Use of the term “stem cell” in aesthetic surgery procedures, such as the “stem cell face lift,” with the implication of improved results.
- Claims that skin quality can be improved from stem cell treatments, and that outcomes from fat grafting can be improved with stem cell therapy.

- Widespread marketing, evidenced by a Google web search using the search terms “stem cell face lift” yielding 197,000 results and “stem cell breast augmentation yielding 302,000 results, respectively.
- A lack of consistency in how these procedures are performed and how stem cells are incorporated into the procedures.
- Instructional courses, some “for profit,” that have emerged which are designed to teach methods of stem cell extraction for aesthetic procedures.
- Many procedures being advertised by practitioners who are not board certified plastic surgeons or members of other core specialties with formal training in aesthetic procedures. Such “noncore” practitioners have not been trained in an approved residency program designed to teach the physician safe and careful evaluation of cosmetic patients or a working knowledge of the full range of aesthetic procedures.
- Specialized equipment being marketed to physicians for use in “stem cell procedures.”
- Specialized equipment to extract stem cells, including devices, may fall under FDA regulations. Some devices, including automated machines to separate fat stem cells from fat tissues, are not yet approved for human use in the United States.
- Claims of purifying or activating stem cells through techniques that have not been fully verified and tested for safety and efficacy in current, peer-reviewed medical journals, or claims of improved outcomes as a result of these therapies.

To look specifically at the evidence supporting the use of stem cells for aesthetic treatments, the Task Force conducted a systematic review of the peer reviewed medical literature. Databases including OvidSP MEDLINE, Embase, ISI Web of Science, ISI Biosis Previews, and Scopus were searched for published clinical reports describing the use of stem cells for aesthetic procedures. This intensive process involved the review of thousands of published articles to identify relevant documents and critically evaluate these clinical studies in terms of study methodology and level of evidence. Of the more than nine thousand articles screened, less than twenty were topic relevant and study designs produced predominantly lower levels of evidence (III-V). While full results are being prepared for publication, the review demonstrates that the scientific evidence and other data are very

limited in terms of assessing the safety or efficacy of stem cell therapies in aesthetic medicine.

On the basis of the current state of knowledge, the task force makes the following recommendations to members of the American Society for Aesthetic Plastic Surgery and the American Society of Plastic Surgeons, and their patients.

- Terms such as “stem cell therapy” or “stem cell procedure” should be reserved to describe those treatments or techniques where the collection, concentration, manipulation, and therapeutic action of the stem cells is the primary goal, rather than a passive result, of the treatment. For example, standard fat grafting procedures which do transfer some stem cells naturally present within the tissue should be described as a fat grafting procedure, not a stem cell procedure.
- The marketing and promotion of stem cell procedures in aesthetic surgery is not adequately supported by clinical evidence at this time.
- While stem cell therapies have the potential to be beneficial for a variety of medical applications, a substantial body of clinical data to assess plastic surgery applications still needs to be collected. Until further evidence is available, stem cell therapies in aesthetic and reconstructive surgery should be conducted within clinical studies under Institutional Review Board approval, including compliance with all guidelines for human medical studies.
- The collection and reporting of data on outcomes and safety by any physician performing stem cell therapies is strongly encouraged to advance the knowledge and science of stem cells.
- Stem cell based procedures should be performed in compliance with FDA regulatory guidelines. If devices are employed that are subject to regulation by the FDA, surgeons should use these devices with appropriate approval in place, especially when used for investigational purposes.

- Patients are advised to seek consultation for aesthetic procedures by a surgeon certified by the American Board of Plastic Surgery. These physicians are able to properly evaluate a patient’s concerns and offer a wide range of safe solutions. Extreme caution should be exercised when a physician is promising results from any treatment that sound too good to be true.

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For reference: Google search on 4-29-11
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